ReWalk Robotics Ltd.
Form F-1/A
August 20, 2014
Table of Contents

As filed with the Securities and Exchange Commission on August 20, 2014.

Registration No. 333-197344

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 2

to

Form F-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

ReWalk Robotics Ltd.

(Exact Name of Registrant as Specified in its Charter)

State of Israel (State or Other Jurisdiction of Incorporation or Organization)	3842 (Primary Standard Industrial Classification Code Number)	Not Applicable (I.R.S. Employer Identification No.)

ReWalk Robotics Ltd.

Kochav Yokneam Building, Floor 6

P.O. Box 161

Yokneam Ilit 20692, Israel

+972 (4) 959-0123

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

ReWalk Robotics, Inc.

33 Locke Drive

Marlborough, MA 01752

(508) 251-1154

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

Colin J. Diamond, Esq. **Gary Kashar, Esq.** **White & Case LLP** **1155 Avenue of the Americas** **New York, NY 10036** **Tel: (212) 819-8200**	**Aaron M. Lampert, Adv.** **Ephraim Peter Friedman, Adv.** **Goldfarb Seligman & Co.** **98 Yigal Alon Street** **Tel Aviv 6789141, Israel** **Tel: +972 (3) 608-9999**	**Ayal Shenhav, Adv.** **Shenhav & Co.** **Or Towers Building, Building B** **4 Hanechoshet Street** **Tel Aviv 69710, Israel** **Tel: +972 (3) 611-0760**	**Phyllis G. Korff, Esq.** **Andrea L. Nicolás, Esq.** **Skadden, Arps, Slate, Meagher & Flom LLP** **Four Times Square** **New York, NY 10036** **Tel: (212) 735-3000**	**Clifford M.J. Felig, Adv.** **Meitar Liquornik Geva Leshem Tal** **16 Abba Hillel Silver Rd.** **Ramat Gan 52506, Israel** **Tel: +972 (3) 610-3100**

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

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

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

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

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

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price(1)(2)	Amount of Registration Fee(3)
Ordinary shares, par value NIS 0.01	$57,500,000	$7,406

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act.
(2) Includes shares granted pursuant to the underwriters option to purchase additional shares.
(3) Previously paid.

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.

Table of Contents

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 we are not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to Completion, dated August 20, 2014

PROSPECTUS

Shares

ReWalk Robotics Ltd.

Ordinary Shares

This is the initial public offering of ReWalk Robotics Ltd. Prior to this offering, there has been no public market for our ordinary shares. We are selling ordinary shares. The estimated initial public offering price is between $ and $ per share.

We have applied to have our ordinary shares listed on the Nasdaq Global Market under the symbol RWLK.

	Per Share	Total
Public offering price	$	$
Underwriting discounts and commissions(1)	$	$
Proceeds to us (before expenses)	$	$

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

We have granted the underwriters an option to purchase up to additional ordinary shares.

We are an emerging growth company as defined under the federal securities laws and, as such, may elect to comply with certain reduced public company reporting requirements for future filings.

Investing in our ordinary shares involves a high degree of risk. See Risk Factors beginning on page 13 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 underwriters expect to deliver the ordinary shares on or about , 2014.

Barclays **Jefferies**

Canaccord Genuity

Prospectus dated , 2014

Table of Contents

TABLE OF CONTENTS

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 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 these ordinary shares in any circumstances under which such offer or solicitation is unlawful.

Table of Contents

SUMMARY

This summary highlights selected information contained elsewhere in this prospectus. This summary does not contain all the information that you should consider before deciding to invest in our ordinary shares. You should read the entire prospectus carefully, including Risk Factors and our consolidated financial statements and the related notes, before making an investment decision. In this prospectus, the terms we, us, our and the Company refer to ReWalk Robotics Ltd. and its subsidiaries.

Overview

We are an innovative medical device company that is designing, developing and commercializing exoskeletons that allow wheelchair-bound individuals with mobility impairments or other medical conditions the ability to stand and walk once again. We have developed and are continuing to commercialize ReWalk, an exoskeleton that uses our patented tilt-sensor technology and an on-board computer and motion sensors to drive motorized legs that power movement.

Current ReWalk designs are intended for people with paraplegia, a spinal cord injury resulting in complete or incomplete paralysis of the legs, who have the use of their upper bodies and arms. We currently offer two products: ReWalk Personal and ReWalk Rehabilitation. ReWalk Personal is designed for everyday use by individuals at home and in their communities, and is custom-fit for each user. ReWalk Rehabilitation is designed for the clinical rehabilitation environment where it provides valuable exercise and therapy. It also enables individuals to evaluate their capacity for using ReWalk Personal in the future. In 2011, we launched ReWalk Rehabilitation for use in hospitals and rehabilitation centers in the United States and Europe. We began marketing ReWalk Personal in Europe with CE mark clearance at the end of 2012 and received FDA clearance to market it in the United States in June 2014. ReWalk is the first exoskeleton cleared by the FDA for personal use. In the future, we will need to obtain approval from the applicable regulatory agency of any additional jurisdiction in which we seek to market ReWalk.

ReWalk is a breakthrough product that can fundamentally change the health and life experiences of users. ReWalk is currently the only commercialized exoskeleton using a tilt sensor to restore self-initiated walking. Designed for all-day use, ReWalk is battery-powered and consists of a light, wearable exoskeleton with integrated motors at the joints, an array of sensors and a computer-based control system to power knee and hip movement. ReWalk controls movement using subtle changes in the user s center of gravity. A forward tilt of the upper body is sensed by the system, which initiates the first step. Repeated body shifting generates a sequence of steps which allows for natural gait with functional walking speed. Because the exoskeleton supports its own weight, users do not expend unnecessary energy while walking. While ReWalk does not allow side-to-side actuation, users are able to turn by shifting their weight to the side. ReWalk also allows users to sit, stand and, in some cases, climb and descend stairs. ReWalk users are able to independently operate the devices, and most are able to put on and remove the devices by themselves. However, our safety guidelines and FDA specifications require users to be accompanied by a trained companion.

Published clinical studies demonstrate ReWalk s ability to deliver a natural gait and functional walking speed, which has not been shown in studies for any competing exoskeleton. In addition, our interim analysis of an ongoing clinical study and our experience working with health care practitioners and ReWalk users suggests that ReWalk has the potential to provide secondary health benefits. These benefits include reducing pain and spasticity and improving bowel and urinary tract function, body and bone composition, metabolism and physical fitness, as well as reducing hospitalizations and dependence on medications. Because of these secondary medical benefits, we believe that ReWalk has the ability to reduce the lifetime healthcare costs of individuals with spinal cord injuries, making it economically attractive for individuals and third-party payors. While we believe that ReWalk offers significant advantages over competing technologies and therapies, disadvantages include the time it takes for a user to put on ReWalk, the slower pace of ReWalk compared to a wheelchair, the weight of ReWalk when carried, which makes it more burdensome for a companion to transport than a wheelchair, and the requirement that users be accompanied by a trained companion.

Table of Contents

We believe that the current design of Rewalk provides a functional technical base that can be easily adapted to address medical indications other than paraplegia that affect the ability to walk. We are currently engaged in research and development efforts to adapt ReWalk to address the mobility needs of quadriplegia and multiple sclerosis patients, and, in the future, we plan to address these needs in stroke and cerebral palsy patients. We are also developing our next generation of ReWalk, with a more efficient drive mechanism, slimmer profile and lighter body, as well as other improvements.

Development of ReWalk took over a decade and was spurred by the experiences of our founder, Dr. Amit Goffer, himself a quadriplegic. As of August 1, 2014, we had placed 62 ReWalk Rehabilitation and 19 ReWalk Personal systems, 88% of which were purchased by our customers and 12% of which were placed with clinics and distributors for training, market development and clinical testing. Through August 1, 2014, we have trained over 400 ReWalk users, representing over 20,000 hours of use.

Our commercialization strategy is to penetrate rehabilitation centers, hospitals and similar facilities that treat patients with spinal cord injuries to become an integral part of their rehabilitation programs and to develop a broad based training network with these facilities to prepare users for home and community use. According to the National Spinal Cord Injury Statistical Center, 87.1% of persons with spinal cord injuries are sent to private, non-institutional residences (in most cases, their homes) after hospital discharge. As a result, while the majority of our sales to date have been ReWalk Rehabilitation units, the primary focus of our commercialization efforts going forward will be marketing ReWalk Personal for routine use at home, work or in the community, and we expect sales of ReWalk Personal to account for the substantial majority of our revenues in the future.

We expect to generate revenues from a combination of self-payors and third-party payors. While no uniform policy of coverage and reimbursement by third-party payors currently exists for electronic exoskeleton technologies such as ReWalk in the United States or elsewhere, we plan to pursue various paths of reimbursement and support fundraising efforts by institutions and clinics. In July 2014, the Bronx VA announced that it would be fully committed to supporting the procurement of ReWalk Personal and providing the staffing support needed for all eligible veterans with spinal cord injury for whom ReWalk is clinically indicated. As the first hospital to research the health-related benefits of an exoskeletal walking device for people with spinal cord injury, the Bronx VA experience supports the clinical use of ReWalk and similar FDA-approved technologies. We believe that additional VAs will adopt similar policies in the future.

Our Competitive Strengths

We believe that the following strengths provide us with sustainable competitive advantages to grow our revenue:

Proprietary Technology Enabling a More Natural Walking Experience. Our patented tilt-sensor technology and proprietary software allow self-initiated movement that we believe delivers a more natural walking experience than competing products. Published clinical studies demonstrate ReWalk s ability to provide a natural gait and functional walking speed, which has not been shown in studies for any competing exoskeleton. In the United States, we have method patent protection covering certain methods of user activation and control of systems such as ReWalk, including by sensing the users torso lean or weight shifts. In addition, we have apparatus patent protection in the United States and Europe covering the design of ReWalk and similar devices that use several sensors to empower tilt-sensor technology. Our patents on the tilt-sensor technology do not begin to expire until 2021. We also rely on trade secrets law to protect our proprietary software and product candidates/products in development.

First Mover Advantage. ReWalk Personal is the first medical exoskeleton cleared by the FDA for personal use in the United States. We do not believe that our competitors have any products that will be cleared by the FDA for personal use in the United States for at least the next two years. As a result, we believe we will be able to capture significant U.S. market share for exoskeletons for personal use. In addition, we were the first exoskeleton provider to have an established commercial infrastructure and to market products in Europe, with our direct sales force in Germany. We are also the first to achieve reimbursement for a personal unit.

Table of Contents

Compelling Clinical Data. We believe that ReWalk s clinical data differentiates us from our competitors. Clinical data published in established medical journals has demonstrated ReWalk s potential as a safe ambulatory device. We are not aware of any comparable clinical data generated in rigorous trials that has been published with respect to competing exoskeleton products. In addition, our interim analysis of an ongoing clinical study demonstrates improvements in secondary physical conditions, such as reduction in pain and spasticity and improvements in bowel and urinary tract function, body and bone composition, metabolism and physical fitness, as well as reduced hospitalizations and dependence on medications. We believe that continued results of this nature will greatly assist our ability to obtain regulatory clearances and third-party reimbursement.

Strategic Alliance with Yaskawa Electric Corporation. We have entered into a strategic alliance with Yaskawa Electric Corporation, a global leader in the fields of industrial robotics and automation. Pursuant to this arrangement, Yaskawa will serve as our distributor in certain Asian markets, where its name and brand recognition provide us with opportunities for growth and market penetration, and can apply its expertise for product and quality improvements to ReWalk. We believe that this arrangement with such a prominent company is unique in this industry. Yaskawa also made an equity investment in our company. In addition, in the future, subject to any necessary regulatory clearance, we may market and sell in the United States and Europe certain healthcare equipment products that Yaskawa is currently developing. See Certain Relationships and Related Party Transactions Series D Preferred Share Purchase Agreement and Agreements with Yaskawa.

Established and Scaleable Manufacturing Capability. We have contracted with Sanmina Corporation, a well-established original equipment manufacturer with expertise in the medical device industry, for the manufacture of all of our products. Pursuant to this arrangement, Sanmina also sources all of the raw materials needed for the production of our products. We believe that this relationship provides us security with respect to quality, price and quantity of our products and offers significant scale-up capacity.

Experienced Management Team and Employees with Personal Experience with Paralysis. Our senior management team has significant experience in the medical device, technology and robotics industries, with an average of over 20 years of experience. The experiences of Dr. Amit Goffer, our founder, President and Chief Technology Officer, and the inventor of ReWalk, who has been paralyzed since 1997, have been one of the greatest drivers in the development and refinement of ReWalk. Additionally, certain of our sales and marketing and research and development employees are paraplegic, which provides us with invaluable perspective to advance the development of our products.

Our Growth Strategies

Our goal is to drive sustainable growth by fundamentally changing the health and life experiences of individuals with mobility impairments. To achieve this goal, we intend to:

Increase Our Salesforce and Infrastructure. We intend to penetrate our target markets and drive sales of ReWalk by increasing our sales force and further strengthening our distribution network and service, training and support functions. We believe that our presence in leading rehabilitation centers, hospitals and similar facilities in the United States and Europe has allowed us to establish a strong training infrastructure, and we plan to use this existing infrastructure as a point of entry to efficiently penetrate the market for ReWalk Personal.

Expand Geographic Coverage. We intend to increase our presence in the United States in response to our receipt of FDA clearance for ReWalk Personal. We also plan to expand into new geographies throughout Europe and, through our arrangements with Yaskawa, in Asia. To date, we have focused our commercialization efforts primarily on the German, French, UK, Italian, Austrian, Canadian and Turkish markets for personal and rehabilitation use and the U.S. market for rehabilitation use.

Table of Contents

Continue Clinical Studies to Further Demonstrate Health and Economic Benefits to Support Reimbursement. We intend to continue to work with hospitals, rehabilitation centers, patient advocacy and support groups and individual users to generate additional data regarding functionality and that supports the health and economic benefits of ReWalk. We will continue to engage and fund researchers and organizations to conduct clinical studies to demonstrate the functionality and utilization of ReWalk and to highlight economic benefits of reductions in medical complications associated with spinal cord injury. We believe that this data will position us to pursue additional third-party reimbursement for our products.

Leverage Our Core Technology Platform to Expand Treatment Indications. We designed ReWalk to provide a functional technical base that can be easily adapted to address medical indications other than paraplegia, and we believe that we have the internal and external experience to develop and commercialize products to address new indications. In addition to developing the next generation of ReWalk, we are currently engaged in research and development efforts to adapt ReWalk to address the mobility needs of quadriplegia and multiple sclerosis patients, and, in the future, we plan to address these needs in stroke and cerebral palsy patients.

Market Opportunity

Confinement to a wheelchair can cause severe physical and psychological deterioration, resulting in bad health, poor quality of life, low self-esteem and high medical expenses. In addition, the secondary medical consequences of paralysis can include difficulty with bowel and urinary tract function, osteoporosis, loss of lean mass, gain in fat mass, insulin resistance, diabetes and heart disease. The cost of treating these conditions is substantial. The National Spinal Cord Injury Statistical Center, or the NSCISC, estimates that complications related to paraplegia cost, excluding indirect costs such as losses in wages, fringe benefits and productivity, approximately $500,000 in the first year post-injury and significant additional amounts over the course of an individual s lifetime. Further, secondary complications related to spinal cord injury can reduce life expectancies for SCI patients.

The NSCISC estimates as of 2013 that there were 273,000 people in the United States living with spinal cord injury, with an annual incidence of approximately 12,000 new cases per year. Approximately 42,000 of such patients are veterans, and are eligible for medical care and other benefits from the Veterans Administration, or VA. With 24 VA spinal cord injury centers, the VA has the largest single network of spinal cord injury care in the United States.

The University of Alabama-Birmingham Department of Physical Medicine and Rehabilitation operates the NSCISC, which maintains the world s largest database on spinal cord injury research. Since 2010, motor vehicle crashes have been the leading cause of reported spinal cord injury cases (36.5%), followed by falls (28.5%), acts of violence (14.3%) and sports injuries (9.2%). Nearly 80% of spinal cord injuries occur among the male population. According to the NSCISC, upon hospital discharge, 87.1% of persons with spinal cord injuries are sent to private, non-institutional residence (in most cases, their homes prior to injury).

Based on U.S. Census Bureau data, the spinal cord injury population gender and age statistics and data from the Spinal Cord Model Systems report, we estimate almost 80% or 218,000, of spinal cord injury patients in the United States could be candidates for current or future ReWalk products. The young average age of injury and significant remaining life expectancy, the likelihood of living at home and lifetime cost of treatment highlight the need for an out-of-hospital solution with demonstrated health and social benefits.

In addition to developing the next generation of ReWalk, we are currently engaged in research and development efforts to adapt ReWalk to address the mobility needs of quadriplegia and multiple sclerosis patients.

According to the National Multiple Sclerosis Society, as many as 400,000 Americans suffer from multiple sclerosis. Research indicates that approximately 53% of these individuals, or approximately 212,000, would be

Table of Contents

classified as either a 6.0 or 7.0 on the Kurtzke Disability Status Scale (DSS), a measure of the need for walking assistance. Individuals with DSS 6.0 require intermittent or unilateral constant assistance (by means of cane, crutch, or brace) to walk approximately 100 meters without resting. Individuals with DSS 7.0 are unable to walk beyond 10 meters without rest while leaning against a wall or holding furniture for support. We believe these individuals could benefit from our technology.

In the future, we plan to address the mobility needs of stroke and cerebral palsy patients. Over five million Americans have suffered a stroke, with 780,000 new incidences expected each year. Physical limitations after stroke vary from case to case, but approximately 20-25% of these individuals are unable to walk without full physical assistance. Cerebral palsy is a disorder of movement, muscle tone or posture that is caused by damage to the developing brain, most often before or during a child s birth, or during the first 3 to 5 years of a child s life. According to United Cerebral Palsy, there are 764,000 cases of cerebral palsy in the United States. Cerebral palsy represents a significant opportunity to address the segment of this market that will meet the physical criteria to use ReWalk.

Our Solutions

ReWalk is a breakthrough product that can fundamentally change the health and life experiences of users. Published clinical studies demonstrate ReWalk s ability to deliver a natural gait and functional walking speed. ReWalk s patented tilt-sensor technology and an on-board computer and motion sensors drive motorized legs that power knee and hip movement and allow self-initiated walking. ReWalk controls movement using subtle changes in the user s center of gravity. A forward tilt of the upper body is sensed by the system, which initiates the first step. Repeated body shifting generates a sequence of steps, which allows natural ambulation with functional walking speed. While ReWalk does not allow side-to-side actuation, users are able to turn by shifting their weight to the side. ReWalk also allows users to sit, stand, and, in some cases, climb and descend stairs.

Designed for all-day use and worn over the clothes of users, ReWalk consists of a light wearable exoskeleton with integrated motors at the joints, an array of sensors and a backpack that contains the batteries and the computer-based control system. The control system utilizes proprietary algorithms to analyze upper-body motions and trigger and maintain gait patterns and other modes of operation (such as stair-climbing and shifting from sitting to standing), leaving the user s hands free for self-support and other functions. Because the exoskeleton supports its own weight, users do not expend unnecessary energy while walking. Safety measures include crutches, which provide additional stability, fall protection, which lowers users slowly and safely in the event of a malfunction, and the secure stand mode, which automatically initiates if the user does not begin walking within two seconds. ReWalk is also equipped with maintenance alarms, warnings and backup batteries. The rechargeable batteries are easily accessible from the system s backpack and can be recharged in any standard power outlet. Upon completion of training, which generally consists of approximately 15 one-hour sessions, most users are able to put on and remove the device by themselves while sitting, typically in less than 15 minutes.

Table of Contents

ReWalk

Current ReWalk designs are intended for people with paraplegia who have the use of their upper bodies and arms. We currently offer two ReWalk products: ReWalk Personal and ReWalk Rehabilitation.

Rehabilitation

ReWalk Personal: intended for everyday use at home, at work or in the community. We began marketing ReWalk Personal in Europe with CE mark clearance at the end of 2012. We received clearance to market ReWalk Personal in the United States in June 2014. ReWalk Personal units are all manufactured according to the same specifications. Each unit is then permanently sized to fit the individual user and the software is configured for the user s specifications by the rehabilitation center, clinic or distributor.

ReWalk Rehabilitation: designed for the clinical rehabilitation environment, ReWalk Rehabilitation has adjustable sizing enabling multiple patient use. ReWalk Rehabilitation provides a valuable means of exercise and therapy. It also enables individuals to evaluate their capacity for using ReWalk Personal in the future. We began marketing ReWalk Rehabilitation for use in hospitals, rehabilitation centers and stand-alone training centers in the United States and Europe in 2011. ReWalk Rehabilitation units are all manufactured according to the same specifications and are equipped with adjustable sizing for multi-patient use.

Our interim analysis of an ongoing clinical study and our experience working with health care practitioners and ReWalk users suggest that ReWalk has the potential to provide secondary health benefits. These benefits include reducing pain and spasticity and improving bowel and urinary tract function, body and bone composition, metabolism and physical fitness, as well as reducing hospitalizations and dependence on medications. Because of these secondary medical benefits, we believe that ReWalk has the ability to reduce the lifetime healthcare costs of individuals with spinal cord injuries, making it economically attractive for individuals, healthcare providers such as hospitals and rehabilitation centers, and third-party payors.

ReWalk Q We are currently developing our next generation of ReWalk, with a more efficient drive mechanism, slimmer profile and lighter body, as well as other improvements. We are also developing ReWalk Q for individuals with quadriplegia who are unable to hold crutches, which will include attached crutches with wheels. We expect to complete the development of ReWalk Q in the near future, at which time we will begin clinical testing and apply for regulatory clearances. We plan to expand the designs and indications that we address beyond paraplegia and quadriplegia to include other disabilities affecting gait and ability to walk, such as multiple sclerosis, stroke and cerebral palsy.

Risk Factors

Investing in our ordinary shares involves risks. You should carefully consider the risks described in Risk Factors 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:

We currently rely, and in the future will rely, on sales of our ReWalk systems and related service contracts and extended warranties for our revenue, and we may not be able to achieve or maintain market acceptance.

Table of Contents

The market for medical exoskeletons is new and unproven, and important assumptions about the potential market for our products may be inaccurate.

We have a limited operating history upon which you can evaluate our business plan and prospects.

If we are unable to expand our sales, marketing and training infrastructure, we may fail to increase our sales.

The health benefits of ReWalk have not been substantiated by long-term clinical data, which could limit sales.

We may fail to secure or retain adequate coverage or reimbursement for ReWalk by third-party payors.

We depend on a single third-party to manufacture ReWalk and a limited number of third-party suppliers for certain components of ReWalk.

Our future growth and operating results will depend on our ability to develop and commercialize new products and penetrate new markets.

We operate in a competitive industry that is subject to rapid technological change, and we expect competition to increase.

We have incurred net losses since our inception.

The accountants report on our financial statements for the year ended December 31, 2013 includes an explanatory paragraph that expresses substantial doubt about our ability to continue as a going concern.

We are subject to extensive governmental regulations relating to the manufacturing, labeling and marketing of our products.

Our Principal Shareholders

Upon the closing of this offering, entities affiliated with SCP Vitalife Partners, Yaskawa Electric Corporation, or Yaskawa, Israeli Health Care Ventures II, L.P. and entities affiliated with Pontifax (Cayman) II, L.P. will beneficially own % of our outstanding ordinary shares in the aggregate (or % if the underwriters exercise in full their option to purchase additional shares). Upon the closing of this offering, we will not be a party to and are not otherwise aware of any voting agreement that will exist among our shareholders. For further information about the ownership of our ordinary shares upon the closing of this offering, see Principal Shareholders.

We have entered into a Strategic Alliance Agreement with Yaskawa pursuant to which, among other arrangements, we and Yaskawa will collaborate with respect to the marketing, distribution and commercialization of our products by Yaskawa, the marketing and distribution of future Yaskawa products by us and the improvement and quality control of our products. In the future, subject to any necessary regulatory clearance, this agreement entitles us to market and sell certain of Yaskawa s products currently under development in the United States and Europe. The term of the agreement is ten years, but it may be terminated by either party after seven years or upon 60 days notice in the event of an uncured default under the agreement.

