ReWalk Robotics Ltd.
Form 10-K
February 17, 2017
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2016

or

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

For the transition period from _____ to _____

Commission File Number: 001-36612

ReWalk Robotics Ltd.
(Exact name of registrant as specified in charter)

Israel	Not applicable
(State or other jurisdiction of incorporation or organization)	(I.R.S. employer identification no.)
3 Hatnufa Street, Floor 6, Yokneam Ilit, Israel	2069203
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: +972.4.959.0123

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Ordinary Shares, par value NIS 0.01 per share	The Nasdaq Stock Market LLC

Securities Registered Pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No x

Indicate by a check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer”, “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer o	Accelerated filer x
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

The aggregate market value of the Ordinary Shares held by non-affiliates of the Registrant based upon the closing price of the Ordinary Shares as reported by the Nasdaq Global Market on June 30, 2016 (the last business day of the Registrant’s most recently completed second fiscal quarter) was $59,417,492.

As of February 15, 2017, the Registrant had outstanding 16,351,009 Ordinary Shares, par value NIS 0.01 per share.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of our proxy statement for our 2017 Annual Meeting of Shareholders, which is to be filed within 120 days after the end of our 2016 fiscal year, are incorporated by reference into Part III of this annual report on Form 10-K.

REWALK ROBOTICS LTD.

FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2016

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Definitions and Introduction

Our legal and commercial name is ReWalk Robotics Ltd. We are a company limited by shares organized under the laws of the State of Israel and were founded in 2001. In September 2014, we listed our shares on the Nasdaq Global Market. We have irrevocably appointed ReWalk Robotics, Inc. as our agent to receive service of process in any action against us in any United States federal or state court. The address of ReWalk Robotics, Inc. is 200 Donald Lynch Blvd., Marlborough, Massachusetts 01752. As used herein, and unless the context clearly indicates otherwise, the terms "ReWalk", "the Company", "we", "us", "our" or "ours" refer to ReWalk Robotics Ltd. and its subsidiaries.

Special Note Regarding Forward-Looking Statements

This annual report on Form 10-K, or annual report, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, that are based on our management's beliefs and assumptions and on information currently available to our management. Forward-looking statements include information concerning our possible or assumed future results of operations, business strategies, financing plans, competitive position, industry environment, potential growth opportunities, potential market opportunities and the effects of competition. Forward-looking statements may include projections regarding our future performance and, in some cases, can be identified by words like "anticipate," "assume," "believe," "could," "seek," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "future," or similar expressions that convey uncertainty of future events or outcomes and the negatives of those terms. These statements may be found in this section of this quarterly report titled "Part I, Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this quarterly report. These statements include, but are not limited to, statements regarding:

- our expectations regarding future growth, including our ability to increase sales in our existing geographic markets, expand to new markets and achieve our planned expense reductions;
- our management's conclusion, and our independent registered public accounting firm's statement in its opinion relating to our accompanying consolidated financial statements, that there is a substantial doubt as to our ability to continue as a going concern;
- 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 ability to repay our secured indebtedness;
- our expectations as to our clinical research program and clinical results;
- our expectations as to the results of and Food and Drug Administration's, or the FDA's, potential regulatory developments with respect to our mandatory post-market surveillance study;
- the outcome of ongoing shareholder class action litigation relating to our initial public offering;
- 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 use effectively the proceeds of our follow-on public offering of ordinary shares and warrants;
- our ability to secure capital from our at-the-market equity distribution program based on the price range of our ordinary shares and conditions in the financial markets;
- our ability to maintain relationships with existing customers and develop relationships with new customers; and,

- the risk that we are currently not in compliance with The Nasdaq Stock Market LLC's, or Nasdaq, continued listing requirements, which may cause us to be delisted.

The preceding list is not intended to be an exhaustive list of all of our statements. The 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 statements. In particular, you should consider the risks provided under “Part I. Item 1A. Risk Factors" in this annual report.

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.

These statements may also be found in the sections of this annual report titled “Part I. Item 1. Business,” “Part I. Item 1A. Risk Factors,” “Part II. Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this annual report.

You should not put undue reliance on any forward-looking statements. Any forward-looking statement in this annual report speaks only as of the date hereof. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this annual report, to conform these statements to actual results or to changes in our expectations.

Where You Can Find Other Information

Our principal executive offices are located at 3 Hatnufa Street, Floor 6, Yokneam Ilit 2069203, Israel, and our telephone number is +972 (4) 959-0123. Our website is www.rewalk.com. Information contained, or that can be accessed through, our website does not constitute a part of this annual report and is not incorporated by reference herein. We have included our website address in this annual report solely for informational purposes. Information that we furnish with or file with the Securities and Exchange Commission, or the SEC, including annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to, or exhibits included in, these reports are available for download, free of charge, on our website as soon as reasonably practicable after such materials are filed or furnished with the SEC. As we were subject to the information reporting requirements applicable to foreign private issuers prior to January 1, 2016, we filed with the SEC an annual report on Form 20-F for the year ended December 31, 2014 and submitted to the SEC, on Form 6-K, unaudited quarterly financial information during the fiscal year ended December 31, 2015. These reports may also be downloaded free of charge on our website. Our SEC filings, including exhibits filed or furnished therewith, are also available on the SEC’s website at SEC.gov. You may obtain and copy any document we furnish or file with the SEC at the SEC’s public reference room at 100 F Street, NE, Room 1580, Washington, D.C. 20549. You may obtain information on the operation of the SEC’s public reference facilities by calling the SEC at 1-800-SEC-0330. You may request copies of these documents, upon payment of a duplicating fee, by writing to the SEC at its principal office at 100 F Street, NE, Room 1580, Washington, D.C. 20549.

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PART I

ITEM 1. BUSINESS

Overview

We are an innovative medical device company that is designing, developing and commercializing exoskeletons that allow 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 currently designed for everyday use by paraplegic individuals at home and in their communities, and is custom fitted for each user. ReWalk Rehabilitation is currently designed for use by paraplegia patients in 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 U.S. Food and Drug Administration, or FDA, clearance to market it in the United States in June 2014. Additionally, we have received regulatory approval to sell the ReWalk device in other countries. In the future we intend to seek approval from the applicable regulatory agencies in other jurisdictions where we seek to market the ReWalk device.