We and Yaskawa also entered into an Exclusive Distribution Agreement which provides that Yaskawa will be our exclusive distributor in Japan, China (including Hong Kong and Macau), Taiwan, South Korea, Singapore and Thailand. In addition, Yaskawa has a right of first refusal to serve as distributor in certain other Asian markets, subject to an agreement on minimum purchase requirements. In addition, if we offer better

pricing to any other distributor than what we offer Yaskawa, Yaskawa will be entitled to that pricing. The term of the Exclusive Distribution Agreement is ten years, but it may be terminated by either party upon 90 days written notice after seven years or upon certain other events. See Certain Relationships and Related Party Transactions Agreements with Yaskawa.

Table of Contents

Corporate Information

We are incorporated under the laws of the State of Israel. Our corporate headquarters are located at Kochav Yokneam Building, Floor 6, Yokneam Ilit 20692, Israel, and our telephone number is +972 (4) 959 0123. We also have offices in Marlborough, Massachusetts and Berlin, Germany. Our website address is http://rewalk.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. We have included our website address in this prospectus solely for informational purposes. Our agent for service of process in the United States is ReWalk Robotics, Inc., located at 33 Locke Drive, Marlborough, Massachusetts 01752, and its telephone number is (508) 251-1154.

ReWalk® is our registered trademark in Israel. Other trademarks and service marks appearing in this prospectus are the property of their respective holders.

Table of Contents

The Offering

Ordinary shares offered by us	ordinary shares
Ordinary shares to be outstanding after this offering	ordinary shares
Underwriters option	We have granted the underwriters an option for a period of 30 days after the date of this prospectus to purchase up to additional ordinary shares.
Use of proceeds	We intend to use the net proceeds from this offering for general corporate purposes, including sales and marketing expenditures aimed at growing our business and research and development expenditures focused on product development. We may also use net proceeds to make acquisitions or investments in complementary companies or technologies, although we do not have any agreement or understanding with respect to any such acquisition or investment at this time. See Use of Proceeds.
Risk factors	See Risk Factors and other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our ordinary shares.
Proposed Nasdaq Global Market symbol	RWLK

The number of ordinary shares to be outstanding after this offering is based on 8,318,286 ordinary shares outstanding as of August 1, 2014:

- assuming the exercise for cash on such date of warrants to purchase 18,910 of our preferred shares (representing 340,380 ordinary shares after the share split described below) that expire upon the consummation of this offering, and the conversion on such date of all outstanding ordinary A shares, ordinary B shares, preferred shares and preferred shares issuable upon the exercise of such outstanding warrants into ordinary shares;

- excluding 1,243,746 ordinary shares reserved for issuance under our equity incentive plans as of August 1, 2014, of which there were outstanding options to purchase 1,115,640 shares at a weighted average exercise price of $1.30 per share;

- excluding warrants to purchase 777,996 of our ordinary shares that will remain outstanding after this offering; and

- assuming the issuance to our founder, Dr. Amit Goffer, of 335,484 ordinary shares immediately prior to the closing of this offering, such that the value of his ownership interest equals 6% of our valuation, in accordance with our Articles of Association and our Fourth Amended and Restated Shareholders Agreement.

For more information regarding the securities that Dr. Goffer has the right to receive, see Certain Relationships and Related Party Transactions Arrangements with Founder.

Unless otherwise indicated, this prospectus:

reflects the exercise immediately prior to the closing of this offering of our outstanding warrants described above that expire upon the consummation of this offering and the conversion of all outstanding ordinary A shares, ordinary B shares, preferred shares and preferred shares issuable upon the exercise of such warrants into ordinary shares;

gives effect to the adoption of our amended articles of association immediately prior to the closing of this offering, which will replace our articles of association currently in effect;

Table of Contents

gives effect to an 18-for-1 share split of our ordinary shares effected on August , 2014 by means of a share dividend of 17 ordinary shares for each ordinary share then outstanding;

assumes an offering of ordinary shares and an initial public offering price of $ per ordinary share, the midpoint of the estimated initial public offering price range set forth on the cover page of this prospectus; and

assumes no exercise of the underwriters option to purchase up to additional ordinary shares from us.

Table of Contents

Summary Consolidated Financial Data

The summary consolidated financial data set forth below for the years ended December 31, 2012 and 2013 is derived from our audited consolidated financial statements, which have been prepared in accordance with U.S. GAAP and are presented elsewhere in this prospectus. The summary consolidated financial statement data for the six months ended June 30, 2013 and 2014, and as of June 30, 2014, is derived from our unaudited interim consolidated financial statements presented elsewhere in this prospectus. In the opinion of management, these unaudited interim consolidated financial statements include all adjustments, consisting of normal recurring adjustments, necessary for a fair statement of our financial position and operating results for these periods.

You should read the following summary consolidated financial data in conjunction with, and it is qualified in its entirety by reference to, our consolidated financial statements and the related notes appearing elsewhere in this prospectus and other information provided in this prospectus, including Selected Consolidated Financial Data and Management s Discussion and Analysis of Financial Condition and Results of Operations. The historical results set forth below are not necessarily indicative of the results to be expected in future periods and results for interim periods are not necessarily indicative of the results that may be expected for the entire year.

	Year Ended December 31,		Six Months Ended June 30,	
	2012	2013	2013	2014
	(in thousands, except per share data)			
Statements of Operations Data:				
Revenues	$ 972	$ 1,588	$ 797	$ 945
Cost of revenues	983	2,017	1,074	1,368
Gross loss	(11)	(429)	(277)	(423)
Operating expenses:				
Research and development	1,757	2,463	1,062	2,158
Sales and marketing, net	2,334	4,091	1,644	2,891
General and administrative	1,657	1,762	801	1,382
Total operating expenses	5,748	8,316	3,507	6,431
Operating loss	5,759	8,745	3,784	6,854
Financial expenses, net	878	3,410	1,656	2,855
Loss before income taxes	6,637	12,155	5,440	9,709
Income taxes	21	22	12	32
Net loss	$ 6,658	$ 12,177	$ 5,452	$ 9,741
Net loss per ordinary share, basic and diluted(1)	$ (41.26)	$ (74.53)	$ (32.72)	$ (59.42)
Weighted average number of shares used in computing net loss per ordinary share, basic and diluted	185,688	185,688	185,688	187,398
Pro forma net loss per ordinary share, basic and diluted(2)(3)		$ (2.54)		$ (1.37)
Pro forma weighted average number of shares used in computing net loss per ordinary share, basic and diluted(2)		4,349,664		6,552,972

11

Table of Contents

	As of June 30, 2014	
	Actual	**As Adjusted(4)**
	(in thousands)	
Balance Sheet Data:		
Cash and cash equivalents	$ 904	
Total assets	5,236	
Total long-term liabilities	5,149	
Accumulated deficit	(36,647)	
Total shareholders deficiency	(2,612)	

(1) Net loss per ordinary share, basic and diluted, is calculated by dividing our net loss excluding dividends accrued on our convertible preferred shares outstanding during the period presented by the weighted average number of shares outstanding during the period presented. See Note 2u to our consolidated financial statements presented elsewhere in this prospectus.

(2) Pro forma net loss per ordinary share and pro forma weighted average number of shares outstanding assume the conversion of our preferred shares, including preferred shares issuable in connection with the exercise of outstanding warrants, into ordinary shares, which will occur immediately prior to the closing of this offering, but does not include the issuance of shares in connection with this offering. For additional information on the conversion of the preferred shares, see Note 9 to our consolidated financial statements included elsewhere in this prospectus.

(3) Pro forma net loss per ordinary share, basic and diluted, assumes an adjustment to net loss in order to eliminate the revaluation expenses of our warrants liability. See Note 2e to our consolidated financial statements presented elsewhere in this prospectus.

(4) As adjusted gives effect to (a) the conversion of our preferred shares, including preferred shares issuable in connection with the exercise of outstanding warrants, into ordinary shares, which will occur immediately prior to the closing of this offering, (b) the receipt of $ million by us upon the closing of this offering from the exercise of warrants prior to the closing of this offering; and (c) 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 on the front cover of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

Table of Contents

RISK FACTORS

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

Risks Related to Our Business and Our Industry

We currently rely, and in the future will rely, on sales of our ReWalk systems and related service contracts and extended warranties for our revenue, and we may not be able to achieve or maintain market acceptance.

We currently rely, and in the future will rely, on sales of our ReWalk systems and related service contracts and extended warranties for our revenue. ReWalk is a new product, and market acceptance and adoption depend on educating people with limited upright mobility and health care providers as to the distinct features, ease-of-use, positive lifestyle impact and other benefits of ReWalk compared to alternative technologies and treatments. ReWalk may not be perceived to have sufficient potential benefits compared with these alternatives. Users may also choose other therapies due to disadvantages of ReWalk, including the time it takes for a user to put on ReWalk, the slower pace of ReWalk compared to a wheelchair, the weight of ReWalk when carried, which makes it more burdensome for a companion to transport than a wheelchair, and the requirement that users be accompanied by a trained companion. Also, we believe that healthcare providers tend to be slow to change their medical treatment practices because of perceived liability risks arising from the use of new products and the uncertainty of third-party reimbursement. Accordingly, healthcare providers may not recommend ReWalk until there is sufficient evidence to convince them to alter the treatment methods they typically recommend, such as prominent healthcare providers or other key opinion leaders in the spinal cord injury community recommending ReWalk as effective in providing identifiable immediate and long-term health benefits.

In addition, health insurance companies and other third-party payors may not provide adequate coverage or reimbursement for our products. We may be unable to sell ReWalk systems on a profitable basis if third-party payors deny coverage, limit reimbursement or reduce their levels of payment, or if our costs of production increase faster than increases in reimbursement levels. In addition, we may not obtain coverage and reimbursement approvals in a timely manner. Our failure to receive such approvals would negatively impact market acceptance of ReWalk.

Achieving and maintaining market acceptance of ReWalk could be negatively impacted by many other factors, including, but not limited to:

- lack of sufficient evidence supporting the benefits of ReWalk over competitive products or other available treatment, or lifestyle management, methodologies;
- results of clinical studies relating to ReWalk or similar products;
- claims that ReWalk, or any component thereof, infringes on patent or other intellectual property rights of third-parties;
- perceived risks associated with the use of ReWalk or similar products or technologies;
- the introduction of new competitive products or greater acceptance of competitive products;
- adverse regulatory or legal actions relating to ReWalk or similar products or technologies; and
- problems arising from the outsourcing of our manufacturing capabilities, or our existing manufacturing and supply relationships.

Any factors that negatively impact sales of ReWalk would adversely affect our business, financial condition and operating results.

13

Table of Contents

The market for medical exoskeletons is new and unproven, and important assumptions about the potential market for our products may be inaccurate.

The market for medical exoskeletons is new and unproven. Accordingly, it is difficult to predict the future size and rate of growth of the market. We cannot be certain whether the market will continue to develop or if medical exoskeletons will achieve and sustain a level of market acceptance and demand sufficient for us to continue to generate revenue and achieve profitability.

Limited sources exist to obtain reliable market data with respect to the number of mobility impaired individuals and the incurrence of spinal cord injuries in our target markets. In addition, there are no third-party reports or studies regarding what percentage of those with limited mobility or spinal cord injuries would be able to use exoskeletons in general, or our current or planned future products in particular. In order to use our current products marketed to those with paraplegia, users must have healthy hands and shoulders, weigh less than 220 pounds/100 kilograms and be between 5 ft. 1 inch and 6 ft. 6 inches/1.55 meters and 2 meters. Users must also not have balance, brain or vestibular disorders that would affect their balance. Future products for those with paraplegia, quadriplegia or other mobility impairments or spinal cord injuries may have the same or other restrictions. Our business strategy is based, in part, on our estimates of the number of mobility impaired individuals and the incurrence of spinal cord injuries in our target markets and the percentage of those groups that would be able to use our current and future products. Our assumptions may be inaccurate and may change.

If the medical exoskeleton market fails to develop or develops more slowly than we expect, or if we have relied on sources or made assumptions that are not accurate, our business could be adversely affected.

In addition, because we operate in a new market, the actions of our competitors could adversely affect our business. Adverse events such as product defects or legal claims with respect to competing or similar products could cause reputational harm to the exoskeleton market on the whole. Further, adverse regulatory findings or reimbursement-related decisions with respect to other exoskeleton products could negatively impact the entire market and, accordingly, our business.

We have a limited operating history upon which you can evaluate our business plan and prospects.

Although we were incorporated in 2001, we did not begin selling ReWalk Rehabilitation until 2011, and we did not begin selling ReWalk Personal in Europe until 2012. We expect to begin selling ReWalk Personal in the United States in the third quarter of 2014 as we received FDA clearance to do so in June 2014. Therefore, we have limited operating history upon which you can evaluate our business plan and prospects. Our business plan and prospects must be considered in the light of the potential problems, delays, uncertainties and complications encountered in connection with a newly established business. The risks include, but are not limited to, that:

- a market will not develop for our products;
- we will not be able to develop scalable products and services, or that although scalable, our products and services will not be economical to market;
- we will not be able to establish brand recognition and competitive advantages for our products;
- we will not receive necessary regulatory clearances or approvals for our products; and
- our competitors market an equivalent or superior product or hold proprietary rights that preclude us from marketing our products.

There are no assurances that we can successfully address these challenges. If we are unsuccessful, our business, financial condition and operating results could be materially and adversely affected.

If we are unable to expand our sales, marketing and training infrastructure, we may fail to increase our sales.

A key element of our business strategy is the continued expansion of our sales and marketing infrastructure, through the hiring, training, retaining and motivating of skilled sales and marketing representatives with industry

Table of Contents

experience and knowledge. In order to grow our business efficiently, we must coordinate the expansion of this infrastructure with the timing of regulatory approvals, decisions regarding reimbursements, and other factors in various geographies. Developing a sales and marketing infrastructure is expensive and time consuming and an inability to develop such an organization in a timely manner, or in coordination with regulatory or other developments, could inhibit potential sales and delay the successful adoption of ReWalk.

We expect to face significant challenges as we manage and grow our sales and marketing infrastructure and work to retain the individuals who make up those networks. Recently hired sales representatives require training and take time to achieve full productivity. If we fail to train recent hires adequately, or if we experience high turnover in our sales force in the future, we cannot be certain that new hires will become as productive as may be necessary to maintain or increase our sales. In addition, if we are not able to recruit and retain a network of internal trainers, we may not be able to successfully train customers on the use of ReWalk, which could inhibit new sales and harm our reputation. If we are unable to expand our sales, marketing and training capabilities, we may not be able to effectively commercialize ReWalk, or enhance the strength of our brand, which could have a material adverse effect on our operating results.

The health benefits of ReWalk have not been substantiated by long-term clinical data, which could limit sales.

Although our interim analysis of an ongoing study demonstrates improvements in secondary physical conditions such as reduction in pain and spasticity and improving bowel and urinary tract function, decreasing pain, emotional and psychosocial benefits, the health benefits of our current ReWalk products have not been substantiated by long-term clinical data. As a result, potential customers and healthcare providers may be slower to adopt or recommend ReWalk and third-party payors may not be willing to provide coverage or reimbursement for our products. In addition, future studies or clinical experience may indicate that treatment with our current or future ReWalk products is not superior to treatment with alternative products or therapies. Such results could slow the adoption of our products and significantly reduce our sales.

We may fail to secure or retain adequate coverage or reimbursement for ReWalk by third-party payors.

We expect that in the future a significant source of payment for ReWalk systems will be private insurance plans and managed care programs, government programs such as the Veterans Administration, Medicare and Medicaid, worker s compensation and other third-party payors. Currently, no uniform policy of coverage and reimbursement for electronic exoskeleton medical technology exists among third-party payors in the United States or elsewhere. To date, payments for our products have been made primarily by self-payers, through case-by-case determinations by third-party payors and by negotiating the cost of a ReWalk into accident settlements. There is limited clinical data related to ReWalk, and third-party payors may consider use of ReWalk to be experimental and therefore refuse to cover it. For example, Aetna recently announced its determination that certain lower-limb prostheses, including ReWalk, are experimental and investigational because there is inadequate evidence of their effectiveness. Private insurance companies do not currently cover or provide reimbursement for any medical exoskeleton products for personal use, including ReWalk, and may never provide such coverage.

Many private third-party payors use coverage decisions and payment amounts determined by the Centers for Medicare and Medicaid Services, or CMS, which administers the Medicare program, as guidelines in setting their coverage and reimbursement policies. In the future, we will pursue economic benefit clinical studies for CMS, which we expect to demonstrate the secondary medical benefits and long-term cost savings potential of ReWalk. While we believe that a positive response from CMS in respect of such studies will broaden coverage by private insurers, we expect that it could take three to five years to receive a decision from CMS. Even with a positive decision from CMS regarding ReWalk Personal, future action by CMS or other government agencies may diminish possible payments to physicians, outpatient centers and/or hospitals that purchase ReWalk Rehabilitation, and possible payments to individuals who purchase ReWalk Personal. Additionally, a decision by CMS to provide reimbursement could influence other payors, including private insurers. If CMS declines to provide for reimbursements of ReWalk or if its reimbursement price is lower than that of other payors, ReWalk

Table of Contents

may not be reimbursed at a cost-effective level or at all. Those private third-party payors that do not follow the Medicare guidelines may adopt different coverage and reimbursement policies for purchase of ReWalk, or use of ReWalk Rehabilitation at a hospital or rehabilitation center. In addition, we expect that the purchase of ReWalk Rehabilitation systems will require the approval of senior management at hospitals or rehabilitation facilities, inclusion in the hospitals or rehabilitation facilities budget process for capital expenditures, and in the case of ReWalk Personal, fundraising and financial planning or assistance.

Third-party payors are developing increasingly sophisticated methods of controlling healthcare costs. These cost control methods include prospective payment systems, capitated rates, benefit redesigns and an exploration of other cost-effective methods of delivering healthcare. These cost control methods potentially limit the amount that healthcare providers may be willing to pay for electronic exoskeleton medical technology, if they provide coverage at all. We may be unable to sell ReWalk systems on a profitable basis if third-party payors deny coverage or provide insufficient levels of reimbursement.

We depend on a single third-party to manufacture ReWalk and a limited number of third-party suppliers for certain components of ReWalk.

We have contracted with Sanmina Corporation, a well-established contract manufacturer with expertise in the medical device industry, for the manufacture of all of our products and the sourcing of all of our components and raw materials. Pursuant to this contract, Sanmina manufactures ReWalk, pursuant to our specifications, at its facility in Ma alot, Israel. We may terminate our relationship with Sanmina at any time upon written notice. In addition, either we or Sanmina may terminate the relationship in the event of a material breach, subject to a 30-day cure period. For our business strategy to be successful, Sanmina must be able to manufacture our products in sufficient quantities, in compliance with regulatory requirements and quality control standards, in accordance with agreed upon specifications, at acceptable costs and on a timely basis. Increases in our product sales, whether forecasted or unanticipated, could strain the ability of Sanmina to manufacture an increasingly large supply of our current or future products in a manner that meets these various requirements. In addition, although we are not restricted from engaging an alternative manufacturer, and have the capabilities to manufacture ReWalk in-house, the process of moving our manufacturing activities would be time consuming and costly, and may limit our ability to meet our sales commitments, which could harm our reputation and could have a material adverse effect on our business.

We also rely on third-party suppliers, which contract directly with Sanmina, to supply certain components of ReWalk. Sanmina does not have long-term supply agreements with most of their suppliers and, in many cases, makes purchases on a purchase order basis. Sanmina s ability to secure adequate quantities of such products may be limited. Suppliers may encounter problems that limit their ability to manufacture components for our products, including financial difficulties or damage to their manufacturing equipment or facilities. If Sanmina fails to obtain sufficient quantities of high quality components to meet demand on a timely basis, we could lose customer orders, our reputation may be harmed and our business could suffer.

Sanmina generally uses a small number of suppliers for ReWalk. Depending on a limited number of suppliers exposes us to risks, including limited control over pricing, availability, quality and delivery schedules. If any one or more of our suppliers ceases to provide sufficient quantities of components in a timely manner or on acceptable terms, Sanmina would have to seek alternative sources of supply. It may be difficult to engage additional or replacement suppliers in a timely manner. Failure of these suppliers to deliver products at the level our business requires would limit our ability to meet our sales commitments, which could harm our reputation and could have a material adverse effect on our business. Sanmina also may have difficulty obtaining similar components from other suppliers that are acceptable to the FDA or other regulatory agencies, and the failure of Sanmina s suppliers to comply with strictly enforced regulatory requirements could expose us to regulatory action including warning letters, product recalls, termination of distribution, product seizures or civil penalties. It could also require Sanmina to cease using the components, seek alternative components or technologies and we could be forced to modify our products to incorporate alternative components or technologies, which could result in a requirement to seek additional regulatory approvals. Any disruption of this nature or increased expenses could harm our commercialization efforts and adversely affect our operating results.

Table of Contents

We also rely on a limited number of suppliers for the batteries used by ReWalk and do not maintain any long-term supply agreement with respect to batteries. If we or our third-party distributors fail to obtain sufficient quantities of batteries in a timely manner, our reputation may be harmed and our business could suffer.

Our future growth and operating results will depend on our ability to develop and commercialize new products and penetrate new markets.

In the next few years, we expect that a significant portion of our revenues will be derived from ReWalk products that we adapt for use by individuals with quadriplegia and other mobility impairments besides paraplegia. As such, our future results will depend on our ability to successfully develop and commercialize such products. We cannot ensure you that we will be able to introduce new products or products currently under development for additional indications in a timely manner, or at all. In addition, we may not be able to clinically demonstrate the medical benefits of our products for new indications, and we do not yet have any clinical data demonstrating the benefits of our products for indications other than paraplegia. We may also be unable to gain necessary regulatory approvals to enable us to market ReWalk for additional indications or the regulatory process may be more costly and time consuming than expected.

Even if we are successful in the design and development of new products, our growth and results of operations will depend on our ability to penetrate new markets and gain acceptance by the quadriplegia community and non-spinal cord injury markets such as the stroke and multiple sclerosis communities. We may not be able to gain such market acceptance in these communities in a timely manner, or at all.

While they will utilize the same core technology platform, our new products and products currently under development will have design features and components that differ from our current products. Accordingly, these products will also be subject to the risks described above under We currently rely, and in the future will rely, on sales of our ReWalk systems and related service contracts and extended warranties for our revenue. To the extent we are unable to successfully develop and commercialize products to address indications other than paraplegia, we will not meet our projected results of operations and future growth.

We operate in a competitive industry that is subject to rapid technological change, and we expect competition to increase.

There are several other companies developing technology and devices that compete with ReWalk. Our principal competitors in the medical exoskeleton market consist of Ekso Bionics, Rex Bionics, Cyberdyne, and Parker Hannifin. These companies have products currently available for institutional use and some are in the early stages of the FDA clearance process for personal use. We expect some of such products to become available for personal use in the next few years. In addition, we compete with alternative devices and alternative therapies, including treadmill-based gait therapies, such as those offered by Hocoma, AlterG, Aretech and Reha Technology. These or other medical device or robotics companies, academic and research institutions, or others, may develop new technologies or therapies that provide a superior walking experience, are more effective in treating the secondary medical conditions that we target or are less expensive than ReWalk or future products. Our technologies and products could be rendered obsolete by such developments. We may also compete with other treatments and technologies that address the secondary medical conditions that ReWalk seeks to mitigate.

Our competitors may respond more quickly to new or emerging technologies, undertake more extensive marketing campaigns, have greater financial, marketing and other resources than we do or may be more successful in attracting potential customers, employees and strategic partners. In addition, potential customers, such as hospitals and rehabilitation centers, could have long-standing or contractual relationships with competitors or other medical device companies. Potential customers may be reluctant to adopt ReWalk, particularly if it competes with or has the potential to compete with or diminish the need/utilization of products or treatments supported through these existing relationships. If we are not able to compete effectively, our business and results of operations will be negatively impacted.

Table of Contents

We have incurred net losses since our inception.

We have experienced operating losses since our inception in 2001. We expect that we will continue to incur losses for at least the next two years as we continue to commercialize our ReWalk systems, expand our sales and marketing capabilities, continue our ongoing research and development and continue to develop the corporate infrastructure necessary to market and sell our products. Additionally, following this offering, we expect general and administrative expenses to increase due to the additional operational and reporting costs associated with being a public company. Our ability to achieve profitability and positive cash flow is subject to the risks described in this section. If we are unable to become profitable with positive cash flow, the value of your investment will be adversely affected.

We may not have sufficient funds to meet our future capital requirements.

We believe that the combination of the proceeds of this offering and our other current sources of liquidity will be sufficient to meet our anticipated cash needs for at least the next 24 months. However, if we require additional funds during that period or in later periods, we may need to seek additional sources of funds, including potentially by selling additional equity securities, borrowing or selling or licensing our assets. However, we may be unable to obtain additional funds on reasonable terms, or at all. As a result, we may be required to reduce the scope of, or delay or eliminate, some or all of our current and planned commercialization and research and development activities. We also may have to reduce marketing, customer service or other resources devoted to our business. Any of these actions could materially harm our business and results of operations. Any sale of additional equity may result in dilution to our shareholders and agreements governing any borrowing arrangement may contain covenants that could restrict our operations.

We utilize independent distributors who are free to market products that compete with ReWalk.

While we expect that the percentage of our sales generated from independent distributors will decrease over time as we increase our direct sales efforts in the United States in response to the receipt of FDA clearance for ReWalk Personal, we believe that a meaningful percentage of our sales will continue to be generated by independent distributors in the future. None of our independent distributors has been required to sell our products exclusively. Our distributor agreements generally have one year initial terms and automatic renewals for an additional year. If any of our key independent distributors were to cease to distribute our products, our sales could be adversely affected. In such a situation, we may need to seek alternative independent distributors or increase our reliance on our other independent distributors or our direct sales representatives, which may not prevent our sales from being adversely affected. Additionally, to the extent that we enter into additional arrangements with independent distributors to perform sales, marketing, or distribution services, the terms of the arrangements could cause our product margins to be lower than if we directly marketed and sold our products.

We are dependent on a single facility for the manufacturing and assembly of our products.

All manufacturing and assembly of our products is conducted at a single facility of our contract manufacturer, Sanmina, located in Ma alot, Israel. Accordingly, we are highly dependent on the uninterrupted and efficient operation of this facility. If operations at this facility were to be disrupted as a result of equipment failures, earthquakes and other natural disasters, fires, accidents, work stoppages, power outages, acts of war or terrorism or other reasons, our business, financial condition and results of operations could be materially adversely affected. In particular, this facility is located in the north of Israel within range of rockets that have from time to time been fired into the country during armed conflicts with Hezbollah in Lebanon. Although our manufacturing and assembly operations could be transferred elsewhere, either in-house or to an alternative Sanmina facility, the process of relocating these operations would cause delays in production. Lost sales or increased costs that we may experience during the disruption, or a forced relocation, of operations may not be recoverable under our insurance policies, and longer-term business disruptions could result in a loss of customers. If this were to occur, our business, financial condition and operations could be materially negatively impacted.

Table of Contents

We may receive a significant number of warranty claims or our ReWalk system may require significant amounts of service after sale.

Sales of ReWalk generally include a two-year warranty for parts and services, other than for normal wear and tear. We also provide customers with the option to purchase an extended warranty for up to an additional three years. If product returns or warranty claims are significant or exceed our expectations, we could incur unanticipated expenditures for parts and services, which could have a material adverse effect on our operating results.

Defects in our products or the software that drives them could adversely affect the results of our operations.

The design, manufacture and marketing of ReWalk involve certain inherent risks. Manufacturing or design defects, unanticipated use of ReWalk, or inadequate disclosure of risks relating to the use of ReWalk can lead to injury or other adverse events. In addition, because the manufacturing of our products is outsourced to Sanmina, our original equipment manufacturer, we may not be aware of manufacturing defects that could occur. Such adverse events could lead to recalls or safety alerts relating to ReWalk (either voluntary or required by the FDA or similar governmental authorities in other countries), and could result, in certain cases, in the removal of ReWalk from the market. A recall could result in significant costs. To the extent any manufacturing defect occurs, our agreement with Sanmina contains a limitation on Sanmina s liability, and therefore we could be required to incur the majority of related costs. Product defects or recalls could also result in negative publicity, damage to our reputation or, in some circumstances, delays in new product approvals.

When a human exoskeleton is used by a paralyzed individual to walk, the individual relies completely on the exoskeleton to hold him or her upright. In addition, ReWalk incorporates sophisticated computer software. Complex software frequently contains errors, especially when first introduced. Our software may experience errors or performance problems in the future. If any part of ReWalk s hardware or software were to fail, the user could experience death or serious injury. Additionally, users may not use ReWalk in accordance with safety protocols and training, which could enhance the risk of death or injury. Any such occurrence could cause delay in market acceptance of ReWalk, damage to our reputation, additional regulatory filings, product recalls, increased service and warranty costs, product liability claims and loss of revenue relating to such hardware or software defects.

The medical device industry has historically been subject to extensive litigation over product liability claims. We have been, and anticipate that as part of our ordinary course of business we may be, subject to product liability claims alleging defects in the design, manufacture or labeling of our products. A product liability claim, regardless of its merit or eventual outcome, could result in significant legal defense costs and high punitive damage payments. Although we maintain product liability insurance, the coverage is subject to deductibles and limitations, and may not be adequate to cover future claims. Additionally, we may be unable to maintain our existing product liability insurance in the future at satisfactory rates or adequate amounts.

We may not be able to enhance our product offerings through our research and development efforts.

In order to increase our sales and our market share in the exoskeleton market, we must enhance and broaden our research and development efforts and product offerings in response to the evolving demands of people with paraplegia or paralysis and healthcare providers, as well as competitive technologies. We may not be successful in developing, obtaining regulatory approval for, or marketing our proposed products. In addition, notwithstanding our market research efforts, our future products may not be accepted by consumers, their caregivers, healthcare providers or third-party payors who reimburse consumers for our products. The success of any proposed product offerings will depend on numerous factors, including our ability to:

- identify the product features that people with paraplegia or paralysis, their caregivers and healthcare providers are seeking in a medical device that restores upright mobility and successfully incorporate those features into our products;

- develop and introduce proposed products in sufficient quantities and in a timely manner;

Table of Contents

adequately protect our intellectual property and avoid infringing upon the intellectual property rights of third-parties;

demonstrate the safety, efficacy and health benefits of proposed products; and

obtain the necessary regulatory approvals for proposed products.

If we fail to generate demand by developing products that incorporate features desired by consumers, their caregivers or healthcare providers, or if we do not obtain regulatory clearance or approval for proposed products in time to meet market demand, we may fail to generate sales sufficient to achieve or maintain profitability. We have in the past experienced, and we may in the future experience, delays in various phases of product development, including during research and development, manufacturing, limited release testing, marketing and customer education efforts. Such delays could cause customers to delay or forego purchases of our products, or to purchase our competitors products. Even if we are able to successfully develop proposed products when anticipated, these products may not produce sales in excess of the costs of development, and they may be quickly rendered obsolete by changing consumer preferences or the introduction by our competitors of products embodying new technologies or features.

There is no long-term clinical data with respect to the effects of ReWalk, and our products could cause unforeseen negative effects.

While short-term clinical studies have established the safety of ReWalk, there is no long-term clinical data with respect to the safety or physical effects of ReWalk. Future results and experience could indicate that our products are not safe for long-term use or cause unexpected complications or other unforeseen negative effects. Because ReWalk users generally do not have feeling in their lower body, users may not immediately notice damaging effects, which could exacerbate their impact. If in the future ReWalk is shown to be unsafe or cause such unforeseen effects, we could be subject to mandatory product recalls, suspension or withdrawal of FDA clearance or approval, significant legal liability or harm to our business reputation.

We may enter into collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships with third-parties that may not result in the development of commercially viable products or the generation of significant future revenues.

In the ordinary course of our business, in the future we may enter into collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships to develop ReWalk and to pursue new markets. Proposing, negotiating and implementing collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships may be a lengthy and complex process. We may not identify, secure, or complete any such transactions or arrangements in a timely manner, on a cost-effective basis, on acceptable terms or at all. We have limited institutional knowledge and experience with respect to these business development activities, and we may also not realize the anticipated benefits of any such transaction or arrangement. In particular, these collaborations may not result in the development of products that achieve commercial success or result in significant revenues and could be terminated prior to developing any products. For example, we have entered into an arrangement with Yaskawa for the distribution of our products in certain Asian markets, which may not be as productive or successful as we hope.

If we pursue collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships, we may not be in a position to exercise sole decision making authority regarding the transaction or arrangement, which could create the potential risk of creating impasses on decisions, and our collaborators may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. It is possible that conflicts may arise with our collaborators. Our collaborators may act in their self-interest, which may be adverse to our best interest, and they may breach their obligations to us. Any such disputes could result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements are contractual in nature and may be terminated or dissolved under the terms of the applicable agreements.

Table of Contents

Exchange rate fluctuations between the U.S. dollar, the euro and the NIS may negatively affect our earnings.

The U.S. dollar is our functional and reporting currency. In 2013, most of our revenues were denominated in U.S. dollars, approximately half of our expenses were denominated in U.S. dollars, and the remainder of our expenses were denominated in NIS and euros. In 2014, we expect that the denominations of our revenues and expenses will be consistent with what we experienced in 2013. Accordingly, any appreciation of the NIS or euro relative to the U.S. dollar would adversely impact our net loss or net income, if any. We have in the past engaged in limited hedging activities, and any hedging strategies that we may implement in the future to mitigate currency risks, such as forward contracts, options and foreign exchange swaps related to transaction exposures, may not eliminate our exposure to foreign exchange fluctuations. For further information, see Management s Discussion and Analysis of Financial Condition and Results of Operations Quantitative and Qualitative Disclosure About Market Risk Foreign Currency Risk.

We may seek to grow our business through acquisitions of complementary products or technologies, and the failure to manage acquisitions, or the failure to integrate them with our existing business, could have a material adverse effect on our business, financial condition and operating results.

From time to time, we may consider opportunities to acquire other products or technologies that may enhance our product platform or technology, expand the breadth of our markets or customer base, or advance our business strategies. Potential acquisitions involve numerous risks, including:

- problems assimilating the acquired products or technologies;
- issues maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with acquisitions;
- diversion of management s attention from our existing business;
- risks associated with entering new markets in which we have limited or no experience; and
- increased legal and accounting costs relating to the acquisitions or compliance with regulatory matters.

We have no current commitments with respect to any acquisition. We do not know if we will be able to identify acquisitions we deem suitable, whether we will be able to successfully complete any such acquisitions on favorable terms or at all, or whether we will be able to successfully integrate any acquired products or technologies. Our potential inability to integrate any acquired products or technologies effectively may adversely affect our business, operating results and financial condition.

If there are significant disruptions in our information technology systems, our business, financial condition and operating results could be adversely affected.

The efficient operation of our business depends on our information technology systems. We rely on our information technology systems to effectively manage sales and marketing data, accounting and financial functions, inventory management, product development tasks, research and development data, customer service and technical support functions. Our information technology systems are vulnerable to damage or interruption from earthquakes, fires, floods and other natural disasters, terrorist attacks, attacks by computer viruses or hackers, power losses, and computer system or data network failures. In addition, our data management application is hosted by a third-party service provider whose security and information technology systems are subject to similar risks, and ReWalk systems contain software which could be subject to computer virus or hacker attacks or other failures.

The failure of our or our service providers information technology systems or ReWalk s software to perform as we anticipate or our failure to effectively implement new information technology systems could disrupt our entire operation or adversely affect our software products and could result in decreased sales, increased overhead costs, and product shortages, all of which could have a material adverse effect on our reputation, business, financial condition and operating results.

Table of Contents

If we fail to properly manage our anticipated growth, our business could suffer.

Our rapid growth has placed, and we expect that it will continue to place, a significant strain on our management team and on our financial resources. Failure to manage our growth effectively could cause us to misallocate management or financial resources, and result in losses or weaknesses in our infrastructure, which could materially adversely affect our business. Additionally, our anticipated growth will increase the demands placed on our suppliers, resulting in an increased need for us to manage our suppliers and monitor for quality assurance. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our business objectives.

We depend on the knowledge and skills of our senior management.

We have benefited substantially from the leadership and performance of our senior management. For example, we depend on our Chief Executive Officer s experience successfully scaling an early stage medical device company, as well as the experience of other members of management. In addition, we depend on the personal experiences with paralysis of our founder, President and Chief Technology Officer in the development of our products. We carry key man insurance on Dr. Amit Goffer, our founder, President and Chief Technology Officer, but not on any other executive officer, and the amount of such coverage would likely be insufficient to offset the impact to our business of the loss of his services. Our success will depend on our ability to retain our current management. Competition for senior management in our industry is intense and we cannot guarantee that we will be able to retain our personnel. The loss of the services of certain members of our senior management could prevent or delay the implementation and completion of our strategic objectives, or divert management s attention to seeking qualified replacements.

Risks Related to Government Regulation

We are subject to extensive governmental regulations relating to the manufacturing, labeling and marketing of our products.

Our medical products and manufacturing operations are subject to regulation by the FDA, the European Union, the Ministry of Health in Israel, and other governmental authorities both inside and outside of the United States. These agencies enforce laws and regulations that govern the development, testing, manufacturing, labeling, storage, installation, servicing, advertising, promoting, marketing, distribution, import, export and market surveillance of ReWalk.

Our products are regulated as medical devices in the United States under the Federal Food, Drug, and Cosmetic Act, or FFDCA, as implemented and enforced by the FDA. Under the FFDCA, medical devices are classified into one of three classes Class I, Class II or Class III depending on the degree of risk associated with the medical device and the extent of control needed to provide reasonable assurance of safety and effectiveness. Classification of a device is important because the class to which a device is assigned determines, among other things, the necessity and type of FDA review required prior to marketing the device. See Business Government Regulation.

In June 2014, the FDA granted our petition for *de novo* classification, which is a route to market for medical devices that are low to moderate risk, but are not substantially equivalent to a predicate device, and classified ReWalk as Class II subject to certain special controls. The special controls established in the *de novo* order include compliance with medical device consensus standards; performance of a postmarket surveillance clinical study demonstrating a reasonable assurance of safety and effectiveness in urban terrain; non-clinical performance testing of the system s function and durability; a training program; and labeling related to device use and user training. In order for us to market ReWalk, we must comply with both general controls, including controls related to quality, facility registration, reporting of adverse events and labeling, and the special controls established for the device. Failure to comply with the general and special controls could lead to removal of ReWalk from the market, which would have a material adverse effect on our business.

Table of Contents

Following the introduction of a product, the governmental agencies will periodically review our manufacturing processes and product performance, and we are under a continuing obligation that all applicable regulatory requirements continue to be met. The process of complying with the applicable good manufacturing practices, adverse event reporting, clinical trial and other requirements can be costly and time consuming, and could delay or prevent the production, manufacturing or sale of ReWalk. In addition, if we fail to comply with applicable regulatory requirements, it could result in fines, delays or suspensions of regulatory clearances, closure of manufacturing sites, seizures or recalls of products and damage to our reputation. Recent changes in enforcement practice by the FDA, European Union and other agencies have resulted in increased enforcement activity, which increases the compliance risk that we and other companies in our industry are facing. In addition, governmental agencies may impose new requirements regarding registration, labeling or prohibited materials that may require us to modify or re-register ReWalk once it is already on the market or otherwise impact our ability to market ReWalk in those countries. The process of complying with these governmental regulations can be costly and time consuming, and could delay or prevent the production, manufacturing or sale of ReWalk.

If we or our third-party manufacturers or suppliers fail to comply with the FDA s Quality System Regulation, our manufacturing operations could be interrupted.

We, Sanmina and some of our suppliers are required to comply with the FDA s QSR which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products. We and Sanmina and our suppliers are also subject to the regulations of foreign jurisdictions regarding the manufacturing process if we or our distributors market our products abroad. We continue to monitor our quality management in order to improve our overall level of compliance. Our facilities are subject to periodic and unannounced inspection by U.S. and foreign regulatory agencies to audit compliance with the QSR and comparable foreign regulations. If our facilities or those of Sanmina or our suppliers are found to be in violation of applicable laws and regulations, or if we or Sanmina or our suppliers fail to take satisfactory corrective action in response to an adverse inspection, the regulatory authority could take enforcement action, including any of the following sanctions:

untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;

customer notifications or repair, replacement, refunds, detention or seizure of our products;

operating restrictions or partial suspension or total shutdown of production;

refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;

withdrawing 510(k) marketing clearances or PMA approvals that have already been granted;

refusing to provide Certificates for Foreign Government;

refusing to grant export approval for our products; or

pursuing criminal prosecution.

Any of these sanctions could impair our ability to produce ReWalk in a cost-effective and timely manner in order to meet our customers demands, and could have a material adverse effect on our reputation, business, results of operations and financial condition. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and our ability to generate profits.

We are subject to various laws and regulations, including fraud and abuse laws and anti-bribery laws, which, if violated, could subject us to substantial penalties.

Medical device companies such as ours have faced lawsuits and investigations pertaining to alleged violations of numerous statutes and regulations, including anti-corruption laws and health care fraud and abuse laws, such as the federal False Claims Act, the federal Anti-Kickback Statute and the U.S. Foreign Corrupt

Table of Contents

Practices Act, or the FCPA. See Business Government Regulation. U.S. federal and state laws, including the federal Physician Payments Sunshine Act, or the Sunshine Act, and the implementation of Open Payments regulations under the Sunshine Act, require medical device companies to disclose certain payments made to healthcare providers and teaching hospitals or funds spent on marketing and promotion of medical device products. It is widely anticipated that public reporting under the Sunshine Act and implementing Open Payments regulations will result in increased scrutiny of the financial relationships between industry, physicians and teaching hospitals. These anti-kickback, anti-bribery, public reporting and aggregate spend laws affect our sales, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, rehabilitation centers, physicians or other potential purchasers or users of ReWalk. They also impose additional administrative and compliance burdens on us. In particular, these laws influence, among other things, how we structure our sales offerings, including discount practices, customer support, education and training programs and physician consulting and other service arrangements. If we are in violation of any of these requirements or any actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant criminal and civil fines and penalties, exclusion from federal healthcare programs or other sanctions.

The FCPA applies to companies, such as us following this offering, with a class of securities registered under the Exchange Act. The FCPA and other anti-bribery laws to which various aspects of our operations may be subject generally prohibit companies and their intermediaries from making improper payments to officials for the purpose of obtaining or retaining business. In various jurisdictions, our operations require that we and third parties acting on our behalf routinely interact with government officials, including medical personnel who may be considered government officials for purposes of these laws because they are employees of state-owned or controlled facilities. Other anti-bribery laws to which various aspects of our operations may be subject, including the United Kingdom Bribery Act, also prohibit improper payments to private parties and prohibit receipt of improper payments. Our policies prohibit our employees from making or receiving corrupt payments, including, among other things, to require compliance by third parties engaged to act on our behalf. Our policies mandate compliance with these anti-bribery laws, however, we operate in many parts of the world that have experienced governmental and/or private corruption to some degree. As a result, the existence and implementation of a robust anti-corruption program cannot eliminate all risk that unauthorized reckless or criminal acts have been or will be committed by our employees or agents. Violations of these laws, or allegations of such violations, could disrupt our business and harm our financial condition, results of operations, cash flows and reputation.

If we are found to have violated laws protecting the confidentiality of patient health information, we could be subject to civil or criminal penalties, which could increase our liabilities and harm our reputation or our business.

There are a number of federal, state and foreign laws protecting the confidentiality of certain patient health information, including patient records, and restricting the use and disclosure of that protected information. In particular, the U.S. Department of Health and Human Services, or HHS, promulgated patient privacy rules under the Health Insurance Portability and Accountability Act of 1996, or HIPAA. These privacy rules protect medical records and other personal health information by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting of their own health information and limiting most use and disclosures of health information to the minimum amount reasonably necessary to accomplish the intended purpose. If we or any of our service providers are found to be in violation of the promulgated patient privacy rules under HIPAA, we could be subject to civil or criminal penalties, which could increase our liabilities, harm our reputation and have a material adverse effect on our business, financial condition and operating results.

Table of Contents

Risks Related to Our Intellectual Property

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

Our success depends in part on our ability to obtain and maintain protection for the intellectual property relating to or incorporated into our products. We seek to protect our intellectual property through a combination of patents, trademarks, confidentiality and invention assignment agreements with our employees and certain of our contractors and confidentiality agreements with certain of our consultants, scientific advisors and other vendors and contractors. In addition, we rely on trade secrets law to protect our proprietary software and product candidates/products in development.

The patent position of robotic and exoskeleton inventions can be highly uncertain and involves many new and evolving complex legal, factual and technical issues. Patent laws and interpretations of those laws are subject to change and any such changes may diminish the value of our patents or narrow the scope of 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 technology or processes by third parties. Also, we cannot be sure that any patents will be granted in a timely manner or at all with respect to any of our patent pending applications or that any patents that are granted will be adequate to protect our intellectual property for any significant period of time or at all.

Litigation to establish or challenge the validity of patents, or to defend against or assert against others infringement, unauthorized use, enforceability or invalidity claims, can be lengthy and expensive and may result in our patents being invalidated or interpreted narrowly and our not being granted new patents related to our pending patent applications. Even if we prevail, litigation may be time-consuming and force us to incur significant costs, and any damages or other remedies awarded to us may not be valuable and management s attention could be diverted from managing our business. In addition, U.S. patents and patent applications may be subject to interference proceedings, and U.S. patents may be subject to re-examination proceedings in the U.S. Patent and Trademark Office. Foreign patents may also be subject to opposition or comparable proceedings in the corresponding foreign patent offices. Any of these proceedings may be expensive and could result in the loss of a patent or denial of a patent application, or the loss or reduction in the scope of one or more of the claims of a patent or patent application.

In addition, we seek to protect our trade secrets, know-how and confidential information that is not patentable by entering into confidentiality and invention assignment agreements with our employees and certain of our contractors and confidentiality agreements with certain of our consultants, scientific advisors and other vendors and contractors. 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. Enforcing a claim that a third party illegally obtained and is using our trade secrets is expensive and time consuming, and the outcome is unpredictable.

We also have taken precautions to initiate reasonable safeguards to protect our information technology systems. However, these measures may not be adequate to safeguard our proprietary intellectual property, which could lead to the loss or impairment of our intellectual property or to expensive litigation to defend our rights against competitors who may be better funded and have superior resources. In addition, unauthorized parties may attempt to copy or reverse engineer certain aspects of our products that we consider proprietary or our proprietary information may otherwise become known or may be independently developed by our competitors or other third parties. If other parties are able to use our proprietary technology or information, our ability to compete in the market could be harmed.

Further, unauthorized use of our intellectual property may have occurred, or may occur in the future, without our knowledge.

If we are unable to obtain or maintain adequate protection for intellectual property, or if any protection is reduced or eliminated, competitors may be able to use our technologies, resulting in harm to our competitive position.

Table of Contents

Our patents and proprietary technology and processes may not provide us with a competitive advantage.

Robotics and exoskeleton technologies have been developing rapidly in recent years. We are aware of several other companies developing competing exoskeleton devices for individuals with limited mobility and we expect the level of competition and the pace of development in our industry to increase. See Business Competition. While we believe our tilt-sensor technology provides a more natural and superior method of exoskeleton activation, which creates a better user experience, a variety of other activation and control methods exist for exoskeletons, several of which are being developed by our competitors, or may be developed in the future. As a result, our patent portfolio and proprietary technology and processes may not provide us with a significant advantage over our competitors, and competitors may be able to design and sell alternative products that are equal to or superior to our products without infringing on our patents. In addition, our current patents will expire and we may be unable to adequately develop new technologies and obtain future patent protection to preserve our competitive advantage. If we are unable to maintain a competitive advantage, our business and results of operations may be materially adversely affected.

Even in instances where others are found to infringe on our patents, many countries have laws under which a patent owner may be compelled to grant licenses for the use of the patented technology to other parties. In addition, many countries limit the enforceability of patents against other parties, including government agencies or government contractors. In these countries, a patent owner may have limited remedies, which could diminish the value of a patent. Further, the laws of some countries do not protect intellectual property rights to the same extent as the laws of the United States, particularly in the field of medical products and effective enforcement in those countries may not be available. The ability of others to market comparable products could adversely affect our business.

We may not be able to protect our intellectual property rights in all countries.