ReWalk is a breakthrough product that can fundamentally change the health and life experiences of users. 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 shifts 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 a gait, that mimics a natural pattern of the legs with functional walking speed. Because the exoskeleton supports its own weight and facilitates the user's gait, 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, depending on local regulatory approvals, climb and descend stairs. Use on stairs is not cleared by the FDA in the United States. ReWalk users are able to independently operate the devices, and most are able to put on and remove the devices by themselves. Our safety guidelines and FDA specifications, however, require users to be accompanied by a trained companion.

Published clinical studies demonstrate ReWalk's ability to deliver a functional walking speed. In addition, our interim analysis of an ongoing clinical study and our experience working with healthcare practitioners and ReWalk users suggests that ReWalk has the potential to provide secondary health benefits. These benefits include reducing pain and spasticity, improving bowel and urinary tract function, body and bone composition, metabolism and physical fitness, reducing hospitalizations and dependence on medications, as well as emotional and psychological benefits. 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. We believe additional clinical studies currently underway and planned clinical studies will demonstrate these benefits.

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.

Development of ReWalk took over a decade and was spurred by the experiences of our founder, Dr. Amit Goffer, who became a quadriplegic due to an accident. As of December 31, 2016, we had placed 112 units in use at rehabilitation centers and 214 personal units in a home or community use. Furthermore, 51 of the units we placed during the twelve months ended December 31, 2016 were paid for by insurance reimbursement. In the near future, we expect growth in our sales and marketing expense will be driven by our continued investment in our reimbursement efforts, as we

continue to pursue insurance claims on a case-by-case basis, manage claims through the review process and external appeals, and invest in efforts to expand coverage. As of December 31, 2016, there were 199 pending insurance claims relating to coverage for our product, compared to 90 as of December 31, 2015.

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% 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 almost half of our sales to date have been for use in a rehabilitation setting, 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 third-party payors, self-payors and institutions. While a broad uniform policy of coverage and reimbursement by third-party commercial payors currently does not exist for electronic exoskeleton technologies such as ReWalk, we are pursuing various paths of reimbursement and support fundraising efforts by institutions and clinics. In December 2015, the Veterans' Administration, or the VA, issued a national policy for the evaluation, training and procurement of ReWalk Personal exoskeleton systems for all qualifying veterans across the United States. The VA policy, is the first national coverage policy in the United States for qualifying individuals who have suffered spinal cord injury. As of December 31, 2016, we had placed 14 units as part of the VA policy. Additionally, to date, several private insurers in the United States and Europe have provided reimbursement for ReWalk in certain cases.

Recent Developments

- In the second quarter of 2016, we announced our collaboration with Harvard University's Wyss Institute for Biologically Inspired Engineering, or "Harvard". Our collaboration with Harvard centers on the research, design, development and commercialization of lightweight exoskeleton system technologies for lower limb disabilities, which are intended to treat stroke, multiple sclerosis, mobility limitations for the elderly and other medical applications. For more information see, "Research and Development" below.
- On November 1, 2016, we closed our follow-on public offering of 3,250,000 units, each consisting of one ordinary share and 0.75 of a warrant to purchase one ordinary share. The Company's gross proceeds were $12.2 million. For more information see, "Part II. Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations." and Note 8c(2) to our consolidated financial statements set forth in "Part II. Item 8. Financial Statements and Supplementary Data".
- In early January 2017, we announced our plans to reduce our operating expenses by up to 30% as compared to 2016. These reductions will be achieved through a combination of targeted savings, including the completion of specific projects focused on quality improvement initiatives and efforts to reduce overall product cost, a realignment of and reduction in staffing to match the Company's 2017 business goals, and a reduction in other corporate spending.

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.

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.

Image of Separated Spinal Cord of an Adult

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 spinal cord injury, or SCI, patients. The young average age at time 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.

The NSCISC estimates as of 2016 that there were 282,000 people in the United States living with spinal cord injury or SCI, with an annual incidence of approximately 17,000 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. Between 2010 and 2015, motor vehicle crashes have been the leading cause of reported spinal cord injury cases (38%), followed by falls (31%), acts of violence (14%) and sports injuries (9%). Nearly 80% of spinal cord injuries occur among the male population. According to NSCISC data, upon hospital discharge, 87% of persons with spinal cord injuries are sent to private, non-institutional residence (in most cases, their homes prior to injury).

Based on information from a 2013 report by the NSCISC, 41.1% of the total U.S. population of SCI patients suffered injuries between levels T4 and L5. Three published ReWalk trials for SCI patients had an aggregate screening acceptance rate of 79%considering all current FDA limitations, resulting in an estimated 33% of the total population of SCI patients being candidates for current ReWalk products. For important qualifying information about this determination, see “Part I. Item 1A. Risk Factors-The market for medical exoskeletons is new and unproven, and

important assumptions about the potential market for our products may be inaccurate."

Our Solutions

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 or waist pack 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 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.

As discussed above, 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. For a breakdown of our revenues from sales of each of ReWalk Personal and ReWalk Rehabilitation, see "Part II. Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations."

ReWalk Personal 6.0

- 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 mechanical 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 mechanical specifications and are equipped with adjustable sizing for multi-patient use and, software which can be configured for the user's specifications.

Our analysis of published initial clinical studies 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.

We intend to continue to develop future generations of ReWalk, with a range of improvements including additional functionality, more efficient drive mechanism, slimmer profile and lighter body, as well as other improvements.

Future Products

We plan to expand the designs and indications that we address beyond paraplegia to include other lower limb disabilities affecting gait and ability to walk, such as stroke, multiple sclerosis and cerebral palsy.

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 60% of these individuals will have lower limb

disability, which could require them to seek additional assistance in walking.