Filing, prosecuting, maintaining and defending patents on each of our products in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States are less extensive than those in the United States. In addition, the laws of some foreign countries, especially developing countries, do not protect intellectual property rights to the same extent as federal and state laws in the United States. Also, it may not be possible to effectively enforce intellectual property rights in some countries at all or to the same extent as in the United States and other countries. Consequently, we are unable to prevent third parties from using our inventions in all countries, or from selling or importing products made using our inventions in the jurisdictions in which we do not have (or are unable to effectively enforce) patent protection. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop, market or otherwise commercialize their own products, and we may be unable to prevent those competitors from importing those infringing products into territories where we have patent protection, but enforcement is not as strong as in the United States. These products may compete with our products and our patents and other intellectual property rights may not be effective or sufficient to prevent them from competing in those jurisdictions. Moreover, competitors or others in the chain of commerce may raise legal challenges against our intellectual property rights or may infringe upon our intellectual property rights, including through means that may be difficult to prevent or detect.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. Proceedings to enforce our patent rights in the United States or foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert patent infringement or other claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights in the United States and around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license from third parties.

Table of Contents

We may be subject to patent infringement claims, which could result in substantial costs and liability and prevent us from commercializing our current and future products.

The medical device industry is characterized by competing intellectual property and a substantial amount of litigation over patent rights. In particular, our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in competing technologies, have been issued patents and filed patent applications with respect to their products and processes and may apply for other patents in the future. The large number of patents, the rapid rate of new patent issuances, and the complexities of the technology involved increase the risk of patent litigation.

Determining whether a product infringes a patent involves complex legal and factual issues and the outcome of patent litigation is often uncertain. Even though we have conducted research of issued patents, no assurance can be given that patents containing claims covering our products, technology or methods do not exist, have not been filed or could not be filed or issued. In addition, because patent applications can take years to issue and because publication schedules for pending applications vary by jurisdiction, there may be applications now pending of which we are unaware and may result in issued patents which our current or future products infringe. Also, because the claims of published patent applications can change between publication and parent grant, there may be published applications that may issue with claims that we infringe.

Infringement actions and other intellectual property claims brought against us, with or without merit, may cause us to incur substantial costs and could place a significant strain on our financial resources, divert the attention of management and harm our reputation. We cannot be certain that we will successfully defend against any allegations of infringement. If we are found to infringe another party s patents, we could be required to pay damages. We could also be prevented from selling our products that infringe, unless we could obtain a license to use the technology or processes covered by such patents or could redesign our products so that they do not infringe. A license may be available on commercially reasonable terms or at all, and we may not be able to redesign our products to avoid infringement. Further, any modification to our products could require us to conduct clinical trials and revise our filings with the FDA and other regulatory bodies, which would be time consuming and expensive. In these circumstances, we may not be able to sell our products at competitive prices or at all, and our business and operating results could be harmed.

We rely on trademark protection to distinguish our products from the products of our competitors.

We rely on trademark protection to distinguish our products from the products of our competitors. We have registered the trademark ReWalk in Israel and are in the process of registering our trademark in the United States. In jurisdictions where we have not registered our trademark and are using it, and as permitted by applicable local law, we rely on common law trademark protection. Third-parties may oppose our trademark applications, or otherwise challenge our use of the trademarks, and may be able to use our trademarks in jurisdictions where they are not registered or otherwise protected by law. If our trademarks are successfully challenged or if a third party is using confusingly similar or identical trademarks in particular jurisdictions before we do, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote additional resources to marketing new brands. If others are able to use our trademarks, our ability to distinguish our products may be impaired, which could adversely affect our business. Further, we cannot assure you that competitors will not infringe upon our trademarks, or that we will have adequate resources to enforce our trademarks.

We may be subject to damages resulting from claims that our employees or we have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of our employees were previously employed at other medical device companies, including our competitors or potential competitors, and we may hire employees in the future that are so employed. We could in the future be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. If we fail in defending against such claims, a

Table of Contents

court could order us to pay substantial damages and prohibit us from using technologies or features that are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. If any of these technologies or features that are important to our products, this could prevent us from selling those products and could have a material adverse effect on our business. Even if we are successful in defending against these claims, such litigation could result in substantial costs and divert the attention of management.

Risks Related to Our Ordinary Shares and the Offering

Our share price may be volatile, and you may lose all or part of your investment.

The initial public offering price for the ordinary shares sold in this offering will be determined by negotiation between us and representatives of the underwriters. This price may not reflect the market price of our ordinary shares following this offering and the price of our ordinary shares may decline. In addition, the market price of our ordinary shares could be highly volatile and may fluctuate substantially as a result of many factors, including:

- actual or anticipated fluctuations in our growth rate or results of operations or those of our competitors;
- customer acceptance of our products;
- announcements by us or our competitors of new products or services, commercial relationships, acquisitions or expansion plans;
- announcements by us or our competitors of other material developments;
- our involvement in litigation;
- changes in government regulation applicable to us and our products;
- sales, or the anticipation of sales, of our ordinary shares by us, our insiders or other shareholders, including upon expiration of contractual lock-up agreements;
- developments with respect to intellectual property rights;
- competition from existing or new technologies and products;
- changes in key personnel;
- the trading volume of our ordinary shares;
- changes in the estimation of the future size and growth rate of our markets; and

general economic and market conditions.

In addition, the stock markets have experienced extreme price and volume fluctuations. Broad market and industry factors may materially harm the market price of our ordinary shares, regardless of our operating performance. In the past, following periods of volatility in the market price of a company s securities, securities class action litigation has often been instituted against that company. If we were involved in any similar litigation, we could incur substantial costs and our management s attention and resources could be diverted.

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

Prior to this offering, there has been no public market for our ordinary shares. An active trading market may not develop following completion of this offering or, if developed, may not be sustained. The lack of an active market may impair your ability to sell your ordinary 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 ordinary shares. An inactive market may also impair our ability to raise capital by selling our ordinary shares and may impair our ability to acquire other companies by using our ordinary shares as consideration.

Table of Contents

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

The trading market for our ordinary shares will rely in part on the research and reports that equity research analysts publish about us and our business. The analysts estimates are based upon their own opinions and are often different from our estimates or expectations. If our results of operations are below the estimates or expectations of public market analysts and investors, our share price could decline. Moreover, the price of our ordinary shares could decline if one or more securities analysts downgrade our ordinary shares or if those analysts issue other unfavorable commentary or do not publish research or reports about us or our business.

Following the closing of this offering, a small number of our shareholders will have a controlling influence over matters requiring shareholder approval, which could delay or prevent a change of control.

Following the closing of this offering, the largest beneficial owners of our shares, entities affiliated with SCP Vitalife Partners, Yaskawa Electric Corporation, Israeli Health Care Ventures II, L.P. and entities affiliated with Pontifax (Cayman) II, L.P., will beneficially own in the aggregate % of our ordinary shares, or % if the underwriters exercise in full their option to purchase additional ordinary shares. As a result, these shareholders, should they chose to act together or and even if they act individually, will exert significant influence over our operations and business strategy and would together have sufficient voting power to control the outcome of matters requiring shareholder approval. These matters may include:

- the composition of our board of directors, which has the authority to direct our business and to appoint and remove our officers;
- approving or rejecting a merger, consolidation or other business combination;
- raising future capital; and
- amending our articles of association, which govern the rights attached to our ordinary shares.

This concentration of ownership of our ordinary shares could delay or prevent proxy contests, mergers, tender offers, open-market purchase programs or other purchases of our ordinary shares that might otherwise give you the opportunity to realize a premium over the then-prevailing market price of our ordinary shares. This concentration of ownership may also adversely affect our share price.

As a foreign private issuer, we are permitted, and intend, to follow certain home country corporate governance practices instead of otherwise applicable SEC and Nasdaq Global Market requirements, which may result in less protection than is accorded to investors under rules applicable to domestic U.S. issuers.

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 applicable rules of the Nasdaq Global Market for domestic U.S. issuers. 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, our articles of association 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 33 $^{1}/_{3}$% of the issued share capital as required under the applicable rules of the Nasdaq Global Market. We may in the future elect to follow home country practices in Israel with regard to other matters, including the formation and composition of compensation and nominating and corporate 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 shares 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 applicable rules of the Nasdaq Global Market applicable to domestic U.S. issuers.

29

Table of Contents

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 a number of requirements under U.S. securities laws that apply to public companies that are not foreign private issuers. In particular, we will be exempt from the rules and regulations under the United States Securities Exchange Act of 1934, as amended, or the Exchange Act, related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders will be exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we will not be required under the Exchange Act to file annual and current reports and financial statements with the SEC as frequently or as promptly as U.S. domestic companies whose securities are registered under the Exchange Act and we will generally be exempt from filing quarterly reports with the SEC under the Exchange Act. Also, although a recent amendment to the Israeli Companies Law will require us to disclose the annual compensation of our five most highly compensated senior officers on an individual basis (rather than on an aggregate basis, as was permitted under the Israeli Companies Law for Israeli public companies listed overseas, such as in the United States, prior to such amendment), this disclosure will not be as extensive as that required of a U.S. domestic issuer. For example, it currently appears as if the disclosure required under Israeli law would be limited to compensation paid in the immediately preceding year without any requirement to disclose option exercises and vested stock options, pension benefits or potential payments upon termination or a change of control.

We will also be exempt from the provisions of Regulation FD, which prohibits the selective disclosure of material nonpublic information to, among others, broker-dealers and holders of a company s securities under circumstances in which it is reasonably foreseeable that the holder will trade in the company s securities on the basis of the information. Even though we intend to comply voluntarily with Regulation FD, these exemptions and leniencies will reduce the protections and the frequency and scope of information which you would be entitled if we were not a foreign private 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. We would also be required to follow U.S. proxy disclosure requirements in regard to the extent of disclosure of annual compensation of our five most highly compensated senior officers required. 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 SEC, 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 good 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 we cannot be certain whether the reduced requirements applicable to emerging growth companies will make our ordinary shares less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As a result, 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 of 2002, or 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 completion of this offering; (c) the date on which we have, during the previous three-year period, issued more than $1.0 billion in

Table of Contents

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 provided in the JOBS Act discussed above. We cannot predict if investors will find our ordinary shares less attractive as a result of our reliance on exemptions under the JOBS Act. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares and our share price may be more volatile.

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

After this offering, there will be of our ordinary shares outstanding, or ordinary shares if the underwriters exercise in full their option to purchase additional shares. Sales by us or our shareholders of a substantial number of ordinary shares in the public market following this offering, or the perception that these sales might occur, could cause the market price of our ordinary shares to decline or could impair our ability to raise capital through a future sale of, or pay for acquisitions using, our equity securities. Of our issued and outstanding shares, all the ordinary shares sold in this offering will be freely transferable, except for any shares acquired by our affiliates, as that term is defined in Rule 144 under the U.S. Securities Act of 1933, as amended, or the Securities Act. Following completion of this offering, % of our outstanding ordinary shares (or % if the underwriters exercise in full their option to purchase additional ordinary shares) will be considered restricted shares and will be held by our affiliates. Such securities can be resold into the public markets in the future in accordance with the requirements of Rule 144, including volume limitations, manner of sale requirements and notice requirements. See Shares Eligible for Future Sale.

We, our executive officers and directors, and the current holders of substantially all of our outstanding ordinary shares, have agreed with the underwriters that, subject to limited exceptions, for a period of 180 days after the date of this prospectus, we and they will not directly or indirectly offer, pledge, sell, contract to sell, grant any option to purchase or otherwise dispose of any ordinary shares or any securities convertible into or exercisable or exchangeable for ordinary shares, or in any manner transfer all or a portion of the economic consequences associated with the ownership of ordinary shares, or cause a registration statement covering any ordinary shares to be filed except for the ordinary shares offered in this offering, without the prior written consent of the designated representatives of the underwriters, who may, in their sole discretion and at any time without notice, release all or any portion of the shares subject to these lock-up agreements.

At any time following the closing of this offering, subject, however, to the 180-day lock-up agreement entered into with the underwriters, the beneficial owners of up to 9,166,662 of our ordinary shares are entitled to require that we register their shares under the Securities Act for resale into the public markets. All shares sold pursuant to an offering covered by such registration statement will be freely transferable. See Certain Relationships and Related Party Transactions Amended and Restated Shareholders Rights Agreement.

As of August 19, 2014, we had outstanding options to purchase 1,115,640 shares under our share option plans and had an additional 281,106 shares available for future grants under our option plans. Following this offering, we intend to file a registration statement on Form S-8 under the Securities Act registering the shares under our share option plans. Shares included in such registration statement will be available for sale in the public market immediately after such filing, subject to vesting provisions, except for shares held by affiliates who will have certain restrictions on their ability to sell. Shares registered on the Form S-8 will not be subject to the lock-up agreements described above.

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. Passive income for this purpose generally includes, among other things, certain dividends, interest, royalties, rents and

Table of Contents

gains from commodities and securities transactions and from the sale or exchange of property that gives rise to passive income. Passive income also includes amounts derived by reason of the temporary investment of funds, including those raised in a public offering. In determining whether a non-U.S. corporation is a PFIC, a proportionate share of the income and assets of each corporation in which it owns, directly or indirectly, at least a 25% interest (by value) is taken into account. 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 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. 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 end of the year. 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 a 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 Material U.S. and Israeli Tax Consequences for our Shareholders Material 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. See Material U.S. and Israeli Tax Consequences for our Shareholders Material U.S. Federal Income Tax Consequences Passive Foreign Investment Company Considerations.

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

The initial public offering price of our ordinary shares substantially exceeds the net tangible book value per share of our ordinary shares immediately after this offering. Therefore, if you purchase our ordinary shares in this offering, you will suffer, as of , 2014, immediate dilution of $ per ordinary share or $ per ordinary share if the underwriters exercise in full their option to purchase additional ordinary shares, in net tangible book value after giving effect to this offering at an assumed public offering price of $ per ordinary share, the midpoint of the estimated initial public offering price range set forth on the cover page of this prospectus, less underwriting discounts and commissions and the estimated expenses payable by us. If outstanding warrants or options to purchase our ordinary shares are exercised in the future, you will experience additional dilution. See Dilution.

We have broad discretion over the use of proceeds we receive in this offering and may not apply the proceeds in ways that increase the value of your investment.

Our management will have broad discretion in the application of the net proceeds from this offering and, as a result, you will have to rely upon the judgment of our management with respect to the use of these proceeds. Our management may spend a portion or all of the net proceeds in ways that not all shareholders approve of or that may not yield a favorable return. The failure by our management to apply these funds effectively could harm our business.

We have not yet determined whether our existing internal controls 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 SEC and the Public Company Accounting Oversight Board, starting with the second annual report that we file with the SEC after the consummation of this offering, our management will be required to report on the effectiveness of our internal control over financial reporting. In addition, once we no longer qualify as an emerging growth company under the JOBS Act and lose the ability to rely on the exemptions related thereto discussed above, our independent registered public accounting firm will also need to attest to the effectiveness of our internal control over financial

Table of Contents

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. We cannot predict the outcome of this determination and whether we will need to implement remedial actions in order to implement effective control over financial reporting. The determination and any remedial actions required could result in us incurring additional costs that we did not anticipate. Irrespective of compliance with Section 404, any failure of our internal controls could have a material adverse effect on our stated results of operations and harm our reputation. As a result, we may experience higher than anticipated operating expenses, as well as higher independent auditor fees during and after the implementation of these changes. If we are unable to implement any of the required changes to our internal control over financial reporting effectively or efficiently or are required to do so earlier than anticipated, it could adversely affect our operations, financial reporting and/or results of operations and could result in an adverse opinion on internal controls from our management and independent auditors.

Risks Relating to Our Incorporation and Location in Israel

Our technology development and quality headquarters and the manufacturing facility for our products are located in Israel and, therefore, our results may be adversely affected by economic restrictions imposed on, and political and military instability in, Israel.

Our technology development and quality headquarters, which houses substantially all of our research and development and our core research and development team, including engineers, machinists, researchers, and clinical and regulatory personnel, as well as the facility of our contract manufacturer, Sanmina, are located in Israel. Many of our employees, directors and officers are residents of Israel. Accordingly, political, economic and military conditions in Israel and the surrounding region 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 Arab neighbors, Hamas (an Islamist militia and political group in the Gaza Strip) and Hezbollah (an Islamist militia and political group in Lebanon). Any hostilities involving Israel or the interruption or curtailment of trade within Israel or between Israel and its trading partners could materially and adversely affect our business, financial condition and results of operations and could make it more difficult for us to raise capital. In particular, an interruption of operations at the Tel Aviv airport related to the conflict in the Gaza Strip or otherwise could prevent or delay shipments of our components or products. Although we maintain inventory in the United States and Germany, an extended interruption could materially and adversely affect our business, financial condition and results of operations. Recent political uprisings, social unrest and violence in various countries in the Middle East and North Africa, including Israel s neighbors Egypt and Syria, are affecting the political stability of those countries. This instability may lead to deterioration of the political relationships that exist between Israel and these countries and have raised concerns regarding security in the region and the potential for armed conflict. 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. Any losses or damages incurred by us could have a material adverse effect on our business. In addition, Iran has threatened to attack Israel and is widely believed to be developing nuclear weapons. Iran is also believed to have a strong influence among parties hostile to Israel in areas that neighbor Israel, such as the Syrian government, Hamas in Gaza and Hezbollah in Lebanon. Any armed conflicts, terrorist activities or political instability in the region could materially and adversely affect our business, financial condition and results of operations.

Our operations and the operations of our contract manufacturer, Sanmina, may be disrupted as a result of the obligation of Israeli citizens to perform military service.

Many Israeli citizens are obligated to perform one month, and in some cases more, of annual military reserve duty until they reach the age of 45 (or older, for reservists with certain occupations) and, in the event of a military conflict, may be called to active duty. In response to terrorist activity, there have been periods of significant call-ups of military reservists. For example, the Israeli armed forces called up a significant number of reservists to active

Table of Contents

duty in connection with the recent conflict in the Gaza Strip. It is possible that there will be additional military reserve duty call-ups in the future in connection with this conflict or otherwise. Although these call-ups have not had a material impact on our operations or on Sanmina s ability to manufacture our products, our operations and the operations of Sanmina could be disrupted by such call-ups.

Our sales may be adversely affected by boycotts of Israel.

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 whether as a result of hostilities in the region or otherwise. In addition, there have been increased efforts by activists to cause companies and consumers to boycott Israeli goods based on Israeli government policies. Such actions, particularly if they become more widespread, may adversely impact our ability to sell our products.

The tax benefits that are available to us require us to continue to meet various conditions and may be terminated or reduced in the future, which could increase our costs and taxes.

Some of our operations in Israel, referred to as Beneficiary Enterprises, carry certain tax benefits under the Israeli Law for the Encouragement of Capital Investments, 5719-1959, or the Investment Law. Substantially all of our future income before taxes can be attributed to these programs. If we do not meet the requirements for maintaining these benefits or if our assumptions regarding the key elements affecting our tax rates are rejected by the tax authorities, they may be reduced or cancelled and the relevant operations would be subject to Israeli corporate tax at the standard rate, which is currently set at 26.5% for 2014 and thereafter. In addition to being subject to the standard corporate tax rate, we could be required to refund any tax benefits that we may receive in the future, plus interest and penalties thereon. Even if we continue to meet the relevant requirements, the tax benefits that our current Beneficiary Enterprises receive may not be continued in the future at their current levels or at all. If these tax benefits were reduced or eliminated, the amount of taxes that we pay would likely increase, as all of our Israeli operations would consequently be subject to corporate tax at the standard rate, which could adversely affect our results of operations. Additionally, if we increase our activities outside of Israel, for example, by way of acquisitions, our increased activities may not be eligible for inclusion in Israeli tax benefit programs. See Taxation and Israeli Government Programs Applicable to our Company Law for the Encouragement of Capital Investments, 5719-1959 for additional information concerning these tax benefits and Note 13 to our consolidated financial statements for a discussion of our current tax obligations.

We have received Israeli government grants for certain of our research and development activities and we may receive additional grants in the future. The terms of those grants restrict our ability to manufacture products or transfer technologies outside of Israel, and we may be required to pay penalties in such cases or upon the sale of our company.

From our inception through December 31, 2013, we received a total of $0.45 million from the Office of the Chief Scientist in the Israel Ministry of Economy, or OCS. We have applied to receive additional grants to support our research and development activities in 2014. With respect to such grants we are committed to pay royalties at a rate of 3% to 3.5% on sales proceeds up to the total amount of grants received, linked to the dollar and bearing interest at an annual rate of LIBOR applicable to dollar deposits. Even after payment in full of these amounts, we will still be required to comply with the requirements of the Israeli Encouragement of Industrial Research and Development Law, 1984, or the R&D Law, and related regulations, with respect to those past grants. 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. Furthermore, the OCS may impose certain conditions on any arrangement under which it permits us to transfer technology or development out of Israel or may not grant such approvals at all.

Table of Contents

The transfer of OCS-supported technology or know-how outside of Israel may involve the payment of significant amounts to the OCS, 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.

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, and recent decisions by the Israeli Supreme Court and the Israeli Compensation and Royalties Committee, a body constituted under the Patent Law, employees may be entitled to remuneration for intellectual property that they develop for us unless they explicitly waive any such rights. Although we enter into agreements with our employees pursuant to which they agree that any inventions created in the scope of their employment or engagement are owned exclusively by us, we may face claims demanding remuneration. As a consequence of such claims, we could be required to pay additional remuneration or royalties to our current and former employees, or be forced to litigate such claims, which could negatively affect our business.

Provisions of Israeli law and our 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 at least 98% of the company s outstanding shares are tendered. Furthermore, the shareholders, including those who indicated their acceptance of the tender offer (unless the acquirer stipulated in its tender offer that a shareholder that accepts the offer may not seek appraisal rights), 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. See Description of Share Capital Acquisitions under Israeli Law for additional information.

Our articles of association provide that our directors (other than external directors) are elected on a staggered basis, such that a potential acquirer cannot readily replace our entire board of directors at a single annual general shareholder meeting. This could prevent a potential acquirer from receiving board approval for an acquisition proposal that our board of directors opposes.

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 involving an exchange of shares, 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. These and other similar provisions could delay, prevent or impede an acquisition of us or our merger with another company, even if such an acquisition or merger would be beneficial to us or to our shareholders.

Table of Contents

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. The majority of our directors and executive officers, and the Israeli experts 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 articles of association and by Israeli law. These rights and responsibilities differ in some material respects from the rights and responsibilities of shareholders in U.S.-based corporations. 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 shareholder vote or to appoint or prevent the appointment of a director or executive officer in the company has a duty of fairness toward the company. There is limited case law available to assist us in understanding the nature of this duty or the implications of these provisions. These provisions may be interpreted to impose additional obligations and liabilities on holders of our ordinary shares that are not typically imposed on shareholders of U.S. corporations.

Table of Contents

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

We make forward-looking statements in this prospectus that are subject to risks and uncertainties. These forward-looking statements include information about possible or assumed future results of our business, financial condition, results of operations, liquidity, plans and objectives. In some cases, you can identify forward- looking statements by terminology such as believe, may, estimate, continue, anticipate, intend, sh plan, expect, predict, potential, or the negative of these terms or other similar expressions. The statements we make regarding the following matters are forward-looking by their nature:

- our expectations regarding future growth, including our ability to increase sales in our existing geographic markets and to expand to new markets;
- our ability to maintain and grow our reputation and the market acceptance of our products;
- our ability to achieve reimbursement from third-party payors for our products;
- our expectations as to our clinical research program and clinical results;
- our ability to improve our products and develop new products;
- our ability to maintain adequate protection of our intellectual property and to avoid violation of the intellectual property rights of others;
- our ability to gain and maintain regulatory approvals;
- our ability to maintain relationships with existing customers and develop relationships with new customers; and
- our intended use of proceeds of this offering.

The preceding list is not intended to be an exhaustive list of all of our forward-looking statements. The forward-looking statements are based on our beliefs, assumptions and expectations of future performance, taking into account the information currently available to us. These statements are only predictions based upon our current expectations and projections about future events. There are important factors that could cause our actual results, levels of activity, performance or achievements to differ materially from the results, levels of activity, performance or achievements expressed or implied by the forward-looking statements. In particular, you should consider the risks provided under Risk Factors in this prospectus.

You should not rely upon forward-looking statements as predictions of future events. 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.

Table of Contents

USE OF PROCEEDS

We estimate that the net proceeds to us from this offering, after deducting underwriting discounts and estimated offering expenses, will be approximately $ million (or approximately $ million if the underwriters exercise their option to purchase additional ordinary shares in full), assuming the shares are offered at $ per ordinary share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus.