According to the Multiple Sclerosis Foundation, as many as 400,000 Americans suffer from multiple sclerosis. Research indicates that approximately half of these individuals would be classified as somewhere between a 4.0 and a 7.0 on the Kurtzke Disability Status Scale (DSS), a measure of the need for walking assistance. Individuals with DSS 4.0 suffer from relatively severe disability while individuals with DSS 7.0 are generally restricted to a wheelchair. Multiple sclerosis is a progressive disease, as approximately one-third of multiple sclerosis patients end up with full paralysis while two-thirds remain able to walk, though many will need an aid, such as a cane or crutches, and some will use a scooter or wheelchair due to fatigue, weakness or balance problems, or due to a need to conserve energy. We are currently engaged in research and development efforts with Harvard University's Wyss Institute for Biologically Inspired Engineering, to address the mobility needs of stroke, multiple sclerosis and cerebral palsy patients.

ReWalk soft suit exoskeleton

• ReWalk soft suit exoskeleton: We are also developing ReWalk soft suit exoskeleton for individuals who have suffered a stroke. We expect to complete the development of this lightweight exosuit in the near future, at which time we will begin clinical testing and apply for regulatory clearances. We plan to commercialize the ReWalk stroke product in 2018.

Third-Party Reimbursements

United States

In the United States rehabilitation centers generally purchase the ReWalk Rehabilitation unit and then charge patients for ReWalk therapy on a per-session basis. These institutions may then seek reimbursement from insurance companies for each session.

In December 2015, the VA issued a national policy for the evaluation, training and procurement of ReWalk Personal exoskeleton systems for all qualifying veterans across the United States. The VA policy, is the first national coverage policy in the United States for qualifying individuals who have suffered spinal cord injury.

While no broad uniform policy of coverage and reimbursement for electronic exoskeleton medical technology exists among commercial insurance payors in the United States or elsewhere, reimbursement may be achieved on a case-by-case basis. To date, payments for the ReWalk Personal device have been made primarily through case-by-case determinations by third-party payors (including several private insurers in the United States), by self-payors and donations and, to a lesser extent, through the use of funds from insurance and/or accident settlements. Generally, private insurance companies do not currently cover or provide reimbursement for any personal medical exoskeleton products, including ReWalk Personal, and are limited to case-by-case decisions. As of December 31, 2016, We had approximately 85 cases pending in the United States for insurance coverage decisions. For more information, see "Part I. Item 1A. Risk Factors-Risks Related to Our Business and Our Industry-We may fail to secure or maintain adequate insurance coverage or reimbursement for ReWalk by third-party payors…."

As part of our plan for growth, we intend to continue working with commercial insurance companies, health care practitioners, physicians, researchers, and the SCI community to support efforts to demonstrate the benefits and the case to support reimbursement of the ReWalk Personal device.

• We launched our post market surveillance study during the second quarter of 2016, and we also currently support clinical studies and academic publications that demonstrate the medical benefits of ReWalk. For more information on the post-market surveillance study, see "Part I. Item 1A. Risk Factors-Risks Related to Government Regulation-The FDA previously sent us letters regarding potential regulatory action for deficiencies in our mandatory post-market surveillance study on our ReWalk Personal 6.0…."

• In the future, we will pursue coverage through the Centers for Medicare and Medicaid Services, or CMS. 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. For more information, see “Part I. Item 1A. Risk Factors-Risks Related to Our Business and Our Industry-We may fail to secure or maintain adequate insurance coverage or reimbursement for ReWalk by third-party payors….”

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 and Italy.

We are initially focusing our efforts in Europe in Germany where we continue to make progress toward achieving ReWalk coverage from the various government, private and worker's compensation payors. As there is currently no broad coverage policy in Germany, a patient who wishes to use ReWalk must apply for coverage. If such patient is denied, then such patient must appeal the decision in court, relying on supporting documentation from a health care provider and other medical evidence. As of December 31, 2016, there were 114 such cases pending in Germany, and we believe that these will eventually lead German insurers to provide coverage on a broad scale. 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 more routine. For more information, see “Part I, Item 1A. Risk Factors-We may fail to secure or maintain adequate insurance coverage or reimbursement for ReWalk by third-party payors, including the VA, which risk may be heightened if insurers find ReWalk to be investigational or experimental or if new government regulations change existing reimbursement policies.”

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

In addition to being funded by third-party payors, including private insurance plans, government programs such as the VA, and Worker's Compensation, ReWalk is also funded by self-payors. Self-payors also include individuals who purchase ReWalk with funds from legal settlements with insurance companies or third parties.

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, 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 focus our research and development efforts in the future by continually improving and expanding our functional technological platform, developing a lightweight “soft suit” exoskeleton device that will assist patients who had stroke or multiple sclerosis, 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.

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.

Our research and development efforts have been financed, in part, through funding from the Israel Innovation Authority, or the IIA (formerly known as Office of the Chief Scientist in the Israel Ministry of Economy), and from the BIRD Foundation. From our inception through December 31, 2016, we received funding totaling $740,000 from the IIA and $500,000 from the BIRD Foundation. Our research and development expenses, net were approximately $9.0 million, $5.9 million and $8.6 million for the fiscal years ended December 31, 2016, December 31, 2015 and December 31, 2014, respectively. For more information regarding our research and development financing

arrangements and expenses, see “Part II. Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations - Components of Our Statements of Operations - Operating Expenses," "—Liquidity and Capital Resources” and “—Grants and Other Funding.”

Research and Development Collaborations

On May 16, 2016, we entered into the Research Collaboration Agreement, or Collaboration Agreement, and the Exclusive License Agreement, or License Agreement, with Harvard. Under the Collaboration Agreement, we and Harvard agreed to collaborate on research regarding the development of lightweight soft suit exoskeleton system technologies for lower limb disabilities, which are intended to treat stroke, multiple sclerosis, mobility limitations for the elderly and other medical applications. Under the Collaboration Agreement, we must pay Harvard quarterly installment payments to help fund the research. Subject to the terms of the Collaboration Agreement, Harvard and we are required to report our respective research results and findings to each other on a regular basis. The Collaboration Agreement governs ownership of the research results and inventions generated in performance of the research collaboration, and provides us the option to negotiate with Harvard for a license to certain new inventions of Harvard conceived in performance of the collaboration.

The Collaboration Agreement will expire on May 16, 2021. Subject to payment of a minimum funding commitment under applicable circumstances, we may terminate the agreement if there is a loss of Harvard's principal investigator or if we do not believe that we have or can secure sufficient funding to proceed. The Collaboration Agreement may also be terminated by either Harvard or us due to a material uncured breach by the other party or upon termination of the License Agreement.

Under the License Agreement, we are granted an exclusive, worldwide royalty-bearing license under certain patents of Harvard relating to lightweight "soft suit" exoskeleton system technologies for lower limb disabilities, a royalty-free license under certain related know-how and the option to obtain a license under certain inventions conceived under our joint research collaboration. Harvard retains the right to practice the patents for research, educational and scholarly purposes. We are required to use commercially reasonable efforts to develop products under the license in accordance with an agreed-upon development plan and to introduce and market such products commercially. In addition to an upfront fee and royalties on net sales, we are obligated to pay Harvard certain milestone payments upon the achievement of certain product development and commercialization milestones. We also agreed to reimburse Harvard for expenses incurred in connection with the filing, prosecution and maintenance of the licensed patents.

The License Agreement will continue in full force and effect until the expiration of the last-to-expire valid claim of the licensed patents. We may terminate the Agreement for any reason upon 60 days' prior written notice, while Harvard may terminate the Agreement if we do not obtain requisite insurance, becomes insolvent or fail to meet certain development milestones. The License Agreement may also be terminated by Harvard or us due to the other party's material uncured breach.

The Collaboration Agreement and License Agreement contain, as applicable, customary representations and warranties and customary enforcement, indemnification and insurance provisions. For further discussion of the Collaboration Agreement and License Agreement, see Note 9 to our consolidated financial statements in "Part II. Item 8. Financial Statements and Supplementary Date."

In September 2013, we entered into a strategic alliance with Yaskawa Electric Corporation, pursuant to which, among other arrangements, Yaskawa can apply its expertise in 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 "Part III. Item 13. Certain Relationships and Related Transactions, and Director Independence."

Clinical Studies

Multiple clinical studies, some of which are published in peer-reviewed journals, have been carried out to establish the effectiveness and benefits of ReWalk for individuals with spinal cord injuries. Certain of the benefits tested include:

- reduced pain;
- improved bowel and urinary tract function;
- reduced spasticity;
- increases in joint range of motion for the hip and ankle joints;
- improved sleep and reduced fatigue;
- increase in oxygen uptake and heart rate as a result of walking as opposed to sitting and standing;
- ability to ambulate at a speed greater than 0.4 meters per second, which is considered to be conducive to outdoor related community ambulation; and
- reduced hospitalizations.

Although study participants and other ReWalk users have reported the secondary health benefits listed above, currently there is no conclusive 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 third party payors, institutions, including rehabilitation centers, 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. One customer accounted for 33.3% and 14.8% of our total revenues for the years ended December 31, 2016 and 2015, respectively. 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.

Services and Customer Support

Our centers of operations in Marlborough, Massachusetts and Berlin, Germany coordinate all customer support and product service functions for North America and Europe, respectively, through dedicated technical service personnel who provide product services and customer support through training to healthcare providers and support to product users.

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 faster functional walking speed, ReWalk's ability to support its own weight and broad user specifications. 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 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.

In addition to ReWalk's portfolio of issued patents and patent applications, the Company licenses certain patented technology from third party as described above under the "Research and Development" section.

As of February 1, 2017, we have five issued patents in the United States and one issued patent in Europe, as well as 24 pending patent applications in various countries around the world for our technology including the United states and Europe. As such, we have apparatus patent claims in the United States and Europe covering aspects 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 user's 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 claims, which protect the process behind how ReWalk is controlled by the user, provide additional protection for our tilt sensor technology. 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 and former President and Chief Technology Officer, 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. Mr. Goffer retired from serving as our President and Chief Technology Officer on November 18, 2015, and as a member of our board of directors on December 3, 2015. For more information, see “Part III. Item 13. Certain Relationships and Related Transactions, and Director Independence.”

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 Item 1A. “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 the 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.

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, or PMA, meaning, (i) a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, (ii) a device that has been reclassified from Class III to Class II or I, or (iii) 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 yet 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 comply with abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements.

In June 2014, the FDA granted our petition for "de novo" classification, which provides 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 ReWalk is intended to enable individuals with spinal cord injuries to perform ambulatory functions under supervision of a specially trained companion, and inside rehabilitation institutions. The special controls established in the de novo order include the following: compliance with medical device consensus standards; clinical testing to demonstrate safe and effective use considering the level of supervision necessary and the use environment; non-clinical performance testing, including durability testing to demonstrate that the device performs as intended under anticipated conditions of use; a training program; and labeling related to device use and user training. The special controls of this de novo order also apply to competing products seeking FDA clearance. For more information, see Part I. Item 1. Risk Factors-Risks Related to Government Regulation-We are subject to extensive governmental regulations relating to the manufacturing, labeling and marketing of our products, and a failure to comply with such regulations could lead to withdrawal or recall of our products from the market.

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 FFDCA 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:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications or repair, replacement or refunds;
- 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 approval of pre-market approval applications relating to new products or modified products;
- reclassifying a 510(k) cleared device or withdrawing PMA approval;
- refusal to grant export approvals for our products; or
- pursuing 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.

Regulation outside of the U.S.

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 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.

Foreign sales outside of the E.U. 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 Unites States or the E.U. 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.

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

Recently, the U.S. House of Representatives and Senate passed legislation, which, if signed into law, would repeal certain aspects of the PPACA. Further, on January 20, 2017, U.S. President Donald Trump signed an executive order directing federal agencies with authorities and responsibilities under the PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the PPACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices.

Congress also could consider subsequent legislation to replace elements of the PPACA that are repealed. Thus, in light of the stated policies of the new U.S. presidential administration, there is uncertainty with respect to the impact, if any, on the provisions of the PPACA affecting us. While any legislative and regulatory changes will likely take time to develop, and may or may not have an impact on the regulatory regime to which we are subject, we cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

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.