A $1.00 increase (decrease) in the assumed initial public offering price of $ per ordinary share would increase (decrease) the net proceeds to us from this offering by approximately $ million, assuming the number of shares offered by us as set forth on the cover page of this prospectus remains the same and after deducting the underwriting discounts and commissions. 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.

We intend to use the net proceeds from this offering for general corporate purposes, including sales and marketing expenditures aimed at growing our business and research and development expenditures focused on product development. We expect that the net proceeds from this offering will be sufficient for us to expand our sales, marketing and training infrastructure and for our other current development activities, including adapting ReWalk for other indications and the development of our next generation of ReWalk. We may also use net proceeds from this offering to make acquisitions or investments in complementary companies or technologies, although we do not have any agreement or understanding with respect to any such acquisition or investment at this time. We do not currently have specific plans or commitments with respect to the net proceeds from this offering and, accordingly, are unable to quantify the allocation of such proceeds among the various potential uses. We will have broad discretion in the way that we use the net proceeds of this offering.

Table of Contents

DIVIDEND POLICY

We have never declared or paid any cash dividends on our ordinary shares. We do not anticipate paying any cash dividends in the foreseeable future. We currently intend to retain future earnings, if any, to finance operations and expand our business. Our board of directors has sole discretion whether to pay dividends. If our board of directors decides to pay dividends, the form, frequency and amount will depend upon our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors that our directors may deem relevant. The distribution of dividends may also be limited by Israeli law, which permits the distribution of dividends only out of retained earnings or otherwise upon the permission of an Israeli court.

Table of Contents

CAPITALIZATION

The following table sets forth our total capitalization as of June 30, 2014, as follows:

- on an actual basis;
- on a pro forma basis to give effect to (i) the conversion of all of our outstanding ordinary A shares, ordinary B shares and preferred shares as of June 30, 2014 into ordinary shares, which will occur immediately prior to the closing of this offering and (ii) the issuance of 340,380 ordinary shares in connection with the exercise prior to the closing of this offering of warrants held by certain shareholders and the receipt by us of $ million from such exercise; and
- on a pro forma as adjusted basis to give further effect to the issuance and sale of ordinary shares by us in this offering at an assumed initial public offering price of $ per ordinary share after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this information in conjunction with our consolidated financial statements and the related notes appearing at the end of this prospectus and the Management s Discussion and Analysis of Financial Condition and Results of Operations section and other financial information contained in this prospectus.

	As of June 30, 2014		
	Actual	Pro Forma	Pro Forma As Adjusted
	(in thousands, except share and per share amounts)		
Ordinary shares, par value NIS 0.01 per share; 170,413,056 shares authorized, actual and pro forma, 250,000,000 shares authorized, pro forma as adjusted; 187,776 shares issued and outstanding, actual; 6,603,066 shares issued and outstanding, pro forma; shares issued and outstanding, pro forma as adjusted(1)	*		
Preferred shares, par value NIS 0.01 per share; 9,588,186 shares authorized, actual; zero shares authorized, pro forma and pro forma as adjusted; 5,967,612 shares issued and outstanding, actual; zero shares issued and outstanding, pro forma and pro forma as adjusted	*		
Additional paid-in capital	34,035	41,568	
Accumulated deficit	(36,647)	(36,647)	
Total shareholders equity (deficiency)	(2,612)	4,921	
Total capitalization	$ 5,236	$ 7,801	$

* Less than $1

(1) On August , 2014, we effected an 18-for-1 share split by means of a share dividend of 17 ordinary shares for each ordinary share then outstanding.

A $1.00 increase (decrease) in the assumed initial public offering price of $ per ordinary share, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, additional paid-in capital, total shareholders equity and total capitalization by approximately $ million, assuming that the number of ordinary shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The foregoing table excludes the following securities:

Ordinary shares reserved for issuance under our equity incentive plans. As of August 1, 2014, we had 1,243,746 ordinary shares reserved for issuance under our equity incentive plans of which there were outstanding options to purchase 1,115,640 shares at a weighted average exercise price of $1.30 per share.

Table of Contents

75,695 Series E preferred shares (convertible into 1,362,510 ordinary shares) which were issued in July 2014.

6,918 preferred shares issued on July 30, 2014 pursuant to the exercise of warrants. Such preferred shares will automatically convert into 124,524 ordinary shares upon the closing of this offering.

Warrants to purchase 777,996 ordinary shares which will remain outstanding following the closing of this offering.

Table of Contents

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 pro forma as adjusted net tangible book value per ordinary share after this offering. As of June 30, 2014, our net tangible book value per ordinary share was $7.75. Net tangible book value per ordinary share represents our total tangible assets (excluding deferred issuance costs) less our total liabilities (excluding deferred revenues and warrants to purchase convertible preferred shares liability), divided by the number of ordinary shares outstanding.

After giving effect to (i) the sale of ordinary shares that we are offering at an assumed initial public offering price of $ per ordinary share and the deduction of underwriting discounts and commissions and estimated offering expenses payable by us, (ii) the exercise of warrants held by certain of our shareholders and the related issuance of 464,904 ordinary shares and the receipt by us of $ million from such exercise and (iii) the conversion of all of our outstanding ordinary A shares, ordinary B shares and preferred shares, including the preferred shares issued upon the exercise of warrants, into ordinary shares, our pro forma as adjusted net tangible book value as of June 30, 2014 would have been $ per ordinary share. This amount represents an immediate increase in net tangible book value of $ per ordinary share to our existing shareholders and immediate dilution in net tangible book value of $ per ordinary share to new investors purchasing ordinary shares in this offering. We determine dilution by subtracting the pro forma as adjusted net tangible book value per ordinary share after this offering from the assumed price per ordinary share paid by an investor in this offering.

The following table illustrates this dilution:

Assumed initial public offering price per ordinary share		$
Net tangible book value per ordinary share as of June 30, 2014	$	
Increase in net tangible book value per ordinary share attributable to this offering		
Pro forma as adjusted net tangible book value per ordinary share after this offering		
Dilution per ordinary share to new investors in this offering		$

The following table summarizes, as of June 30, 2014, the differences between the number of ordinary shares purchased from us, the total consideration paid to us in cash and the average price per ordinary share paid by existing shareholders and by new investors in this offering. The calculation below is based on an assumed initial public offering price of $ per ordinary share before deducting underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing shareholders		%	$	%	$
New investors					
Total		100%		100%	

The above discussion and the tables are based on 6,603,066 ordinary shares issued and outstanding as of June 30, 2014 and exclude the following securities:

- Ordinary shares reserved for issuance under our equity incentive plans. As of August 1, 2014, we had 1,243,746 ordinary shares reserved for issuance under our equity incentive plans of which there were outstanding options to purchase 1,115,640 shares at a weighted average exercise price of $1.30 per share.

- 75,695 Series E preferred shares (convertible into 1,362,510 ordinary shares) which were issued in July 2014.

42

Table of Contents

6,918 preferred shares issued on July 30, 2014 pursuant to the exercise of warrants. Such preferred shares will automatically convert into 124,524 ordinary shares upon the closing of this offering.

Warrants to purchase 777,996 ordinary shares which will remain outstanding following the closing of this offering.

To the extent any of these outstanding options or warrants are exercised, there will be further dilution to new investors. To the extent options and warrants outstanding as of June 30, 2014 had been exercised as of that date, the as adjusted net tangible book value per ordinary share after this offering would be $, and total dilution per ordinary share to new investors would be $.

This discussion assumes 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 pro forma as adjusted net tangible book value per ordinary share after this offering would be $ per share, and the dilution per ordinary share to new investors in this offering would be $ per share;

the percentage of ordinary shares held by existing shareholders will decrease to approximately % of the total number of our ordinary shares outstanding after this offering; and

the number of shares held by new investors will increase to , or approximately % of the total number of our ordinary shares outstanding after this offering.

Table of Contents

SELECTED CONSOLIDATED FINANCIAL DATA

The selected consolidated financial data set forth below as of and for the years ended December 31, 2012 and 2013 is derived from our audited consolidated financial statements, which have been prepared in accordance with U.S. GAAP and are presented elsewhere in this prospectus. The selected consolidated financial data for the three months ended June 30, 2013 and 2014, and as of June 30, 2014, has been derived from our unaudited interim consolidated financial statements presented elsewhere in this prospectus. In the opinion of management, these unaudited interim consolidated financial statements include all adjustments, consisting of normal recurring adjustments, necessary for a fair statement of our financial position and operating results for these periods. Results for interim periods are not necessarily indicative of the results that may be expected for the entire year.

You should read the following selected consolidated financial data in conjunction with, and it is qualified in its entirety by reference to our consolidated financial statements and the related notes appearing elsewhere in this prospectus and other information provided in this prospectus, including Management s Discussion and Analysis of Financial Condition and Results of Operations. The historical results set forth below are not necessarily indicative of the results to be expected in future periods.

	Year Ended December 31,		Six Months Ended June 30,	
	2012	2013	2013	2014
	(in thousands, except per share data)			
Statements of Operations Data:				
Revenues	$ 972	$ 1,588	$ 797	$ 945
Cost of revenues	983	2,017	1,074	1,368
Gross loss	(11)	(429)	(277)	(423)
Operating expenses:				
Research and development	1,757	2,463	1,062	2,158
Sales and marketing, net	2,334	4,091	1,644	2,891
General and administrative	1,657	1,762	801	1,382
Total operating expenses	5,748	8,316	3,507	6,431
Operating loss	5,759	8,745	3,784	6,854
Financial expenses, net	878	3,410	1,656	2,855
Loss before income taxes	6,637	12,155	5,440	9,709
Income taxes	21	22	12	32
Net loss	$ 6,658	$ 12,177	$ 5,452	$ 9,741
Net loss per ordinary share, basic and diluted(1)	$ (41.26)	$ (74.53)	$ (32.72)	$ (59.42)
Weighted average number of shares used in computing net loss per ordinary share, basic and diluted	185,688	185,688	185,688	187,398
Pro forma net loss per ordinary share, basic and diluted(2)(3)		$ (2.54)		$ (1.37)
Pro forma weighted average number of shares used in computing net loss per ordinary share, basic and diluted(2)		4,349,664		6,552,972

	As of December 31,		As of June 30,
	2012	2013	2014
		(in thousands)	
Balance Sheet Data:			
Cash and cash equivalents	$ 769	$ 8,860	$ 904
Total assets	2,094	11,059	5,236
Total long-term liabilities	2,252	3,525	5,149
Accumulated deficit	(14,729)	(26,906)	(36,647)
Total shareholders equity (deficiency)	(2,264)	5,631	(2,612)

Table of Contents

(1) Net loss per ordinary share, basic and diluted, is calculated by dividing our net loss excluding dividends accrued on our convertible preferred shares outstanding during the period presented by the weighted average number of shares outstanding during the period presented. See Note 2u to our consolidated financial statements presented elsewhere in this prospectus.

(2) Pro forma net loss per ordinary share and pro forma weighted average number of shares outstanding assume the conversion of our preferred shares, including preferred shares issuable in connection with the exercise of warrants, into ordinary shares, which will occur immediately prior to the closing of this offering, but does not include the issuance of shares in connection with this offering. For additional information on the conversion of the preferred shares see Note 9 to our consolidated financial statements included elsewhere in this prospectus.

(3) Pro forma net loss per ordinary share, basic and diluted, assumes an adjustment to net loss in order to eliminate the revaluation expenses of our warrants liability. See Note 2e to our consolidated financial statements presented elsewhere in this prospectus.

Table of Contents

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

The following discussion and analysis should be read in conjunction with Selected Consolidated Financial Data and our consolidated financial statements and the related notes included elsewhere in this prospectus. This discussion contains forward-looking statements that are based on our management s current expectations, estimates and projections for our business, which are subject to a number of risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those set forth under Special Note Regarding Forward-Looking Statements and Risk Factors.

Overview

We have developed and are continuing to commercialize ReWalk, an exoskeleton that uses our patented tilt-sensor technology, and an on-board computer and motion sensors to drive motorized legs that power movement. We currently offer two products: ReWalk Personal and ReWalk Rehabilitation. ReWalk Personal is designed for everyday use by individuals at home and in their communities, and is custom-fit for each user. ReWalk Rehabilitation is designed for the clinical rehabilitation environment where it provides valuable exercise and therapy. It also enables individuals to evaluate their capacity for using ReWalk Personal in the future.

We believe that the current design of ReWalk provides a functional technical base that can be easily adapted to address medical indications other than paraplegia that affect the ability to walk. We are currently engaged in research and development efforts to adapt ReWalk to address the mobility needs of quadriplegia and multiple sclerosis patients, and, in the future, we plan to address these needs in stroke and cerebral palsy patients. We are also developing our next generation of ReWalk, with a more efficient drive mechanism, slimmer profile and lighter body, as well as other improvements.

In 2011, we launched ReWalk Rehabilitation for use in hospitals and rehabilitation centers in the United States and Europe. We began marketing ReWalk Personal in Europe with CE mark approval at the end of 2012 and received FDA clearance to market it in the United States in June 2014. As of August 1, 2014, we have placed 62 ReWalk Rehabilitation and 19 ReWalk Personal systems, 88% of which were purchased by our customers, and 12% of which were placed with clinics and distributors for training, market development and clinical testing.

Our commercialization strategy is to penetrate rehabilitation centers, hospitals and similar facilities that treat patients with spinal cord injuries to become an integral part of their rehabilitation programs and to develop a broad based training network with these facilities to prepare users for home and community use. While the majority of our sales to date have been ReWalk Rehabilitation, the primary focus of our commercialization efforts going forward will be providing ReWalk Personal for routine use at home, work or in the community, and we expect sales of ReWalk Personal to account for the substantial majority of our revenues in the future.

Reimbursement is an important factor in our ability to expand sales. We plan to pursue various pathways of reimbursement and funding, focusing our efforts on our two primary markets: the United States and Western Europe. We intend to continue to work with ReWalk users, health care practitioners, researchers, and the spinal cord injury community to support efforts to demonstrate to insurance companies and other payors the health benefits and the economic case for reimbursement of ReWalk Personal. For more information regarding reimbursement of our products, see Business Reimbursements and Other Funding Sources.

The growth of our business and our future success depend on our ability to increase our sales, which depends on many factors, including our ability to achieve reimbursement from third-party payors, demonstrate the medical benefits and cost savings of ReWalk through clinical data, introduce new products and address new indications and expand our sales force. While each of these areas presents significant opportunities for us, they also pose important challenges and risks that we must successfully address in order to sustain the growth of our business and improve our results of operations.

Table of Contents

We have incurred net losses and negative cash flows from operations since inception. We anticipate that we will continue to incur net losses and negative cash flows from operations for at least the next two years as we expand our production and sales and marketing capabilities, engage in additional clinical studies and continue to develop the infrastructure required to sell and market our products globally.

Components of Our Statements of Operations

Revenue

We currently rely, and in the future will rely, on sales of our ReWalk systems and related service contracts and extended warranties for our revenue. Our revenue is generated from a combination of self-payors and third-party payors. To date, payments for our products have been made primarily by self-payors, through case-by-case determinations by third-party payors and by negotiating the cost of a ReWalk into accident settlements. Third-party payors include, without limitation, private insurance plans and managed care programs, government programs such as the Veterans Administration, Medicare and Medicaid and worker s compensation. We expect that third-party payors will be an increasingly important source of revenue in the future. No uniform policy of coverage and reimbursement for exoskeleton medical technology currently exists among third-party payors in the United States or elsewhere.

All of our ReWalk systems are covered by a two-year warranty from the date of purchase, which is included in the purchase price. We offer customers the ability to purchase, any time during the initial warranty period, an extended warranty for up to three additional years. Both warranties cover all elements of the ReWalk system, including the batteries, other than normal wear and tear.

The following table sets forth the number of ReWalk systems sold for the periods presented:

	Year Ended December 31,		Six Months Ended June 30,	
	2012	2013	2013	2014
ReWalk Rehabilitation	14	17	8	11
ReWalk Personal	4	8	5	5

Cost of Revenues

Prior to the first quarter of 2014, we manufactured our products in-house at our facility in Yokneam, Israel. For the years ended December 31, 2012 and 2013, our cost of revenues consisted primarily of raw materials, as well as salaries, personnel costs and share-based compensation associated with manufacturing, training and inspection personnel, utility and maintenance costs associated with the operation of our manufacturing facility, warranty obligations and shipping and handling. In July 2013, we entered into an agreement with Sanmina Corporation for the manufacture of all of our products. Beginning in the first quarter of 2014, Sanmina assumed production of all ReWalk systems. Beginning in July 2013, our cost of revenues also consisted of costs relating to the transfer of manufacturing to Sanmina and amounts paid to Sanmina pursuant to our contractual arrangement. For the six months ended June 30, 2014, our cost of revenues consisted primarily of systems purchased from Sanmina the cost of systems manufactured by us in 2013 and sold in the first half of 2014, as well as salaries, personnel costs and share-based compensation associated with manufacturing, expenses relating to the transition of our manufacturing activities to Sanmina, training and inspection personnel, warranty obligations and shipping and handling. Cost of revenues also includes royalties we must pay on royalty-bearing research and development grants.

In the future, while our cost of revenues will increase as our sales volume increases, we expect our unit cost to decrease as our sales increase due to economies of scale realized in connection with larger quantities and increased efficiency.

Table of Contents

Operating Expenses

Research and Development Expenses, Net

Research and development expenses, net, consist primarily of salaries, related personnel costs and share-based compensation, costs of clinical trials and obtaining regulatory approvals and patent costs, sponsored research costs and other expenses related to our product development and research programs. We expense all research and development expenses as they are incurred. We believe that continued investment in research and development is crucial to attaining our strategic product objectives. We plan to continue increasing these expenditures, resulting in greater research and development expenses in future periods as we enhance our ReWalk system and pursue the development of new products.

Research and development expenses are presented net of the amount of any grants we receive for research and development in the period in which we receive the grant. We previously received grants and other funding from the BIRD Foundation and the OCS. Certain of those grants require us to pay royalties on sales of ReWalk systems, which are recorded as cost of revenues. See Grants and Other Funding. We may receive additional funding from these entities or others in the future.

Sales and Marketing Expenses, Net

Our sales and marketing expenses, net, consist primarily of salaries, related personnel costs and share-based compensation for our internal sales staff and costs related to marketing activities. Sales and marketing expenses are presented net of the amount of any grants we receive for sales and marketing in the period in which we receive the grant. We intend to continue to expand our sales and marketing activities and, therefore, expect sales and marketing expenses to increase significantly in the future. In general, we expect that the number of our sales representatives will increase as our revenues increase. See Grants and Other Funding.

General and Administrative Expenses

Our general and administrative expenses consist primarily of salaries, related personnel costs and share-based compensation for our administrative, finance, and general management personnel, as well as our legal and accounting consultants. We expect to incur increased general and administrative expenses as a result of becoming a public company in the United States.

Financial Income (Expenses), Net

Financial income (expenses), net, consists of the revaluation of the fair value of warrants to purchase our preferred shares and expenses related to our convertible loans, as well as interest income and expense, foreign currency exchange gains or losses.

Warrants to purchase our convertible preferred shares are classified as a liability on our consolidated balance sheet at fair value. The warrants are subject to revaluation at each balance sheet date and any change in fair value is recognized as a component of financial income (expense), net, on our consolidated statements of operations. We will continue to adjust for changes in fair value until such warrants are exercised or expire. Immediately prior to the completion of this offering, all of such warrants will be exercised or will expire, and we will no longer record any liability in respect of them on our balance sheet or financial expenses in respect of them on our statement of operations.

Interest income and expenses consist of interest earned on our cash and cash equivalent balances and interest accrued on and certain other costs with respect to any indebtedness. We expect interest income to vary depending on our average investment balances and market interest rates during each reporting period. Foreign currency exchange changes reflect gains or losses related to transactions denominated in currencies other than the U.S. dollar. As of the most recent reporting period, we did not have any indebtedness for borrowed amounts although we have had outstanding convertible loans in prior periods.

Table of Contents

Taxes on Income

As of June 30, 2014, we had not yet generated taxable income in Israel. At the end of our last fiscal year, our net operating loss carry forwards for Israeli tax purposes amounted to approximately $22 million. After we utilize our net operating loss carry forwards, we are eligible for certain tax benefits in Israel under the Law for the Encouragement of Capital Investments, 1959. Our benefit period currently ends ten years after the year in which we first have taxable income in Israel provided that the benefit period will not extend beyond 2024. For more information about the tax benefits available to us as a Beneficiary Enterprise, see Taxation and Israeli Government Programs Applicable.

Our taxable income generated outside of Israel will be subject to the regular corporate tax rate in the applicable jurisdictions. As a result, our effective tax rate will be a function of the relative proportion of our taxable income that is generated in those locations compared to our overall net income.

Grants and Other Funding

BIRD Foundation and AO&P

In July 2009, we entered into a grant agreement with the BIRD Foundation and Allied Orthotics & Prosthetics Inc. (AO&P). AO&P was the distributor of our products at the time. We received $0.5 million and AO&P received $0.06 million. The agreement with the BIRD Foundation requires us to pay a royalty at a rate of 5% on sales of ReWalk systems and related services. The amount of repayment is equal to the amount of the grant being repaid multiplied by an increasing contractual percentage in an amount up to 150%.

AO&P is responsible for repayment of its grant. However, pursuant to the agreement, we are required to make any payments on which AO&P defaults. As of December 31, 2013, the aggregate contingent liability to the BIRD Foundation amounted to $0.8 million.

Office of the Chief Scientist

We have also received a total of $0.45 million in funding from the OCS, $0.05 million of which are royalty-bearing grants, while $0.4 million were received in consideration for an investment in our preferred shares. We have applied to receive additional grants to support our research and development activities in 2014. The agreements with OCS require us to pay royalties at a rate of 3% to 3.5% on sales of ReWalk systems and related services up to the total amount of funding received, linked to the dollar and bearing interest at an annual rate of LIBOR applicable to dollar deposits. If we transfer of OCS-supported technology or know-how outside of Israel, we will be liable for additional payments to OCS 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. As of December 31, 2013, the aggregate contingent liability to the OCS was nominal.

Fund for Promoting Overseas Marketing

We also received a total of $0.1 million in funding from the Fund for Promoting Overseas Marketing under the Israeli Ministry of Economy, which are non-royalty-bearing grants, to support our marketing activities. We have applied to receive additional grants to support our marketing activities in 2014.

Compensation Expenses to be Recognized Upon Closing of this Offering

In accordance with our articles of association in effect prior to this offering and the Fourth Amended and Restated Shareholders Agreement to become effective prior to the consummation of this offering, immediately prior to the closing of this offering, our founder, Dr. Amit Goffer, has the right to receive for no consideration, shares or immediately exercisable options with cashless exercise in an amount such that the value of his interests equals 6% of our valuation. In respect of this right, Dr. Goffer will be granted 335,484 ordinary shares immediately prior to the closing of this offering. Assuming an initial public offering price of $ per share,

Table of Contents

the mid-point of the initial public offering price range on the cover of this prospectus, as a result of this issuance, we expect to record estimated share-based compensation expense of $ million in the quarter in which this offering closes.

In addition, if at the time of this offering or at any time thereafter, our valuation reaches an amount that is greater than $200 million, but less than $400 million (based on a third party transaction or our market capitalization), options to purchase 41,364 of our ordinary shares held by our chief executive officer will vest immediately. If at the time of this offering or at any time thereafter, our valuation reaches an amount that is greater than $400 million (based on a third party transaction or our market capitalization), options to purchase 41,364 additional ordinary shares held by our chief executive officer will vest immediately. As a result, assuming an initial public offering price of $ per share, the mid-point of the initial public offering price range on the cover of this prospectus, our valuation would be within the $200 million to $400 million range, options to purchase 41,364 ordinary shares would vest and we would record estimated share-based compensation expense of $ million in the quarter in which this offering closes.

Six Months Ended June 30, 2013 Compared to Six Months Ended June 30, 2014

Revenue

Revenue was $0.8 million for the six months ended June 30, 2013, compared to $0.9 million for the six months ended June 30, 2014, an increase of 19%. This increase is attributable to a $0.1 million increase resulting from an additional three systems sold.

Cost of Revenues

Cost of revenues were $1.1 million for the six months ended June 30, 2013, compared to $1.4 million for the six months ended June 30, 2014, an increase of 27%. This increase is due to an increase of $0.2 million in expenses relating to transitioning manufacturing to Sanmina and an increase of $0.1 million in salary expenses. The increase in total costs due to the number of units sold was partially offset by a decrease in the average cost per unit sold.