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 ("Sanmina"), a well-established 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. 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 December 31, 2016, we had 94 employees (including full-time and hourly employees), of whom 36 are located in the United States, 41 were located in Israel and 17 were located in Germany. As of December 31, 2015, we had 87 employees, of whom 32 were located in the United States, 39 were located in Israel and 16 are located in Germany, and as of December 31, 2014, we had 66 employees, of whom 20 were located in the United States, 33 were located in Israel and 13 were located in Germany. The majority of our employees are, and have been, engaged in sales and marketing and research and development activities. We do not employ a significant number of temporary or part time employees. In early January 2017 we announced our plans to reduce our operating expenses by up to 30% and therefore the total number of employees remaining after the finalizing the process is 70 worldwide.

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 subsidiaries are subject to local labor laws and regulations.

Financial Information about Geographic Areas and Significant Customer Information

The following table sets forth the geographical breakdown of our revenues for each of the years ended December 31, 2016, 2015, 2014:

	Year Ended December 31,		
	2016	2015	2014
Revenues based on customer's location:			
Israel	$—	$—	$—
United States	3,741	2,439	2,186
Europe	1,144	820	1,254
Asia-Pacific	984	487	511
Total revenues	$5,869	$3,746	$3,951

Additional discussion of financial information by reportable segment and geographic area and sales in excess of 10% of total revenues to certain of our customers is contained in Note 12 to our consolidated financial statements set forth in "Part II. Item 8. Financial Statements and Supplementary Data" of this annual report.

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ITEM 1A. RISK FACTORS

Our business faces significant risks. You should carefully consider all of the information set forth in this annual report and in our other filings with the United States Securities and Exchange Commission, or the SEC, including the following risk factors which we face and which are faced by our industry. Our business, financial condition and results of operations could be materially and adversely affected by any of these risks. In that event, the trading price of our ordinary shares would likely decline and you might lose all or part of your investment. This report also contains forward-looking statements that involve risks and uncertainties. Our results could materially differ from those anticipated in these forward-looking statements, as a result of certain factors including the risks described below and elsewhere in this report and our other SEC filings. See also “Special Note Regarding Forward-Looking Statements” on page (iii).

Risks Related to Our Business and Our Industry

We 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 or to generate sufficient revenues from such contracts.

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. We have sold only a limited number of ReWalk systems, 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, while several private insurers in the United States have provided reimbursement for ReWalk in certain cases to date, health insurance companies and other third-party payors in the future may not deliver adequate coverage or reimbursement for our products. The VA may also cancel or materially curtail its current policy of providing coverage in the United States for qualifying individuals who have suffered spinal cord injury, or we may not place enough units through the VA to make our sales profitable under the VA policy. Additionally, any future government measures to restrict healthcare spending could limit or eliminate our ability to provide products to, and gain revenues from, the VA. 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.

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

We have concluded that there are substantial doubts as to our ability to continue as a going concern.
We have incurred accumulated losses in the amount of $106.5 million as of December 31, 2016 and further losses are anticipated in the development of our business. Those factors raise substantial doubt about the Company's ability to continue as a going concern. The ability to continue as a going concern is dependent upon the Company obtaining the necessary financing to meet its obligations and repay its liabilities arising from normal business operations when they come due. The Company intends to finance operating costs over the next twelve months with existing cash on hand, reducing operating spend, issuances under the Company's ATM Offering Program, other future issuances of equity and debt securities, or through a combination of the foregoing. The financial statements have been prepared assuming that we will continue to operate as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Our auditors also included an explanatory paragraph to their audit opinion relating to our accompanying consolidated financial statements for the fiscal year ended December 31, 2016 regarding the substantial doubts about the Company's ability to continue as a going concern.

If we cannot raise the required funds on acceptable terms, we may be forced to substantially curtail our current operations or cease operations altogether. Further, external perceptions regarding our ability to continue as a going concern may make it more difficult for us to obtain financing for the continuation of our operations or require us to obtain financing on terms that are more favorable to investors, and could result in the loss of confidence by investors and suppliers. As such, our failure to continue as a going concern could harm our business, operating results and financial position and severely affect the value of your investment.

We may not have sufficient funds to meet certain future capital requirements, which could impair our efforts to develop and commercialize existing and new products. Future equity financings or borrowings may also dilute our shareholders or place us under restrictive covenants limiting our ability to operate.
Our ability to continue as a going concern depends upon our obtaining the necessary financing to meet our obligations and timely repay our liabilities arising from normal business operations. We intend to finance operating costs over the next 12 months with existing cash on hand, issuances under our ATM Offering Program or other future issuances of equity and debt securities or through a combination of the foregoing. We are party to a loan agreement, dated December 30, 2015 (the Loan Agreement), with Kreos Capital V (Expert Fund) Limited (Kreos), providing us a line of credit in the amount of $20.0 million. As of December 31, 2016 we had drawn down the full $20.0 million under the Loan Agreement, consisting of borrowings of $12.0 million on January 4, 2016 and $8.0 million on December 28, 2016 at an interest rate of 10.75%. We also issued to Kreos a warrant to purchase up to 119,295 of our ordinary shares at an exercise price of $9.64 per share. Pursuant to our ATM Offering Program, we may offer and sell from time to time ordinary shares with an aggregate offering price of up to $25 million pursuant to an equity distribution agreement with Piper Jaffray & Co. dated May 10, 2016. As of December 31, 2016, we had sold 692,062 ordinary shares under our ATM Offering Program, resulting in net proceeds of $4.1 million, after deducting commissions, fees and expenses. On November 1, 2016, we closed a separate follow-on public offering of 3,250,000 units, each consisting of one ordinary share and 0.75 of a warrant to purchase one ordinary share. We raised approximately $11.1 million from this offering, after deducting commissions, fees and expenses, and plan to use the ATM Offering Program opportunistically now that the lock-up period has expired for the underwriting agreement for the November follow-on offering.
We may need to seek additional sources of financing if we require more funds than anticipated during the next twelve months or in later periods, including if we cannot make our loan repayments under our Loan Agreement with Kreos, or if we cannot raise sufficient funds from equity issuances, such as the ATM Offering Program. Depending on the circumstances, this could potentially require us to borrow additional funds, sell or license our assets or sell additional equity securities in private placements or public offerings to pursue strategic transactions, such as the sale of our

business or all or substantially all of our assets. Moreover, even if we believe we have sufficient funds for our current or future operating plans, we may choose to raise additional capital due to market conditions or strategic considerations. Any sale of additional equity may result in dilution to our shareholders and agreements governing any borrowing arrangement may also contain covenants that could restrict our operations. If we are unable to obtain additional funds on reasonable terms, our business and results of operations could be materially harmed.