Research and Development Expenses

Research and development expenses were $1.1 million for the six months ended June 30, 2013, compared to $2.2 million for the six months ended June 30, 2014, an increase of 103%. The increase in expenses is attributable to an increase of $0.6 million in salaries and non-cash related expenses due to the addition of research and development personnel and the reallocation of certain employees salaries and related expenses as research and development expenses, and an increase of $0.4 million related to subcontractors and materials purchased for research and development activities.

Sales and Marketing Expenses, Net

Sales and marketing expenses, net, were $1.6 million for the six months ended June 30, 2013, compared to $2.9 million for the six months ended June 30, 2014, an increase of 76%. This increase is primarily attributable to an increase of $1.0 million in salaries, cash and non-cash related expenses due to the addition of sales and marketing personnel, and an increase of $0.1 million relating to marketing activities.

General and Administrative Expenses

General and administrative expenses were $0.8 million for the six months ended June 30, 2013, compared to $1.4 million for the six months ended June 30, 2014, an increase of 73%. The increase in expenses is primarily attributable to an increase in cash and non-cash employee related expenses, and an increase in legal expenses, professional services and traveling expenses.

Financial Expenses, Net

Financial expenses, net, were $1.7 million for the six months ended June 30, 2013, compared to $2.9 million for the six months ended June 30, 2014, an increase of 72%, primarily as a result of the revaluation of the fair value of our outstanding warrants.

Table of Contents

Income Tax

Income taxes were $12,000 for the six months ended June 30, 2013 with respect to our income in the United States, compared to $32,000 for the six months ended June 30, 2014.

Year Ended December 31, 2012 Compared to Year Ended December 31, 2013

Revenue

Revenue was $1.0 million for the year ended December 31, 2012, compared to $1.6 million for the year ended December 31, 2013, an increase of 63%. This increase is attributable to increased sales of ReWalk Personal due to the commencement of sales of ReWalk Personal in Europe in December 2012 and increased sales of ReWalk Rehabilitation in both the United States and Europe in 2013.

Cost of Revenues

Cost of revenues was $1.0 million for the year ended December 31, 2012, compared to $2.0 million for the year ended December 31, 2013, an increase of 105%. This increase is due to increases in the number of ReWalk systems sold, higher payroll and related expenses due to our increase in headcount and expenses relating to the transition of our manufacturing activities to Sanmina.

Research and Development Expenses

Research and development expenses were $1.8 million for the year ended December 31, 2012 compared to $2.5 million for the year ended December 31, 2013, an increase of 40%. The increase in expenses is attributable to increased payroll and related expenses due to our increase in headcount engaged in our research and development activities, as well as increased regulatory expenses.

Sales and Marketing Expenses, Net

Sales and marketing expenses, net, were $2.3 million for the year ended December 31, 2012, compared to $4.1 million for the year ended December 31, 2013, an increase of 75%. This increase is attributable to an increase in headcount engaged in sales and marketing activities, an increase in the number of demonstration ReWalk systems used for sales activities and increased attendance at trade shows, offset by a grant that we received for sales and marketing in the amount of $0.1 million.

General and Administrative Expenses

General and administrative expenses were $1.7 million for the year ended December 31, 2012, compared to $1.8 million for the year ended December 31, 2013, an increase of 6%. The increase in expenses is primarily attributable to increased professional services and office expenses.

Financial Expenses, Net

Financial expenses, net, were $0.9 million for the year ended December 31, 2012, compared to $3.4 million for the year ended December 31, 2013, an increase of 288% primarily as a result of the revaluation of the fair value of warrants to purchase preferred shares and financial expenses related to convertible loans.

Income Tax

Income taxes were $21,000 for the year ended December 31, 2012 with respect to our income in the United States, compared to $22,000 for the year ended December 31, 2013.

Table of Contents

Liquidity and Capital Resources

Since inception, we have funded our operations primarily through the sale of equity securities and convertible notes to investors in private placements. Through June 30, 2014, we also received funding of $0.5 million from the BIRD Foundation and $0.45 million from the OCS. On June 19, 2014, we entered into a loan agreement with Kreos Capital IV (Expert Fund) Limited, or Kreos, pursuant to which Kreos agreed to extend a line of credit to us of $5.0 million. The line of credit is available for drawdown until September 30, 2014, with a minimum required drawdown of $1.0 million. Amounts drawn will be repaid in an amount of 3.3% per month for 36 months. Pursuant to the loan agreement, we must pay a transaction fee of 1.0% of the total amount of the line of credit upon both the execution and the expiration of the loan agreement. Pursuant to the loan agreement, we will grant to Kreos a security interest with respect to amounts drawn over all of our assets, including intellectual property and equity interests in our subsidiaries. In connection with this agreement, we granted Kreos warrants to purchase 5,372 preferred shares, or to the extent exercised after the closing of this offering, the same number of ordinary shares.

As of June 30, 2014, we had cash and cash equivalents of $0.9 million. In July 2014, we closed our series E financing round for an aggregate purchase price of $13.0 million, providing additional liquidity. See Certain Relationships and Related Party Transactions Series E Preferred Securities Purchase Agreement. Based upon our current business plan, we believe that our current sources of liquidity will be sufficient to meet our anticipated cash needs for at least the next 12 months. Based upon our current business plan, we believe that the combination of the proceeds of this offering and our other current sources of liquidity will be sufficient to meet our anticipated cash needs for at least the next 24 months. The initial issuance of our independent registered public accountants report for the year ended December 31, 2013 included an explanatory paragraph that expressed substantial doubt about our ability to continue as a going concern . However, due to the completion of our series E financing round and the Kreos loan agreement, the conditions that raised substantial doubt about our ability to continue as a going concern no longer exist. See the report of our independent registered public accountants and Note 1e to our consolidated financial statements presented elsewhere in this prospectus.

Our primary current uses of cash are for sales and marketing and research and development activities. Our future cash requirements will depend on many factors, including our rate of revenue growth, the expansion of our sales and marketing activities, the timing and extent of our spending on research and development efforts and international expansion. If our current estimates of revenue, expenses or capital or liquidity requirements change or are inaccurate, we may seek to sell additional equity or debt securities, or arrange debt financing. We cannot be certain that additional funds will be available to us on favorable terms when required, or at all.

Cash Flows

Net Cash Used in Operating Activities

Net cash used in operating activities grew from $5.4 million in 2012 to $8.8 million in 2013 primarily as a result of an increase of $5.5 million in our net loss from 2012 to 2013. Our net losses in each of the periods were offset primarily by non-cash expenses and also by net changes in our working capital. Net cash used in operating activities was $3.9 million in the six months ended June 30, 2013 compared to $7.3 million in the six months ended June 30, 2014, primarily as a result of an increase of $4.3 million in our net losses, and an increase of $0.7 million related to net changes in our working capital from the first half of 2013 to the first half of 2014. The increases in each of the periods were offset by non-cash expenses.

Net Cash Used in Investing Activities

Net cash used in investing activities was $0.2 million in each of the years ended December 31, 2012 and 2013. Net cash used in investing activities was $53,000 and $0.1 million in the six months ended June 30, 2013 and June 30, 2014, respectively. Investing activities in these periods consisted of purchases of property and equipment and, to a lesser extent, increases and decreases in long-term deposits.

Table of Contents

Net Cash Provided by (Used in) Financing Activities

Our financing activities have consisted of the issuance of convertible notes and the sale of preferred shares. In 2012 and 2013, we issued convertible notes in anticipation of new issuances of preferred shares. Upon our subsequent issuance of preferred shares to holders of the convertible notes and others, the convertible notes were converted into preferred shares. As of December 31, 2013, no convertible loans remain outstanding. Net cash provided by financing activities was $5.8 million and $17.1 million for the years ended December 31, 2012 and 2013, respectively. Net cash provided by financing activities was $7.0 million in the six months ended June 30, 2013, consisting primarily of the issuance of convertible loans, compared to net cash used in financing activities of $0.5 million for the six months ended June 30, 2014, consisting primarily of issuance costs related to this offering and our series E financing round.

Contractual Obligations

The following summarizes our contractual obligations as of December 31, 2013:

	Payment Due by Period		
	2014	2015	Total
		(in thousands)	
Operating lease obligations(1)	$ 132	$ 50	$ 182

(1) Consists of future lease payments for our rented office facilities located in Yokneam Ilit, Israel, Marlborough, Massachusetts, and Berlin, Germany.

Off-Balance Sheet Arrangements

We had no off-balance sheet arrangements or guarantees of third-party obligations during the periods presented.

Critical Accounting Policies

Our consolidated financial statements are prepared in accordance with United States generally accepted accounting principles. The preparation of our financial statements requires us to make estimates, judgments and assumptions that can affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. We base our estimates, judgments and assumptions on historical experience and other factors that we believe to be reasonable under the circumstances. Materially different results can occur as circumstances change and additional information becomes known. Besides the estimates identified above that are considered critical, we make many other accounting estimates in preparing our financial statements and related disclosures. See Note 2 to our audited consolidated financial statements presented elsewhere in this prospectus for a description of the significant accounting policies that we used to prepare our consolidated financial statements. The critical accounting policies that were impacted by the estimates, judgments and assumptions used in the preparation of our consolidated financial statements are discussed below.

Revenue Recognition

We recognize revenues in accordance with ASC 605, Revenue Recognition, when delivery has occurred, persuasive evidence of an agreement exists, the fee is fixed and determinable, collectability is reasonably assured and no further obligations exist. Provisions are made at the time of revenue recognition for any applicable warranty cost expected to be incurred. The timing for revenue recognition among the various products and customers is dependent upon satisfaction of such criteria and generally varies from shipment to delivery to the customer depending on the specific shipping terms of a given transaction, as stipulated in the agreement with each customer. Other than pricing terms which may differ due to the different volumes of purchases between distributors and end-users, there are no material differences in the terms and arrangements involving direct and indirect customers. Our products sold through agreements with distributors are non-exchangeable, non-refundable, non-returnable and without any rights of price protection or stock rotation. Accordingly, we consider all the distributors as end-users. We do not grant a right of return for our products.

Table of Contents

In respect of sale of systems with training, we consider the elements in the arrangement to be a single unit of accounting. In accordance with ASC 605, we have concluded that the training is essential to the functionality of our systems. Therefore, we recognize revenue for the system and training only after delivery, in accordance with the agreement delivery terms, to the customer and after the training has been completed, once all other revenue recognition criteria have been met. In certain cases, when product arrangements are bundled with an extended warranty, the separation of the extended warranty falls under the scope of ASC 605- 20-25-1 through 25-6, and the separate price of the extended warranty stated in the agreement is deferred and recognized ratably over the extended warranty period. Deferred revenue includes primarily unearned amounts received in respect of service contracts but not yet recognized as revenues.

Share-Based Compensation

Option Valuations

We account for share-based compensation in accordance with ASC No. 718, Compensation-Stock Compensation. ASC No. 718 requires companies to estimate the fair value of equity-based payment awards on the date of grant using an Option-Pricing Model, or OPM. The value of the portion of the award that is ultimately expected to vest is recognized as an expense over the requisite service periods in our consolidated statements of operations.

We selected the Black-Scholes-Merton option pricing model as the most appropriate method for determining the estimated fair value of options. 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 straight-line method and classify these amounts in the consolidated financial statements based on the department to which the related employee reports.

The determination of the grant date fair value of options using the Black-Scholes-Merton 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:

Fair Value of our Ordinary Shares. Because our shares are not publicly traded, we have estimated the fair value of ordinary shares, as discussed in Ordinary Share Valuations below.

Risk-free Interest 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.

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.

Expected Volatility. Since we do not have a trading history for our ordinary shares, we estimated the expected share price volatility for our ordinary shares by considering the historic price volatility for industry peers based on price observations over a period equivalent to the expected term of the share option grants. Industry peers consist of public companies in the medical device and healthcare industries. We intend to continue to consistently apply this process using the same or similar industry peers until a sufficient amount of historical information regarding the volatility of our ordinary share price becomes available, or unless circumstances change such that the identified companies are no longer similar to us, in which case, more suitable companies whose share prices are publicly available would be utilized in the calculation.

Expected Term. The expected term of options granted represents the period of time that options granted are expected to be outstanding, and is determined based on the simplified method in accordance with ASC No. 718-10-S99-1 (SAB No. 110), as adequate historical experience is not available to provide a reasonable estimate. ASC No. 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

54

Table of Contents

The following table presents the weighted-average assumptions used to estimate the fair value of options granted to employees during the periods presented. The number of options granted to non-employees was immaterial:

	Year Ended December 31, 2013		Six Months Ended June 30, 2014
Risk-free interest rate	0.95%	2.08%	1.95%
Expected dividend yield	0%		0%
Expected volatility	70%	75%	70%
Weighted average expected life (in years)	6.02	6.08	6.08

Ordinary Share Valuations

The following table presents the share option grants made between January 1, 2013 and the date of this prospectus and the related exercise price and estimated fair value per ordinary share at the grant date:

Date of Grant	Number of Shares Subject to Awards Granted	Exercise Price Per Share	Estimated Fair Value Per Share at Grant Date
January 2013	28,800	$ 1.32	$ 3.62
July 2013	21,870	1.32	4.56
December 2013	434,088	1.48	5.81
April 2014	92,862	1.48	7.97

Based on the assumed initial public offering price of $ per share, the midpoint of the estimated initial public offering price range, set forth on the cover page of this prospectus, the intrinsic value of the awards outstanding as of June 30, 2014 was $ million, of which $ million related to vested options and $ million related to unvested options.

Due to the absence of a trading 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 for this offering, 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 also considered independent third-party valuations. The fair value of the underlying ordinary share will be determined by the board of directors until such time as our ordinary shares are listed on an established stock exchange or national market system.

For our valuations associated with option grants in January and July 2013, we determined our enterprise value and allocated the aggregate equity value to each element of our equity capital structure (preferred shares, ordinary shares and options), using the following methodology:

First, we used the discounted cash flow, or DCF, method, to determine our enterprise value. Then, for valuations where our aggregate equity value was such that our preferred shares would not automatically convert to ordinary shares, we used the option pricing method, or OPM, to allocate the equity value to each element of our equity capital structure.

Under the DCF method, our projected after-tax cash flows available to return to holders of invested capital were discounted back to present value, using a discount rate. Since it is not possible to project our after-tax cash flows beyond a limited number of years, the DCF method relies on determining a terminal value representing the aggregate value of either the future after-tax cash flows or estimated sale value of the Company after the end of the period for which annual projections are possible. The discount rate, known as the weighted cost of capital, or WACC, accounts for the time value of money and the appropriate degree of risk inherent in the business. The DCF method requires significant assumptions, in particular, regarding our projected cash flows, terminal value and the discount rate applicable to our business.

55

Table of Contents

Under the OPM, ordinary and preferred shares are treated as call options, with the preferred shares having an exercise price based on the liquidation preference of the preferred shares. Ordinary shares will only have value if funds available for distribution to the shareholders exceed the value of the liquidation preference at the time of a liquidity event such as a merger, sale or initial public offering. The ordinary shares are modeled as call options with an exercise price equal to the liquidation preference of the preferred shares. The value of the call options is determined using the Black-Scholes Merton option-pricing model. The OPM method requires significant assumptions, in particular, the time until investors on our company would experience an exit event and the volatility of our ordinary shares (which we determined based on the volatilities of public companies with business and financial risks comparable to our own).

We also used the guideline company method and the guideline transaction method, initially as reasonableness tests, in order to evaluate whether the DCF / OPM method provided a reliable estimate of our enterprise value.

Under the guideline company method, we identified public companies with business and financial risks comparable to our own. We considered forward enterprise value to revenue multiples of those comparable companies to derive a reasonable estimate for our company s enterprise value. The most significant assumptions in the guideline company method are the selection of comparable companies and the selection of appropriate multiples. We used the same comparable companies for the guideline company method as we used to determine volatility in connection with the OPM method (two additional companies were added for the 2014 valuations, which were not public before those dates).

Under the guideline transaction method, we identified companies with business and financial risks comparable to our own that were recently acquired or that conducted IPOs. We considered the enterprise value to revenue multiples of those comparable companies to derive a reasonable range for our company s enterprise value.

Subsequently, in connection with our grants in December 2013 and thereafter, as we had started to contemplate an IPO, we considered a range of possible valuations in the case of an IPO in tandem with the aforementioned forward guideline company multiples in connection with a possible IPO. Conversely, the DCF / OPM method more closely reflected our value as a private company. Accordingly, starting with the valuation of our ordinary shares in December 2013, when we were first seriously contemplating an IPO, we assigned a probability weighting to the likelihood of an IPO compared to the likelihood of remaining private based on management s discussions with our board of directors and our assessment of market conditions.

We applied a discount to the valuations due to the lack of marketability of the ordinary shares. We calculated this using a put option model based on the Black-Sholes-Merton option-pricing model. The significant assumptions involved were the same as described above.

Income Taxes

As part of the process of preparing our consolidated financial statements, we are required to estimate our taxes in each of the jurisdictions in which we operate. We account for income taxes in accordance with ASC Topic 740, Income Taxes, or ASC Topic 740. ASC Topic 740 prescribes the use of an asset and liability method whereby deferred tax asset and liability account balances are determined based on the difference between book value and the tax bases of assets and liabilities and carryforward tax losses. Deferred taxes are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. We exercise judgment and provide a valuation allowance, if necessary, to reduce deferred tax assets to their estimated realizable value if it is more likely than not that some portion or all of the deferred tax asset will not be realized. We have established a full valuation allowance with respect to our deferred tax assets.

Deferred tax assets are classified as short or long-term based on the classification of the related asset or liability for financial reporting, or according to the expected reversal dates of the specific temporary differences, if not

Table of Contents

related to an asset or liability for financial reporting. We account for uncertain tax positions in accordance with ASC 740 and recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position should be measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. Accordingly, we report a liability for unrecognized tax benefits resulting from uncertain tax positions taken or expected to be taken in a tax return. We recognize interest and penalties, if any, related to unrecognized tax benefits in tax expense.

Quantitative and Qualitative Disclosure About Market Risk

Foreign Currency Risk

Our results of operations and cash flows are affected by fluctuations due to changes in foreign currency exchange rates. In 2012, our revenues were denominated primarily in euro and our expenses were denominated primarily in NIS. In 2013, most of our revenues were denominated in U.S. dollars, approximately half of our expenses were denominated in U.S. dollars, and the remainder of our expenses were denominated in NIS and euros. Accordingly, changes in the value of the NIS relative to the U.S. dollar in 2012 and changes in the value of the NIS and euro relative to the U.S. dollar in 2013 impacted amounts recorded on our consolidated statements of operations for those periods. We expect that the denominations of our revenue and expenses in 2014 will be consistent with what we experienced in 2013.

The following table presents information about the changes in the exchange rates of the NIS and euro against the U.S. dollar in 2012 and 2013:

	Change in Average Exchange Rate	
Period	NIS against the U.S. Dollar (%)	Euro against the U.S. Dollar (%)
2012	7.8	8.3
2013	(6.4)	(3.4)

The figures above represent the change in the average exchange rate in the given period compared to the average exchange rate in the immediately preceding period. Negative figures represent depreciation of the U.S. dollar compared to the NIS or euro. A 10% increase or decrease in the value of the NIS against the U.S. dollar would have decreased or increased our net loss by approximately $0.4 million in 2013. A 10% increase or decrease in the value of the euro against the U.S. dollar would have decreased or increased our net loss by approximately $0.1 million in 2013.

From time to time, we enter into limited hedging arrangements with financial institutions. We do not use derivative financial instruments for speculative or trading purposes.

Other Market Risks

We do not believe that we have material exposure to interest rate risk due to the fact that we have no long-term borrowings.

We do not believe that we have any material exposure to inflationary risks.

New and Revised Financial Accounting Standards

The JOBS Act permits emerging growth companies such as us to delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Recently Issued and Adopted Accounting Pronouncements

There are no recently adopted accounting pronouncements that have a material effect on our company.

57

Table of Contents

BUSINESS

Overview

We are an innovative medical device company that is designing, developing and commercializing exoskeletons that allow wheelchair-bound individuals with mobility impairments or other medical conditions the ability to stand and walk once again. We have developed and are continuing to commercialize ReWalk, an exoskeleton that uses our patented tilt-sensor technology, and an on-board computer and motion sensors to drive motorized legs that power movement.

Current ReWalk designs are intended for people with paraplegia, a spinal cord injury resulting in complete or incomplete paralysis of the legs, who have the use of their upper bodies and arms. We currently offer two products: ReWalk Personal and ReWalk Rehabilitation. ReWalk Personal is designed for everyday use by individuals at home and in their communities, and is custom-fit for each user. ReWalk Rehabilitation is designed for the clinical rehabilitation environment where it provides valuable exercise and therapy. It also enables individuals to evaluate their capacity for using ReWalk Personal in the future. In 2011, we launched ReWalk Rehabilitation for use in hospitals and rehabilitation centers in the United States and Europe. We began marketing ReWalk Personal in Europe with CE mark clearance at the end of 2012 and received FDA clearance to market it in the United States in June 2014. ReWalk is the first exoskeleton cleared by the FDA for personal use. In the future, we will need to obtain approval from the applicable regulatory agency of any additional jurisdiction in which we seek to market ReWalk.

ReWalk is a breakthrough product that can fundamentally change the health and life experiences of users. ReWalk is currently the only commercialized exoskeleton using a tilt sensor to restore self-initiated walking. Designed for all-day use, ReWalk is battery-powered and consists of a light, wearable exoskeleton with integrated motors at the joints, an array of sensors and a computer-based control system to power knee and hip movement. ReWalk controls movement using subtle changes in the user s center of gravity. A forward tilt of the upper body is sensed by the system, which initiates the first step. Repeated body shifting generates a sequence of steps which allows for natural gait with functional walking speed. Because the exoskeleton supports its own weight, users do not expend unnecessary energy while walking. While ReWalk does not allow side-to-side actuation, users are able to turn by shifting their weight to the side. ReWalk also allows users to sit, stand and, in some cases, climb and descend stairs. ReWalk users are able to independently operate the devices, and most are able to put on and remove the devices by themselves. However, our safety guidelines and FDA specifications require users to be accompanied by a trained companion.

Published clinical studies demonstrate ReWalk s ability to deliver a natural gait and functional walking speed, which has not been shown in studies for any competing exoskeleton. In addition, our interim analysis of an ongoing clinical study and our experience working with health care practitioners and ReWalk users suggests that ReWalk has the potential to provide secondary health benefits. These benefits include reducing pain and spasticity and improving bowel and urinary tract function, body and bone composition, metabolism and physical fitness, as well as reducing hospitalizations and dependence on medications. Because of these secondary medical benefits, we believe that ReWalk has the ability to reduce the lifetime healthcare costs of individuals with spinal cord injuries, making it economically attractive for individuals and third-party payors. While we believe that ReWalk offers significant advantages over competing technologies and therapies, disadvantages include the time it takes for a user to put on ReWalk, the slower pace of ReWalk compared to a wheelchair, the weight of ReWalk when carried, which makes it more burdensome for a companion to transport than a wheelchair, and the requirement that users be accompanied by a trained companion.

We believe that the current design of Rewalk provides a functional technical base that can be easily adapted to address medical indications other than paraplegia that affect the ability to walk. We are currently engaged in research and development efforts to adapt ReWalk to address the mobility needs of quadriplegia and multiple sclerosis patients, and, in the future, we plan to address these needs in stroke and cerebral palsy patients. We are also developing our next generation of ReWalk, with a more efficient drive mechanism, slimmer profile and lighter body, as well as other improvements.

Development of ReWalk took over a decade and was spurred by the experiences of our founder, Dr. Amit Goffer, himself a quadriplegic. As of August 1, 2014, we had placed 62 ReWalk Rehabilitation and 19 ReWalk

Table of Contents

Personal systems, 88% of which were purchased by our customers, and 12% of which were placed with clinics and distributors for training, market development and clinical testing. Through August 1, 2014 we have trained over 400 ReWalk users, representing over 20,000 hours of use.

Our commercialization strategy is to penetrate rehabilitation centers, hospitals and similar facilities that treat patients with spinal cord injuries to become an integral part of their rehabilitation programs and to develop a broad based training network with these facilities to prepare users for home and community use. According to the National Spinal Cord Injury Statistical Center, 87.1% of persons with spinal cord injuries are sent to private, non-institutional residences (in most cases, their homes) after hospital discharge. As a result, while the majority of our sales to date have been ReWalk Rehabilitation units, the primary focus of our commercialization efforts going forward will be marketing ReWalk Personal for routine use at home, work or in the community, and we expect sales of ReWalk Personal to account for the substantial majority of our revenues in the future.