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.

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We obtained FDA clearance for our ReWalk Personal device in June 2014. This clearance permits us to market the device for use by individuals with spinal cord injury at levels T7 to L5 and for use by individuals in rehabilitation institutions with spinal cord injury at levels T4 to L5. The FDA's clearance requires users of the device to meet the following criteria: healthy hands and shoulders that can support crutches, healthy bone density, no skeletal fractures, in good general health, ability to stand with a stander device, weight of less than 220 pounds/100 kilograms and height between 5 feet 3 inches and 6 feet 2 inches/1.60 meters and 1.88 meters. Additionally, the FDA clearance contraindicates psychiatric or cognitive conditions that could interfere with a user's proper operation of the device and various other clinical conditions, including pregnancy, severe concurrent medical diseases, a history of severe neurological injuries other than spinal cord injury, impaired joint mobility, unhealed limbs or pelvic fractures or unstable spine, severe spasticity and significant and chronic loss of joint mobility due to structural changes in non-bony tissue. Future products for those with paraplegia 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. 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. Our assumptions may be inaccurate and may change.

The NSCISC estimates that as of 2016 there were 282,000 people in the United States living with SCI, and that the annual incidence of SCI cases is approximately 17,000 new cases per year. Based on information from a 2015 report by the NSCISC, 41.1% of the total U.S. population of SCI patients suffered injuries between levels T4 and L5. Three published ReWalk trials with respect to such eligible SCI patients had an aggregate screening acceptance rate of 79% considering all current FDA limitations, resulting in an estimated 33% of the total population of SCI patents being candidates for current ReWalk products. For more information on our expectations regarding these plans, see "-Our future growth and operating results will depend on our ability to develop and commercialize new products and penetrate new markets" below.

We cannot assure you that our estimate regarding our current products is accurate or that our estimate regarding future products will remain the same. FDA clearance for such products, if received at all, may contain different limitations from the ones the FDA has placed on the devices we currently market for paraplegia patients. If our estimates of our current or future addressable market are incorrect, our business may not develop as we expect and the price of our securities may suffer.

We may fail to secure or maintain adequate insurance coverage or reimbursement for ReWalk by third-party payors, including the VA, which risk may be heightened if insurers find ReWalk to be investigational or experimental or if new government regulations change existing reimbursement policies. Additionally, such coverage or reimbursement, even if maintained, may not produce revenues that are high enough to allow us to sell our products profitably.

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 VA, Medicare and Medicaid, worker's compensation and other third-party payors. In December 2015, the VA issued a national reimbursement policy for the ReWalk system, which entails the evaluation, training and procurement of ReWalk Personal exoskeleton systems for all qualifying veterans across the United States. However, no broad uniform policy of coverage and reimbursement for electronic exoskeleton medical technology exists among third-party payors in the United States or elsewhere, although reimbursement may be achieved on a case-by-case basis. To date, payments for our products have been made primarily through case-by-case determinations by third-party payors (including several private insurers in the United

States), by self-payors and, to a lesser extent, through the use of funds from insurance and/or accident settlements.

Generally, private insurance companies do not cover or provide reimbursement for any medical exoskeleton products for personal use, including ReWalk Personal, and may ultimately provide no coverage at all. Additionally, 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 has determined that certain lower-limb prostheses, including ReWalk, are experimental and investigational because there is inadequate evidence of their effectiveness. Additionally, the majority of independent medical review decisions made following the denial of ReWalk coverage have determined that ReWalk is experimental and/or investigational, citing a lack of clinical data.

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Many private third-party payors use coverage decisions and payment amounts determined by the Center for Medicare and Medicaid Services, or the CMS, which administers the Medicare program, as guidelines in setting their coverage and reimbursement policies. In the future, we intend to pursue reimbursement coverage from CMS. While we believe that a positive response from CMS 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 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.

Future legislation could result in modifications to the existing public and private health care insurance systems that would have a material adverse effect on the reimbursement policies discussed above. It is uncertain what impact the new U.S. presidential administration will have on healthcare spending. If enacted and implemented, any measures to restrict health care spending could result in decreased revenue from our products and decrease potential returns from our research and development initiatives.

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 began 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 light of the potential problems, delays, uncertainties and complications encountered in connection with a more 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.

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If we are unable to leverage and expand our sales, marketing and training infrastructure, including in light of our announced plan to reduce corporate spending, we may fail to increase our sales.

A key element of our long-term business strategy is the continued enhancement of our sales and marketing infrastructure, through the training, retaining and motivating of skilled sales and marketing representatives with industry experience and knowledge. In order to continue growing our business efficiently, we must coordinate the development of this infrastructure with the timing of regulatory approvals, decisions regarding reimbursements, and other factors in various geographies. Managing and maintaining our sales and marketing infrastructure is expensive and time consuming, and an inability to leverage such an organization effectively, or in coordination with regulatory or other developments, could inhibit potential sales and the penetration and adoption of ReWalk into both existing and new markets. In addition, as previously announced, we have set a goal to reduce total operating expenses in 2017 by up to 30% as compared to 2016, in part through a realignment of and reduction in staffing to match our 2017 business goals. As we move forward with these plans, we intend to continue funding field sales, service and training efforts for our ReWalk products. However, certain decisions we make regarding staffing in these areas in our efforts to decrease expenses could have unintended negative effects on our revenues, such as by weakening our sales infrastructure and/or harming the quality of our customer service.

Additionally, we expect to face significant challenges as we manage and continue to improve our sales and marketing infrastructure and work to retain the individuals who make up those networks. Newly hired sales representatives require training and take time to achieve full productivity. If we fail to train new 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 retain, subject to our plans to cut operating expenses, and continue to recruit our 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 study participants and other ReWalk users have reported the secondary health benefits such as a reduction in pain and spasticity, improved bowel and urinary tract functions and emotional and psychosocial benefits, among others, currently there is no conclusive clinical data establishing any secondary health benefits of ReWalk.

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 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 its 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.

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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.

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

We are currently engaged in research and development efforts to address the needs of patients with mobility impairments besides paraplegia, such as stroke and multiple sclerosis, and, in the future, we plan to address these needs in elderly assistance and cerebral palsy. For more information, see Part I. Item 1. Business - Future Products. In addition to other research and development projects, we collaborate with Harvard University's Wyss Institute for Biologically Inspired Engineering to design, research and develop lightweight exoskeleton system technologies for lower limb disabilities intended to treat stroke, multiple sclerosis, mobility limitations for the elderly and other medical applications. As part of the collaboration, Harvard has also licensed to us certain of its intellectual property relating to lightweight exoskeleton system technologies for lower limb disabilities. We are obligated to use commercially reasonable efforts to develop products under the license in accordance with an agreed-upon development plan and to introduce and market such products commercially.

We expect that a portion of our revenues will be derived, in the next few years, from new products we create for use by individuals suffering from a stroke or multiple sclerosis, and, in later years, from other new products of ours aimed at addressing other medical indications which affect the ability to walk, including elderly assistance and cerebral palsy. As such, our future results will depend on our ability to successfully develop and commercialize such new products. We cannot ensure you that we will be able to introduce new products, products currently under development and products contemplated for future development for additional indications in a timely manner, or at all. Harvard may also terminate its license agreement with us if we fail to obtain the requisite insurance, become insolvent or do not meet certain developmental milestones with respect to the products we develop using the patents licensed to us. Any such termination of this aspect of the collaboration with Harvard could impair our research and development efforts into lightweight exoskeleton system technologies for lower limb disabilities. 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 new products 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 non-spinal cord injury markets such as the stroke and multiple sclerosis communities, and, in the longer term, elderly assist and cerebral palsy patients. We may not be able to gain such market acceptance in these communities in a timely manner, or at all.

While our new products currently under development will share some aspects of the core technology platform in our current products, their design features and components may differ from our current products. Accordingly, these products will also be subject to the risks described above under "-We 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 or to generate sufficient revenues from such contracts." 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.

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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, Parker Hannifin, Rex Bionics, Cyberdyne, and others. These companies have products currently available for institutional use and in some cases 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.

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 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 the near term we continue to commercialize our ReWalk systems and pursue certain research and development initiatives.

Additionally, as a domestic Exchange Act reporting company, we have faced, and may continue to face, higher regulatory, compliance and financial costs than those we incurred as a foreign private issuer due to the increased reporting requirements applicable to domestic issuers, and our general and administrative expenses could increase.

As previously announced, we have set a goal to reduce total operating expenses in 2017 by up to 30% as compared to 2016. These reductions will be achieved through a combination of targeted savings: the completion of specific projects focused on quality improvement initiatives and efforts to reduce overall product cost; a realignment of and reduction in staffing to match our 2017 business goals; and a reduction in other corporate spending. We intend to continue funding reimbursement efforts, clinical studies to expand data on the effectiveness of the SCI products, field sales, service and training efforts for the ReWalk system and the commercialization pathway for the Stroke Softsuit program. However, if we are unable to cut expenses effectively and decrease our net losses, or if we are otherwise unable to reduce our cash usage from operations, the value of your investment may be adversely affected. Our management has also concluded, and our auditors have added an explanatory paragraph to their audit opinion relating

to our accompanying consolidated financial statements for the fiscal year ended December 31, 2016, that there is a substantial doubt about our ability to continue as a going concern.Our ability to continue as a going concern depends upon our accessing the necessary financing to meet our obligations and repay our liabilities arising from normal business operations when they come due. If we cannot raise the required funds on acceptable terms, we may be forced to substantially curtail our current operations or to cease operations altogether. For more information, see -“ We have concluded that there are substantial doubts as to our ability to continue as a going concern.”

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In the event that we default under the Loan Agreement with Kreos, Kreos could foreclose on its lien and take possession over all of our assets.

On December 30, 2015, we entered into the Loan Agreement with Kreos, pursuant to which Kreos extended a line of credit to us in the amount of $20.0 million. On January 4, 2016, we drew down $12.0 million and on December 28, 2016, we drew down the remaining $8.0 million. The principal amount of each drawdown is repayable monthly over a period of 24 months commencing 12 months after the applicable drawdown date, which period will be extended to 36 months if we raise $20.0 million or more in connection with the issuance of shares of our capital stock (including debt convertible into shares of our capital stock) before the respective 24-month period expires. Interest on each drawdown is payable monthly in arrears at a rate of 10.75% per year from the applicable drawdown date through the date on which all such principal is repaid.

Pursuant to the Loan Agreement, we granted Kreos a first priority security interest over all of our assets, including intellectual property and equity interests in our subsidiaries, subject to certain permitted security interests. For more information, see “Part II. Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations-Liquidity and Capital Resources” and “Part II. Item 8. Financial Statements and Supplementary Data-Notes to Consolidated Financial Statements.” In the event that we are unable to make the interest payments when due under the Loan Agreement or to pay the outstanding principal amount following the termination of the Loan Agreement, Kreos could take actions under the Loan Agreement and seek to take possession of or sell our assets to satisfy our obligations thereunder. Any of these actions would have an immediate material adverse effect on our business, operating results and financial condition.

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 continue to 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. Additionally, our reliance on Sanmina as a contract manufacturer makes us vulnerable to possible capacity constraints and reduced control over component availability, delivery schedules, manufacturing yields and costs.

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.

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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 an 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 are also currently involved in research and development efforts directed to the needs of patients with other mobility impairments, such as stroke and multiple sclerosis. In the future, we plan to address these needs in elderly assistance and cerebral palsy. We may not be successful in developing, obtaining regulatory approval for, or marketing our currently proposed products and products proposed to be created in the future. 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;

- 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 forgo 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.

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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 or other regulatory 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 arrangements with Yaskawa for the distribution of our products in certain Asian markets. In May 2016, we announced our collaboration with Harvard University’s Wyss Institute for Biologically Inspired Engineering for the research, design, development and commercialization of lightweight exoskeleton system technologies for lower limb disabilities, aimed to treat stroke, multiple sclerosis, mobility limitations for the elderly and other medical applications. Our arrangements with Yaskawa and Harvard 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.