We expect to generate revenues from a combination of self-payors and third-party payors. While no uniform policy of coverage and reimbursement by third-party payors currently exists for electronic exoskeleton technologies such as ReWalk, we plan to pursue various paths of reimbursement and support fundraising efforts by institutions and clinics. In July 2014, the Bronx VA announced that it would be fully committed to supporting the procurement of ReWalk Personal and providing the staffing support needed for all eligible veterans with spinal cord injury for whom ReWalk is clinically indicated. As the first hospital to research the health-related benefits of an exoskeletal walking device for people with spinal cord injury, the Bronx VA experience supports the clinical use of ReWalk and similar FDA-approved technologies. We believe that additional VAs will adopt similar policies in the future.

We have offices in Yokneam, Israel, Marlborough, Massachusetts and Berlin, Germany.

Our Competitive Strengths

We believe that the following strengths provide us with sustainable competitive advantages to grow our revenue:

Proprietary Technology Enabling a More Natural Walking Experience. Our patented tilt-sensor technology and proprietary software allow self-initiated movement that we believe delivers a more natural walking experience than competing products. Published clinical studies demonstrate ReWalk s ability to provide a natural gait and functional walking speed, which has not been shown in studies for any competing exoskeleton. In the United States, we have method patent protection covering certain methods of user activation and control of systems such as ReWalk, including by sensing the users torso lean or weight shifts. In addition, we have apparatus patent protection in the United States and Europe covering the design of ReWalk and similar devices that use several sensors to empower tilt-sensor technology. Our patents on the tilt-sensor technology do not begin to expire until 2021. We also rely on trade secrets law to protect our proprietary software and product candidates/products in development.

First Mover Advantage. ReWalk Personal is the first medical exoskeleton cleared by the FDA for personal use in the United States. We do not believe that our competitors have any products that will be cleared by the FDA for personal use in the United States for at least the next two years. As a result, we believe we will be able to capture significant U.S. market share for exoskeletons for personal use. In addition, we were the first medical exoskeleton provider to have an established commercial infrastructure, and to market products in Europe, with our direct sales force in Germany. We are also the first to achieve reimbursement for a personal unit.

Compelling Clinical Data. We believe that ReWalk s clinical data differentiates us from our competitors. Clinical data published in established medical journals has demonstrated ReWalk s potential as a safe ambulatory device. We are not aware of any comparable clinical data generated in rigorous trials that has been published with respect to competing exoskeleton products. In addition, our interim analysis of an ongoing clinical study demonstrates improvements in secondary physical conditions, such as reduction in pain and spasticity and improving bowel and urinary tract function, body and bone composition, metabolism and physical fitness, as well as reduced hospitalizations and

Table of Contents

dependence on medications. We believe that continued results of this nature will greatly assist our ability to obtain regulatory clearances and third-party reimbursement.

Strategic Alliance with Yaskawa Electric Corporation. We have entered into a strategic alliance with Yaskawa Electric Corporation, a global leader in the fields of industrial robotics and automation. Pursuant to this arrangement, Yaskawa will serve as our distributor in certain Asian markets, where its name and brand recognition provide us with opportunities for growth and market penetration and can apply its expertise for product and quality improvements to ReWalk. We believe that this arrangement with such a prominent company is unique in this industry. Yaskawa also made an equity investment in our company. In addition, in the future, subject to any necessary regulatory clearance, we may market and sell in the United States and Europe certain healthcare equipment products that Yaskawa is currently developing. See Certain Relationships and Related Party Transactions Series D Preferred Share Purchase Agreement and Agreements with Yaskawa.

Established and Scaleable Manufacturing Capability. We have contracted with Sanmina Corporation, a well-established original equipment manufacturer with expertise in the medical device industry, for the manufacture of all of our products. Pursuant to this arrangement, Sanmina also sources all of the raw materials needed for the production of our products. We believe that this relationship provides us security with respect to quality, price and quantity of our products and offers significant scale-up capacity.

Experienced Management Team and Employees with Personal Experience with Paralysis. Our senior management team has significant experience in the medical device, technology and robotics industries, with an average of over 20 years of experience. The experiences of Dr. Amit Goffer, our founder, President and Chief Technology Officer, and the inventor of ReWalk, who has been paralyzed since 1997, have been one of the greatest drivers in the development and refinement of ReWalk. Additionally, certain of our sales and marketing and research and development employees are paraplegic, which provides us with invaluable perspective to advance the development of our products.

Our Growth Strategies

Our goal is to drive sustainable growth by fundamentally changing the health and life experiences of individuals with mobility impairments. To achieve this goal, we intend to:

Increase Our Salesforce and Infrastructure. We intend to penetrate our target markets and drive sales of ReWalk by increasing our sales force and further strengthening our distribution network and service, training and support functions. We believe that our presence in leading rehabilitation centers, hospitals and similar facilities in the United States and Europe has allowed us to establish a strong training infrastructure, and we plan to use this existing infrastructure as a point of entry to efficiently penetrate the market for ReWalk Personal.

Expand Geographic Coverage. We intend to increase our presence in the United States in response to receipt of FDA clearance for ReWalk Personal. We also plan to expand into new geographies throughout Europe and, through our arrangements with Yaskawa, in Asia. To date, we have focused our commercialization efforts primarily on the German, French, UK, Italian, Austrian, Canadian and Turkish markets for personal and rehabilitation use and the U.S. market for rehabilitation use.

Continue Clinical Studies to Further Demonstrate Health and Economic Benefits to Support Reimbursement. We intend to continue to work with hospitals, rehabilitation centers, patient advocacy and support groups and individual users to generate additional data regarding functionality and that supports the health and economic benefits of ReWalk. We will continue to engage and fund researchers and organizations to conduct clinical studies to demonstrate the functionality and utilization of ReWalk and to highlight economic benefits of reductions in medical complications associated with spinal cord injury. We believe that this data will position us to pursue additional third-party reimbursement for our products.

Leverage Our Core Technology Platform to Expand Treatment Indications. We designed ReWalk to provide a functional technical base that can be easily adapted to address medical indications other than

Table of Contents

paraplegia, and we believe that we have the internal and external experience to develop and commercialize products to address new indications. In addition to developing the next generation of ReWalk we are currently engaged in research and development efforts to adapt ReWalk to address the mobility needs of quadriplegia and multiple sclerosis patients, and, in the future, we plan to address these needs in stroke and cerebral palsy patients.

Overview of Spinal Anatomy and Spinal Cord Injury

Spinal Anatomy

The spine is the central core of the human skeleton and provides structural support, alignment and flexibility to the body. It consists of 24 interlocking bones, called vertebrae, which are stacked on top of one another. The spine is comprised of five regions, of which there are three primary regions: cervical, thoracic and lumbar. In addition, there is also the sacral region, or sacrum, a triangular-shaped bone and the coccyx, or tailbone, the bottom portion of the spine.

The spinal cord, housed inside the bony spinal column, is a complex bundle of nerves serving as the main pathway for information connecting the brain and nervous system. The spinal cord is divided into 31 segments that feed sensory impulses into the spinal cord, which in turn relays them to the brain. Conversely, motor impulses generated in the brain are relayed by the spinal cord to the spinal nerves, which pass the impulses to muscles and glands. The spinal cord mediates the reflex responses to some sensory impulses directly, without recourse to the brain, for example, when a person s leg is tapped, producing the knee jerk reflex.

Spinal Cord Injury

Spinal cord injury is the result of a direct trauma to the nerves themselves or damage to the surrounding bones and soft tissues which ultimately impacts the spinal cord. Spinal cord damage results in a loss of function, such as mobility or feeling. In most people who have spinal cord injury, the spinal cord is intact. Spinal cord injury is not the same as back injury, which may result from pinched nerves or ruptured disks. Even when a person sustains a break in a vertebra or vertebrae, there may not be any spinal cord injury if the spinal cord itself is not affected. There are two types of spinal cord injury complete and incomplete. In a complete injury, a person loses all ability to feel and voluntarily move below the level of the injury. In an incomplete injury, there is some functioning below the level of the injury.

Image of Separated Spinal Cord of an Adult

Upon examination, a patient is assigned a level of injury depending on the location of the spinal cord injury. Cervical level injuries cause paralysis or weakness in both arms and legs and is referred to as quadriplegia. Sometimes this type of injury is accompanied by loss of physical sensation, respiratory issues, bowel, bladder, and sexual dysfunction. Thoracic level injuries can cause paralysis or weakness of the legs (paraplegia) along with loss of physical sensation, bowel, bladder, and sexual dysfunction. In most cases, arms and hands are not affected. Lumbar level injuries result in paralysis or weakness of the legs (paraplegia). Loss of physical sensation, bowel, bladder, and sexual dysfunction can occur. The shoulder, arm, and hand functions are usually unaffected. Sacral level injuries primarily cause loss of bowel and bladder function as well as sexual dysfunction.

The history of exoskeleton development began in the 19th century, with the first patent for a mechanical suit appearing in 1890. The use of motors and gears to power these suits is not new, with General Electric developing an early exoskeleton device in the 1960s. Called the Hardiman, it was a hydraulic and electric body suit, but its weight and bulk made practical use prohibitive. Innovation of an advanced exoskeleton that restores a natural walking experience has been a key technological goal of the industry, and the lack of such a system has hindered sector growth. Advances in computer hardware and software and proprietary technological breakthroughs pioneered by us have resulted in the development of an advanced exoskeleton, ReWalk, that restores walking with a natural gait and functional speed.

Table of Contents

Market Opportunity

Confinement to a wheelchair can cause severe physical and psychological deterioration, resulting in bad health, poor quality of life, low self-esteem and high medical expenses. In addition, the secondary medical consequences of paralysis can include difficulty with bowel and urinary tract function, osteoporosis, loss of lean mass, gain in fat mass, insulin resistance, diabetes and heart disease. The cost of treating these conditions is substantial. The National Spinal Cord Injury Statistical Center, or the NSCISC, estimates that complications related to paraplegia cost, excluding indirect costs such as losses in wages, fringe benefits and productivity, approximately $500,000 in the first year post-injury and significant additional amounts over the course of an individual s lifetime. Further, secondary complications related to spinal cord injury can reduce life expectancies for SCI patients.

The NSCISC estimates as of 2013 that there were 273,000 people in the United States living with spinal cord injury, with an annual incidence of approximately 12,000 new cases per year. Approximately 42,000 of such patients are veterans, and are eligible for medical care and other benefits from the VA. With 24 VA spinal cord injury centers, the VA has the largest single network of spinal cord injury care in the United States.

The University of Alabama-Birmingham Department of Physical Medicine and Rehabilitation operates the NSCISC, which maintains the world s largest database on spinal cord injury research. Since 2010, motor vehicle crashes have been the leading cause of reported spinal cord injury cases (36.5%), followed by falls (28.5%), acts of violence (14.3%) and sports injuries (9.2%). Nearly 80% of spinal cord injuries occur among the male population. According to the NSCISC, upon hospital discharge, 87.1% of persons with spinal cord injuries are sent to private, non-institutional residence (in most cases, their homes prior to injury).

Based on U.S. Census Bureau data, the spinal cord injury population gender and age statistics and data from the Spinal Cord Model Systems report, we estimate almost 80%, or 218,000, of spinal cord injury patients in the United States could be candidates for current or future ReWalk products. The young average age of injury and significant remaining life expectancy, the likelihood of living at home and lifetime cost of treatment highlight the need for an out-of-hospital solution with demonstrated health and social benefits.

In addition to developing the next generation of ReWalk, we are currently engaged in research and development efforts to adapt ReWalk to address the mobility needs of quadriplegia and multiple sclerosis patients.

According to the National Multiple Sclerosis Society, as many as 400,000 Americans suffer from multiple sclerosis. Research indicates that approximately 53% of these individuals, or approximately 212,000, would be classified as either a 6.0 or 7.0 on the Kurtzke Disability Status Scale (DSS), a measure of the need for walking assistance. Individuals with DSS 6.0 require intermittent or unilateral constant assistance (by means of cane, crutch, or brace) to walk approximately 100 meters without resting. Individuals with DSS 7.0 are unable to walk beyond 10 meters without rest while leaning against a wall or holding furniture for support. We believe these individuals could benefit from our technology.

In the future, we plan to address the mobility needs of stroke and cerebral palsy patients. Over five million Americans have suffered a stroke, with 780,000 new incidences expected each year. Physical limitations after stroke vary from case to case, but approximately 20-25% of these individuals are unable to walk without full physical assistance. Cerebral palsy is a disorder of movement, muscle tone or posture that is caused by damage to the developing brain, most often before or during a child s birth, or during the first 3 to 5 years of a child s life. According to United Cerebral Palsy, there are 764,000 cases of cerebral palsy in the United States. Cerebral palsy represents a significant opportunity to address the segment of this market that will meet the physical criteria to use ReWalk.

Our Solutions

ReWalk is a breakthrough product that can fundamentally change the health and life experiences of users. Published clinical studies demonstrate ReWalk s ability to deliver a natural gait and functional walking speed. ReWalk s patented tilt-sensor technology and an on-board computer and motion sensors drive motorized legs that power knee and hip movement and allow self-initiated walking. ReWalk controls movement using subtle changes in the user s center of gravity. A forward tilt of the upper body is sensed by the system, which initiates the first step. Repeated body shifting generates a sequence of steps, which allows natural ambulation with

functional walking speed. While ReWalk does not allow side-to-side actuation, users are able to turn by shifting their weight to the side. ReWalk also allows users to sit, stand and, in some cases, climb and descend stairs. Use on stairs is not approved by the FDA in the United States.

Designed for all-day use and worn over the clothes of users, ReWalk consists of a light wearable exoskeleton with integrated motors at the joints, an array of sensors and a backpack that contains the batteries and the computer-based control system. The control system utilizes proprietary algorithms to analyze, upper-body motions and trigger and maintain gait patterns and other modes of operation (such as stair-climbing and shifting from sitting to standing), leaving the user s hands free for self-support and other functions. Because the exoskeleton supports its own weight, users do not expend unnecessary energy while walking. Safety measures include crutches, which provide additional stability, fall protection, which lowers users slowly and safely in the event of a malfunction, and the secure stand mode, which automatically initiates if the user does not begin walking within two seconds. ReWalk is also equipped with maintenance alarms, warnings and backup batteries. The rechargeable batteries are easily accessible from the system s backpack and can be recharged in any standard power outlet. Upon completion of training, which generally consists of approximately 15 one-hour sessions, most users are able to put on and remove the device by themselves while sitting, typically in less than 15 minutes.

Current ReWalk designs are intended for people with paraplegia who have the use of their upper bodies and arms. We currently offer two ReWalk products: ReWalk Personal and ReWalk Rehabilitation.

ReWalk

Rehabilitation

ReWalk Personal: intended for everyday use at home, at work or in the community. We began marketing ReWalk Personal in Europe with CE mark clearance at the end of 2012. We received clearance to market ReWalk Personal in the United States in June 2014. ReWalk Personal units are all manufactured according to the same specifications. Each unit is then permanently sized to fit the individual user and the software is configured for the user s specifications by the rehabilitation center, clinic or distributor.

ReWalk Rehabilitation: designed for the clinical rehabilitation environment, ReWalk Rehabilitation has adjustable sizing enabling multiple patient use. ReWalk Rehabilitation provides a valuable means of exercise and therapy. It also enables individuals to evaluate their capacity for using ReWalk Personal in the future. We began marketing ReWalk Rehabilitation for use in hospitals, rehabilitation centers and stand-alone training centers in the United States and Europe in 2011. ReWalk Rehabilitation units are all manufactured according to the same specifications and are equipped with adjustable sizing for multi-patient use.

Our interim analysis of an ongoing clinical study and our experience working with health care practitioners and ReWalk users suggest that ReWalk has the potential to provide secondary health benefits. These benefits include reducing pain and spasticity and improving bowel and urinary tract function, body and bone composition, metabolism and physical fitness, as well as reducing hospitalizations and dependence on medications.

Because of these secondary medical benefits, we believe that ReWalk has the ability to reduce the lifetime healthcare costs of individuals with spinal cord injuries, making it economically attractive for individuals, healthcare providers such as hospitals and rehabilitation centers, and third-party payors.

ReWalk users must have healthy hands and shoulders, weigh less than 220 pounds (100 kilograms) and be between 5 feet 1 inch and 6 feet 3 inches (1.55 meters and 1.87 meters). Based on U.S. Census Bureau data, the spinal cord injury population gender and age statistics and data from the Spinal Cord Model Systems report, we estimate that approximately 80% of persons with spinal cord injury in the United States comply with these restrictions and other requirements for current and future ReWalk products. ReWalk systems have an estimated useful life of five years and come with a two year warranty covering all elements beyond normal wear and tear.

Table of Contents

As part of the warranty, users receive software upgrades and an annual inspection. We offer extended warranties for purchase and, outside of the warranty program, provide repairs and service on a fee-for-service basis. ReWalk batteries, which are covered by our warranties, have an estimated life of approximately 600 charges, which for a typical user lasts two to three years.

ReWalk Q We are currently developing our next generation of ReWalk, with a more efficient drive mechanism, slimmer profile and lighter body, as well as other improvements. We are also developing ReWalk Q for individuals with quadriplegia who are unable to hold crutches, which will include attached crutches with wheels. We expect to complete the development of ReWalk Q in the near future, at which time we will begin clinical testing and apply for regulatory clearances. We plan to expand the designs and indications that we address beyond paraplegia and quadriplegia to include other disabilities affecting gait and ability to walk, such as multiple sclerosis, stroke and cerebral palsy.

Reimbursements and Other Funding Sources

We rely on self-payers, third-party reimbursements and various other funding sources for the payment of our products. ReWalk is currently primarily funded by self-payers. We plan to pursue additional pathways of reimbursement and funding, focusing our efforts on our two primary markets: the United States and Western Europe.

Third-Party Reimbursements

United States

In the United States, purchasers of ReWalk Rehabilitation have received reimbursement in certain cases. Private rehabilitation centers generally purchase ReWalk Rehabilitation out-of-pocket and then charge patients for ReWalk therapy on a per-session basis. Patients can then seek reimbursement from their insurance companies. Academic facilities such as teaching hospitals generally purchase ReWalk Rehabilitation out-of-pocket and provide patients the opportunity to use the ReWalk without charging for each session. These institutions may then seek reimbursement from insurance companies and may be willing to accept lower reimbursement rates than private facilities due to fewer pricing pressures.

While in some cases insurance companies have provided reimbursement for ReWalk Rehabilitation upon request, certain insurance companies view ReWalk as an experimental therapy and therefore will not provide coverage at this time. Medicaid and Medicare have provided reimbursement for ReWalk Rehabilitation sessions, although this coverage may have limits in terms of number or frequency of sessions. Worker s compensation has also provided reimbursement.

Private insurance companies do not currently cover or provide reimbursement for any personal medical exoskeleton products, including ReWalk Personal.

As part of our plan for growth, we intend to work with ReWalk users, health care practitioners, researchers, and the spinal cord injury community to support efforts to demonstrate to insurance companies the health benefits and the economic case for reimbursement of ReWalk Personal. Initially, coverage from private payers will be made on a case-by-case basis. Once a sufficient number of these cases have been approved, applications for local coverage decisions from the private payers will be made. We currently sponsor clinical studies and academic publications that demonstrate the medical benefits of ReWalk. In the future, we will pursue economic benefit clinical studies for the Centers for Medicare/Medicaid Services, or CMS, which would demonstrate the secondary medical benefits and long-term cost savings potential of ReWalk. We believe that a positive response from CMS in respect of such studies will broaden coverage by private insurers. We expect that it could take three to five years to receive a decision from CMS, but we believe that other sources of payment will be sufficient to support our business.

Table of Contents

Western Europe

Reimbursement for ReWalk in Europe varies by country. While we are not aware of any public or private payor that regularly covers ReWalk for rehabilitation or personal use, third-party payors have provided reimbursement for our products in certain cases in Germany, France and Italy.

We are initially focusing our efforts in Europe in Germany, which has a single-payer system and where we believe we have made significant progress toward achieving ReWalk coverage from the government. Because ReWalk is not currently covered in Germany, a patient who wishes to use ReWalk must apply for coverage and receive an official denial. He or she must then appeal the decision in court, relying on supporting documentation from a health care provider and other medical evidence. There are approximately 30 such cases pending in Germany, and we believe that these will result in eventual coverage. We plan to continue to pursue this case-by-case strategy and expect that once the precedent for coverage is established, seeking coverage will become easier and more routine. We continue to support clinical research and academic publications, which we believe will further support the case for coverage.

We are also pursuing reimbursement by private insurers and worker s compensation in various European countries.

Other Funding Sources

ReWalk is currently primarily funded by self-payers. Self-payers also include individuals who purchase ReWalk with funds from legal settlements with insurance companies or third parties. We also sell ReWalk Rehabilitation to VA hospitals, in which case the VA pays for the product. In July 2014, the Bronx VA announced that it would be fully committed to supporting the procurement of ReWalk Personal and providing the staffing support needed for all eligible veterans with spinal cord injury for whom ReWalk is clinically indicated. As the first hospital to research the health-related benefits of an exoskeletal walking device for people with spinal cord injury, the Bronx VA experience supports the clinical use of ReWalk and similar FDA-approved technologies. We believe that additional VAs will adopt similar policies in the future. We support financing and fund raising activities of foundations and prospective users. Funding may also be achieved from a number of other sources on a case-by-case basis, including foundations and philanthropic organizations, labor unions, and, in Europe, BG worker s compensation clinics.

Research and Development

We are committed to investing in a robust research and development program to enhance our current ReWalk products and to develop our pipeline of new and complementary products, and we believe that ongoing research and development efforts are essential to our success. Our research and development team includes engineers, machinists, researchers, marketing, quality, manufacturing, regulatory and clinical personnel, who work closely together to design, enhance and validate our technologies. This research and development team conceptualizes technologies and then builds and tests prototypes before refining and/or redesigning as necessary. Our regulatory and clinical personnel work in parallel with engineers and researchers, allowing us to anticipate and resolve potential issues at early stages in the development cycle.

We plan to increase our investment in research and development in the future by continually improving our functional technological platform, developing our next generation of ReWalk with design improvements and building upon our technological platform to address new medical indications that affect the ability to walk such as quadriplegia, multiple sclerosis, stroke and cerebral palsy.

We conduct our research and development efforts at our facility in Yokneam, Israel. We believe that the close interaction among our research and development, marketing and manufacturing groups allows for timely and effective realization of our new product concepts. Certain of our sales and marketing and research and development employees are paralyzed, including Dr. Amit Goffer, our founder, President and Chief Technology Officer, and the inventor of ReWalk, which provides us with invaluable prospective to advance the development of our products.

Table of Contents

Our research and development efforts are financed, in part, through funding from the OCS and from the BIRD Foundation. From our inception through June 30, 2014, we received funding totaling $0.45 million from the OCS and $0.5 million from the BIRD Foundation. For more information regarding these arrangement, see Management s Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources and Grants and Other Funding.

In September 2013, we entered into a strategic alliance with Yaskawa Electric Corporation, pursuant to which, among other arrangements, Yaskawa can apply its expertise product and quality improvements to ReWalk. Yaskawa is a global leader in the fields of industrial robotics and automation, and we believe that this relationship provides us with opportunities for product improvement and increased product offerings in the future. For more information regarding our relationship with Yaskawa, see Sales and Marketing and Certain Relationships and Related Party Transactions.

Clinical Studies

We coordinate and fund clinical studies intended to establish the effectiveness and benefits of ReWalk for individuals with spinal cord injuries. To date, there have been three studies of ReWalk published in peer-reviewed journals:

The first study, published in *The Journal of Spinal Cord Medicine* in 2012, included six participants and was designed to assess the safety and tolerance of use of ReWalk by patients with a spinal cord injury. The participants were all able to walk 100 meters with ReWalk. The study found no adverse safety events (which included falls, status of the skin, status of the spine and joints, blood pressure, pulse and electrocardiography) and concluded that use of ReWalk was well-tolerated by participants with no increase in pain and a moderate level of fatigue after use. The participants generally had positive feedback regarding ReWalk. No adverse effects were noted.

The second study included 24 participants and was designed to assess the safety and performance of ReWalk in enabling individuals with paraplegia to carry out routine ambulatory functions. Results with respect to a 12-participant subset were published in the *American Journal of Physical Medicine & Rehabilitation* in 2012. The results from this subset demonstrated that all participants were able to independently walk, without assistance from another person, for at least 50 meters and at least five minutes. Some participants reported improvements in pain, bowel function, bladder function and spasticity. All participants had strong positive feedback regarding the emotional and psychosocial benefits of using ReWalk. ReWalk was found to hold significant potential as a safe ambulatory powered orthotic for spinal cord injury patients. Significant performance variability was noted between participants. There were no serious adverse events reported. Five participants reported mild to moderate adverse effects, consisting of skin abrasions, lightheadedness and edema of the lower limbs. These adverse effects were managed by the appropriate use of padding, caffeine intake and adjustment of blood pressure medication, elastic stockings and rest.

The third study, published in *The Journal of Spinal Cord Medicine* in 2013, included six participants and found that participants with spinal cord injury, walking independently with ReWalk, demonstrated a stance and gait similar to that of an able-bodied individual. No adverse effects were noted.

The fourth study, which is ongoing and includes 30 participants, was designed to assess the mobility skills and levels of training and assistance needed to use and benefit from ReWalk. Results with respect to a seven-participant subset have been finalized and were presented at the *STO Human Factors and Medicine Panel Symposium*, Milan, Italy, in 2013. The results from this subset demonstrated that over the course of the training, all of the participants learned to move from sitting to standing and standing to sitting and to walk 50 to 166 meters in six minutes. Some assistance was needed for participants with the most limiting spinal cord injuries. Four of the participants were able to climb and descend stairs. The study concluded that ReWalk assisted walking can be performed independently by individuals with certain cases of spinal cord injury and that future technological advances and ongoing training could

Table of Contents

improve mobility and independence. Certain participants reported adverse effects in the form of mild to moderate skin abrasions, which were resolved with equipment adjustments, additional padding, and, in certain cases, allowing the skin to heal.

Although study participants and other ReWalk users have reported secondary physical and mental health benefits such as reduced pain and spasticity and improved bowel function and urinary tract function, fewer hospitalizations, reduced dependence on medications and improvements in mood, currently there is no formal clinical data establishing any secondary health benefits of ReWalk.

Community Engagement and Education

We devote significant resources to engagement with and education of the spinal cord injury community with respect to the benefits of ReWalk. We actively seek opportunities to partner with hospitals, rehabilitation centers and key opinion leaders to engage in research and development and clinical activities. We also seek to support educational and charitable organizations with fundraising and outreach programs. We believe that our success has been, and will continue to be driven in part by, our reputation and acceptance within the spinal cord injury community.

Sales and Marketing

We market and sell our products directly to institutions and individuals and through third-party distributors. We sell our products directly in Germany and the United States and primarily through distributors in our other markets. In our direct markets, we have established relationships with rehabilitation centers and the spinal cord injury community, and in our indirect markets, our distributors maintain these relationships. Sales of ReWalk Personal are generated primarily from the patient base at our rehabilitation centers, referrals through the spinal cord injury community and direct inquiries from potential users.

In the United States, we have a commercial infrastructure in place, which, until receipt of FDA clearance to market ReWalk Personal in the United States, focused on selling ReWalk Rehabilitation. We now plan to redirect our U.S. sales and marketing efforts toward ReWalk Personal by expanding our sales organization with dedicated business development managers for the United States. In Germany, we have successfully sold the ReWalk Rehabilitation and ReWalk Personal. We have begun to expand our German sales and marketing team and will continue to do so in the future to drive sales. We believe that our established commercial infrastructure in Germany has provided us with the knowledge and experience necessary to do so efficiently in the United States. We also believe that this experience will allow us to swiftly establish a direct sales force in other geographies in the future.

We also maintain arrangements with third-party distributors in Austria, China, France, Italy, Japan, Korea, Russia, Singapore, Taiwan, Thailand, Turkey, and the United Kingdom. We have achieved sales pursuant to these arrangements in the European markets and we expect to begin generating revenues pursuant to these arrangements in the Asian markets in 2014.

We have established centers of operations in Marlborough, Massachusetts, Berlin, Germany and Yokneam, Israel, to manage sales in North America, Europe, and the rest of world, respectively. We maintain training centers at our German and U.S. locations, where our personnel offers training for our sales representatives and distributors.

In September 2013, we entered into a strategic alliance with Yaskawa Electric Corporation, in connection with which Yaskawa has agreed to be our exclusive distributor in certain Asian markets. We believe that this relationship provides us with a significant opportunity for growth in Asia. Our arrangement with Yaskawa also provides that in the future, subject to any necessary regulatory clearance, we may market and sell certain of Yaskawa s healthcare equipment products currently under development in the United States and Europe. For more information regarding our relationship with Yaskawa, see Certain Relationships and Related Party Transactions.

Services and Customer Support

Our centers of operations in Marlborough, Massachusetts and Berlin, Germany coordinate all service functions for North America and Europe, respectively, through dedicated technical service personnel and

Table of Contents

customer service call centers. We aim to provide high-level support to our customers to build long-standing relationships. The following are the main categories of service and customer support functions that we provide:

Training. We provide on-site, hands-on, basic and advanced technical training for health care providers. These providers, who then train individual users, are subject to rigorous training and certification requirements. We have also implemented a rigorous, multi-level training and licensure program for users and their companions. We believe that these training programs serve an important safety and support function.

Communications Centers. We operate communications centers in our U.S. and Germany locations, which provide support hotlines, installation, maintenance, and periodic, preventive servicing. Outside of our direct markets, service functions are generally coordinated through our third-party distributors.

Spare Parts and Logistics Channels. We operate warehouses in the U.S., Germany and Israel, which house our inventory, parts and accessories.

Competition

The market in which we operate is characterized by active competition and rapid technological change, and we expect competition to increase. Competition arises from providers of other mobility systems and prosthetic devices.

We are aware of a number of other companies developing competing technology and devices, and some of these competitors may have greater resources, greater name recognition, broader product lines, or larger customer bases than we do. Our principal competitors in the medical exoskeleton market consist of Ekso Bionics (OTC: EKSO), Rex Bionics (London Stock Exchange: RXB), Cyberdyne (Tokyo Stock Exchange: 7779), and Parker Hannifin (NYSE: PH). We believe we have key competitive advantages over these companies, such as our tilt-sensor technology that provides a self-initiated walking experience, more natural gait and functional walking speed, slimmer and lighter design, ReWalk s ability to support its own weight and broad user specifications. Additionally, we are not aware of any medical exoskeleton product that is cleared or in the process of seeking clearance from the FDA for personal use. ReWalk Personal is the first medical exoskeleton cleared by the FDA for personal use in the United States.

In addition, we compete with alternative devices and alternative therapies, including treadmill-based gait therapies, such as those offered by Hocoma, AlterG, Aretech and Reha Technology. Other medical device or robotics companies, academic and research institutions, or others may develop new technologies or therapies that provide a superior walking experience, are more effective in treating the secondary medical conditions that we target or are less expensive than our current or future products. Our technologies and products could be rendered obsolete by such developments.

We may also compete with other treatments and technologies that address the secondary medical conditions that ReWalk seeks to mitigate.

Intellectual Property

Protection of our intellectual property is important to our business. We seek to protect our intellectual property through a combination of patents, trademarks, confidentiality and invention assignment agreements with our employees and certain of our contractors and confidentiality agreements with certain of our consultants, scientific advisors and other vendors and contractors. In addition, we rely on trade secrets law to protect our proprietary software and product candidates/products in development.

As of August 1, 2014, we have three issued method and device patents in the United States and Europe on our tilt sensor technology. We have apparatus patent claims in the United States and Europe covering the design of ReWalk and similar devices which use a plurality of sensors to empower tilt-sensor technology. In addition, in the United States, we have method patent claims covering certain methods of user activation and control of systems such as ReWalk, including by sensing the users torso lean or weight shifts. While our apparatus claims focus on protecting ReWalk in terms of its physical and structural characteristics, we believe that our method

68

Table of Contents

claims, which protect the process behind how ReWalk is controlled by the user, provide additional protection for our tilt sensor technology. We also have six pending patent applications in various countries around the world covering supporting technology with respect to our existing ReWalk systems and planned future products, including one pending international application filed under the Patent Cooperation Treaty, which provides an applicant one filing date for patent applications that may be filed in 148 countries. We do not currently license any of the technology contained in our products other than with respect to technology that is generally publicly available, but we may do so in the future.

Patents filed both in the United States and Europe generally have a life of 20 years from the filing date. As the oldest of our issued patents relating to our tilt-sensor technology was filed in May 2001, our patents on that technology do not begin to expire until May 2021.

We currently hold a registered trademark in Israel for the mark ReWalk and are in the process of registering this trademark in the United States.

The employment agreement of our founder, Dr. Amit Goffer, provides that a patent pending relating to a standing wheelchair is his individual property and that he may independently engage in the development of a standing wheelchair. The agreement also provides that we and any of our affiliates or successors have the royalty-free right to the exclusive use in the field of exoskeletons of any intellectual property developed by Dr. Goffer, alone or jointly with others (whether or not as part of the development of a standing wheelchair and whether or not developed through a company), while he is our employee, consultant or board member and for three years thereafter. See Certain Relationships and Related Party Transactions Arrangements with Founder.

We cannot be sure that our intellectual property will provide us with a competitive advantage or that we will not infringe on the intellectual property rights of others. In addition, we cannot be sure that any patents will be granted in a timely manner or at all with respect to any of our patent pending applications. For a more comprehensive discussion of the risks related to our intellectual property, see Risk Factors Risks Related to Our Intellectual Property.

Government Regulation

U.S. Regulation

Our medical products and manufacturing operations are subject to regulation by the FDA and other federal and state agencies. Our products are regulated as medical devices in the United States under the Federal Food, Drug, and Cosmetic Act, or FFDCA, as implemented and enforced by the FDA. The FDA regulates the development, testing, manufacturing, labeling, storage, installation, servicing, advertising, promotion, marketing, distribution, import, export, and market surveillance of our medical devices.

Premarket Regulation

Unless an exemption applies, each medical device commercially distributed in the United States requires either a substantial equivalence determination under a 510(k) premarket notification submission, or an approval of a premarket approval application (PMA). Under the FFDCA, medical devices are classified into one of three classes Class I, Class II or Class III depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurance of safety and effectiveness. Classification of a device is important because the class to which a device is assigned determines, among other things, the necessity and type of FDA review required prior to marketing the device. Class I devices are those for which reasonable assurance of safety and effectiveness can be assured by adherence to general controls that include compliance with the applicable portions of the FDA s Quality System Regulation, or QSR, facility registration and product listing, reporting of adverse medical events, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials. Class I also includes devices for which there is insufficient information to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but that are not life-supporting or life-sustaining or for a use which is of substantial importance in preventing impairment of human health, and that do not present a potential unreasonable risk of illness of injury.

Table of Contents

Class II devices are those for which general controls alone are insufficient to provide reasonable assurance of safety and effectiveness and there is sufficient information to establish special controls. These special controls can include performance standards, postmarket surveillance, patient registries and FDA guidance documents. While most Class I devices are exempt from the 510(k) premarket notification requirement, only about 60 types of Class II devices are exempt from premarket notification. As a result, manufacturers of most Class II devices are required to submit to the FDA premarket notifications under Section 510(k) of the FFDCA requesting classification of their devices in order to market or commercially distribute those devices. To obtain a 510(k), a substantial equivalence determination for their devices, manufacturers must submit to the FDA premarket notifications demonstrating that the proposed device is substantially equivalent to a predicate device already on the market. A predicate device is a legally marketed device that is not subject to premarket approval, *i.e.*, a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was found substantially equivalent through the 510(k) process. If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If the device is not substantially equivalent to a previously cleared device, the device is automatically a Class III device. The device sponsor must then fulfill more rigorous premarket approval requirements, or can request a risk-based classification determination for the device in accordance with the de novo process, which is a route to market for medical devices that are low to moderate risk, but are not substantially equivalent to a predicate device.

Devices that are intended to be life sustaining or life supporting, devices that are implantable, devices that present a potential unreasonable risk of harm or are of substantial importance in preventing impairment of health, and devices that are not substantially equivalent to a predicate device are placed in Class III and generally require approval of a PMA, unless the device is a pre-amendment device not subject to a regulation requiring premarket approval. The PMA process is more demanding than the 510(k) premarket notification process. In a PMA, the manufacturer must demonstrate that the device is safe and effective, and the PMA must be supported by extensive data, including data from preclinical studies and clinical trials. The PMA must also contain a full description of the device and its components, a full description of the methods, facilities and controls used for manufacturing, and proposed labeling. Following receipt of a PMA, the FDA determines whether the application is sufficiently complete to permit a substantive review. If the FDA accepts the application for review, it has 180 days under the FFDCA to complete its review of a PMA, although in practice, the FDA s review often takes significantly longer, and can take up to several years.

Clinical trials are almost always required to support PMAs and are sometimes required to support 510(k) submissions. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA s investigational device exemption, or IDE, regulations that govern investigational device labeling, prohibit promotion of the investigational device, and specify recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a significant risk, as defined by the FDA, the agency requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. The IDE will automatically become effective 30 days after receipt by the FDA, unless the FDA denies the application or notifies the company that the investigation is on hold and may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE that requires modification, the FDA may permit a clinical trial to proceed under a conditional approval. In addition, the study must be approved by, and conducted under the oversight of, an Institutional Review Board, or IRB, for each clinical site. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements.

We currently distribute ReWalk product to medical/rehabilitation institutions and take the position that the ReWalk for this use qualifies as powered exercise equipment, which is a Class I device and does not require a 510(k). Although the FDA disagrees with this position, the agency is exercising enforcement discretion, *i.e.*, it is permitting us to continue to distribute the ReWalk to institutions for therapeutic use. This exercise of enforcement discretion is in the context of our working with the FDA through the *de novo* classification process to obtain a

Table of Contents

classification determination for the ReWalk for uses that go beyond the institutional/rehabilitation setting, potentially leading to a limited community ambulation use. We submitted a *de novo* petition to the FDA in June 2013 and have had ongoing communications with the agency, including an in-person meeting in October 2013.

In June 2014, the FDA granted our petition for *de novo* classification, which is a route to market for medical devices that are low to moderate risk, but are not substantially equivalent to a predicate device, and classified ReWalk as Class II subject to special controls. The special controls established in the *de novo* order include compliance with medical device consensus standards; performance of a postmarket surveillance clinical study demonstrating a reasonable assurance of safety and effectiveness in urban terrain; non-clinical performance testing of the system s function and durability; a training program; and labeling related to device use and user training. The special controls of this *de novo* order will also apply to competing products seeking FDA clearance.

Postmarket Regulation

After a device is cleared for marketing, and prior to marketing, numerous regulatory requirements apply. These include:

- establishment registration and device listing;
- development of a quality assurance system, including establishing and implementing procedures to design and manufacture devices;
- labeling regulations that prohibit the promotion of products for unapproved or off-label uses and impose other restrictions on labeling; and
- medical device reporting regulations that require manufacturers to report to the FDA if a device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; and corrections and removal reporting regulations that require manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the U.S. Food, Drug and Cosmetic Act that may present a risk to health.

Our manufacturing processes are required to comply with the applicable portions of the Quality System Regulation that covers the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. We actively maintain compliance with the FDA s Quality System Regulation, 21 CFR Part 820, and the European Union s Quality Management Systems requirements, ISO 13485:2003.

As a manufacturer, we are subject to periodic scheduled or unscheduled inspections by the FDA. If the FDA believes we or any of our contract manufacturers are not in compliance with the quality system requirements, or other postmarket requirements, it has significant enforcement authority. Specifically, if the FDA determines that we failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- recalls, withdrawals, or administrative detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;

refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;

refusal to grant export approvals for our products; or

criminal prosecution.

Any such action by the FDA would have a material adverse effect on our business. In addition, these regulatory controls, as well as any changes in FDA policies, can affect the time and cost associated with the development, introduction and continued availability of new products. Where possible, we anticipate these factors in our product development processes.

Table of Contents

Foreign Regulation

In addition to regulations in the United States, we are subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products. In particular, we are subject to regulation by in the E.U. which has directives and standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices. Devices that comply with the requirements of a relevant directive are entitled to bear the CE conformity marking, indicating that the device conforms to the essential requirements of the applicable directive and, accordingly, can be commercially distributed throughout Europe. The method of assessing conformity varies depending on the class of the product, but normally involves a combination of self-assessment by the manufacturer and a third party assessment by a Notified Body. This third party assessment may consist of an audit of the manufacturer s quality system or specific testing of the manufacturer s product. We comply with the E.U. requirements and have received the CE mark for all of our ReWalk systems distributed in the E.U.

We are also subject to regulation in certain Asian markets in connection with our distribution agreement with Yaskawa. Pursuant to such agreement, Yaskawa has the rights to distribute ReWalk in Japan, China, Taiwan, Korea, Singapore and Thailand. The Japanese Ministry of Health, Labour and Welfare, or the MHLW, approved ReWalk in February 2014 as a welfare device due to its ability to restore mobility to users. Yaskawa has begun evaluating ReWalk at several hospitals and, with such approval of MHLW, Yaskawa may begin selling ReWalk in Japan. In each other country listed above, we will need to obtain approval from the relevant governmental agency prior to marketing ReWalk. We have begun to evaluate the approval process in China and Taiwan, but have not yet begun to do so in Korea, Singapore or Thailand. We expect that obtaining the necessary approvals in these countries could take between one and a half and two years after we submit the initial application.

Foreign sales outside of the E.U. and the Asian markets described above are subject to the foreign government regulations of the relevant jurisdiction, and we must obtain approval by the appropriate regulatory authorities before we can commence clinical trials or marketing activities in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required to obtain a marketing authorization in the U.S., the E.U. or the Asian markets described above. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

The policies of the FDA and foreign regulatory authorities may change and additional government regulations may be enacted that could prevent or delay regulatory approval of our products and could also increase the cost of regulatory compliance. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

U.S. Anti-kickback, False Claims and Other Healthcare Fraud and Abuse Laws

In the United States, there are federal and state anti-kickback laws that prohibit the payment or receipt of kickbacks, bribes or other remuneration intended to induce the purchase or recommendation of healthcare products and services. Violations of these laws can lead to civil and criminal penalties, including exclusion from participation in federal healthcare programs. These laws apply to manufacturers of products, such as us, with respect to our financial relationship with hospitals, physicians and other potential purchasers or acquirers of our products. The U.S. government has published regulations that identify safe harbors or exemptions for certain practices from enforcement actions under the federal anti-kickback statute, and we will seek to comply with the safe harbors where possible. To qualify for a safe harbor, the activity must fit squarely within the safe harbor. Arrangements that do not meet a safe harbor are not necessarily illegal, but must be evaluated on a case by case basis. Other provisions of state and federal law provide civil and criminal penalties for presenting, or causing to be presented, to third-party payers for reimbursement claims that are false or fraudulent, or for items or services that were not provided as claimed. False claims allegations under federal and some state laws may be brought on behalf of the government by private persons, whistleblowers, who then receive a share of any recovery.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, the PPACA. The PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare

Table of Contents

fraud statutes. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them. In addition, the PPACA provides that the government may assert that a claim that includes items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act. The PPACA also imposes new reporting and disclosure requirements on device manufacturers for any transfer of value made or distributed to physicians and teaching hospitals. Device manufacturers will also be required to report and disclose any investment interests held by physicians and their immediate family members during the preceding calendar year. A number of provisions of PPACA also reflect increased focus on and funding of healthcare fraud enforcement.

Environmental Matters

We are subject to various environmental, health and safety laws and regulations, including those governing air emissions, water and wastewater discharges, noise emissions, the use, transport, management and disposal of chemicals and hazardous materials, the import, export and registration of chemicals, and the cleanup of contaminated sites. Based on information currently available to us, we do not expect environmental costs and contingencies to have a material adverse effect on us. The operation of our business and facilities, however, entails risks in these areas. Significant expenditures could be required in the future to comply with environmental or health and safety laws, regulations or requirements.

In Israel, where our contract manufacturer produces all of our products, businesses storing or using certain hazardous materials (including materials necessary for our manufacturing process) are required, pursuant to the Israeli Dangerous Substances Law 5753-1993, to obtain a toxin permit from the Ministry of Environmental Protection.

In the European marketplace, electrical and electronic equipment is required to comply with the Directive on Waste Electrical and Electronic Equipment, which aims to prevent waste by encouraging reuse and recycling, and the Directive on Restriction of Use of Certain Hazardous Substances, which restricts the use of six hazardous substances in electrical and electronic products. Our products and certain components of such products put on the market in the EU (whether or not manufactured in the EU) are subject to these directives. Additionally, we are required to comply with certain laws, regulations and directives, including the Toxic Substances Control Act in the United States and REACH in the EU, governing chemicals. These and similar laws and regulations require the testing, reporting and registration of certain chemicals we use and ship. We believe we are in compliance in all material respects with applicable environmental laws and regulations.

Facilities, Manufacturing and Suppliers

Facilities

Our corporate headquarters are located in Yokneam, Israel, our U.S. headquarters are located in Marlborough, Massachusetts, and our European headquarters are located in Berlin, Germany.

All of our facilities are leased and we do not own any real property. The table below sets forth details of the square footage of our current leased properties, all of which are fully utilized. We have no material tangible fixed assets apart from the properties described below.

	Square feet (approximate)
Marlborough, Massachusetts	3,300
Yokneam, Israel	6,500
Berlin, Germany	370
Total	10,170

We believe our facilities are adequate and suitable for our current needs.

Manufacturing

ReWalk includes off-the-shelf and custom-made components produced to our specifications by various third parties, for technical and cost effectiveness. We have contracted with Sanmina Corporation, a well-established

73

Table of Contents

contract manufacturer with expertise in the medical device industry, for the manufacture of all of our products. Pursuant to this contract, Sanmina manufactures ReWalk at its facility in Ma alot, Israel. All ReWalk Personal units are manufactured pursuant to the same set of specifications, and all ReWalk Rehabilitation units are manufactured pursuant to another set. We place our manufacturing orders with Sanmina pursuant to purchase orders or by providing forecasts for future requirements. Sanmina requires us to send an advance payment for components with respect to each purchase order. We may terminate our relationship with Sanmina at any time upon written notice. Either we or Sanmina may terminate the relationship in the event of a material breach, subject to a 30-day cure period. Our agreement with Sanmina contains a limitation on liability that applies equally to both us and Sanmina.

We believe that this relationship allows us to operate our business efficiently by focusing our internal efforts on the development of our technology and our products and provides us with substantial scale-up capacity. We regularly test quality on-site at Sanmina s facility and we obtain full quality inspection reports. We maintain a non-disclosure agreement with Sanmina.

We develop certain of the software components internally and license other software components that are generally available for commercial use as open source software.

We manufacture products based upon internal sales forecasts. We deliver products to customers and distributors based upon purchase orders received, and our goal is to fulfill each customer s order for products in regular production within two weeks of receipt of the order.

Suppliers

We have contracted with Sanmina for the sourcing of all components and raw materials necessary for the manufacture of our products. Components of our products and raw materials come from suppliers in Europe, China and Israel, and we depend on certain of these components and raw materials, including certain electronic parts, for the manufacture of our products. To date, we have not experienced significant volatility in the prices of these components and raw materials. However, such prices are subject to a number of factors, including purchase volumes, general economic conditions, currency exchange rates, industry cycles, production levels and scarcity of supply.

We believe that our and Sanmina s facilities, our contracted manufacturing arrangement, and our supply arrangements are sufficient to support our potential capacity needs for the foreseeable future.

Employees

As of August 1, 2014, we had 63 employees, of whom 19 are located in the United States, 33 are located in Israel and 11 are located in Germany. The majority of our employees are engaged in sales and marketing and research and development activities. We do not employ a significant number of temporary or part time employees.

We are subject to Israeli labor laws and regulations with respect to our employees located in Israel. These laws and regulations principally concern matters such as pensions, paid annual vacation, paid sick days, length of the workday and work week, minimum wages, overtime pay, insurance for work-related accidents, severance pay and other conditions of employment. Our employees are not represented by a labor union. We consider our relationship with our employees to be good. To date, we have not experienced any work stoppages.

The employees of our U.S. and German