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 2015 and 2016, most of our revenues were denominated in U.S. dollars and the remainder of our revenues was denominated in euros and British pound, and most of our expenses were denominated in U.S. dollars and the remainder of our expenses were denominated in NIS and euros. Throughout 2017, we expect that the denominations of our revenues and expenses will be consistent with what we experienced in 2016 and 2015. 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. For example, we are exposed to the risks that the shekel may appreciate relative to the dollar, or, if the shekel instead devalues relative to the dollar, that the inflation rate in Israel may exceed such rate

of devaluation of the shekel, or that the timing of such devaluation may lag behind inflation in Israel. In any such event, the dollar cost of our operations in Israel would increase and our dollar-denominated results of operations would be adversely affected.

We cannot predict any future trends in the rate of inflation in Israel or the rate of devaluation (if any) of the shekel against the dollar. For example, while the shekel appreciated against the dollar at a rate of approximately 1.5% during the fiscal year of 2016, the rate of devaluation of the shekel against the dollar was approximately 0.3% and 12.0% in 2015 and 2014, respectively. In 2015 and 2014, this had the effect of increasing the dollar cost of our operations in Israel. If the dollar cost of our operations in Israel increases once again, our dollar-measured results of operations will be adversely affected. Our operations also could be adversely affected if we are unable to effectively hedge against currency fluctuations in the future.

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We have in the past engaged in limited hedging activities, and we may enter into other hedging arrangements with financial institutions from time to time. 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 “Part II, Item 7A Quantitative and Qualitative Disclosures About Market Risk” "The economic effects of Brexit may affect relationships with existing and future customers and could have an adverse impact on our business and operating results." below.

The economic effects of "Brexit" may affect relationships with existing and future customers and could have an adverse impact on our business and operating results.

On June 23, 2016, the United Kingdom (the "U.K.") held a referendum in which voters approved an exit from the European Union ("E.U."), commonly referred to as "Brexit." On February 8, 2017, the U.K.’s House of Commons approved a bill authorizing the government to start exit talks with the European Union. The impact on us from Brexit will depend, in part, on the outcome of tariff, trade, regulatory and other negotiations.

As a result, the global markets and currencies have been adversely impacted, including a sharp decline in the value of the British pound as compared to the U.S. dollar. A potential devaluation of the local currencies of our international buyers relative to the U.S. dollar may impair the purchasing power of our international buyers and could cause international buyers to decrease their participation in our marketplaces or use of our services.

Further, volatility in exchange rates resulting from Brexit is expected to continue in the short term as the U.K. negotiates its exit from the E.U. We translate sales and other results denominated in foreign currency into U.S. dollars for our financial statements. During periods of a strengthening dollar, our reported international sales and earnings could be reduced because foreign currencies may translate into fewer U.S. dollars.

Finally, Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the U.K. determines which E.U. laws to replace or replicate, and those laws and regulations may be cumbersome, difficult or costly in terms of compliance. Any of these effects of Brexit, among others, could adversely affect our business, financial condition, operating results and cash flows.

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.

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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.

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

Our 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. 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. Additionally, we do not carry key man insurance on any of our current executive officers. 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.

We are subject to securities class action lawsuits against us that may result in an adverse outcome.

Between September 2016 and January 2017, eight putative class actions on behalf of alleged shareholders that purchased or acquired our ordinary shares pursuant and/or traceable to our registration statement on Form F-1 (File No. 333-197344) used in connection with our initial public offering, or our IPO, were commenced in the Superior Court of the State of California, County of San Mateo, the Superior Court of the Commonwealth of Massachusetts, Suffolk County, the United States District Court for the Northern District of California, and the United States District Court for the District of Massachusetts.The actions involve claims under various sections of the Securities Act against us, certain of our current and former directors and officers, the underwriters of our IPO and certain entities referred to by plaintiffs as the "Venture Capital Defendants." Although the four actions commenced in the Superior Court of the State of California, County of San Mateo have been dismissed for lack of personal jurisdiction, the four actions

commenced in the other forums remain pending (two of which have been consolidated). For more information, see "Part I. Item 3- Legal Proceedings."

We are generally required, to the extent permitted by Israeli law, to indemnify our current and former directors and officers who are named as defendants in these types of lawsuits. We also have certain contractual indemnification obligations to the underwriters of our IPO regarding the securities class action lawsuits. While a certain amount of insurance coverage is available for expenses or losses associated with these lawsuits, this coverage may not be sufficient. Based on information currently available, we are unable to reasonably estimate a possible loss or range of possible losses, if any, with regard to these lawsuits; therefore, no litigation reserve has been recorded in our consolidated balance sheets. Although we plan to defend against these lawsuits vigorously, there can be no assurances that a favorable final outcome will be obtained. These lawsuits or future litigation may require significant attention from management and could result in significant legal expenses, settlement costs or damage awards that could have a materially adverse impact on our financial position, results of operations and cash flows.

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U.S. healthcare reform measures and other recent legislative initiatives could adversely affect our business. Recently, the U.S. House of Representatives and Senate passed legislation, which, if signed into law, would repeal certain aspects of the PPACA. Further, on January 20, 2017, U.S. President Donald Trump signed an executive order directing federal agencies with authorities and responsibilities under the PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the PPACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers or manufacturers of pharmaceuticals or medical devices. Congress also could consider subsequent legislation to replace elements of the PPACA that are repealed.
Healthcare reforms stemming from the repeal of, and potential replacement for, the PPACA may result in more rigorous coverage criteria and lower reimbursement among regulated third-party payors, and in additional downward pressure on the prices that we receive for sales of our device. Any reduction in reimbursement from Medicare or other government-funded federal programs, including the VA, or state healthcare programs could lead to a similar reduction in payments from private commercial payors. The implementation of cost containment measures or other healthcare reforms may thus prevent us from being able to generate revenue, attain profitability or further commercialize our existing or future ReWalk devices.
We are currently unable to predict what additional legislation or regulation, if any, relating to the health care industry may be enacted in the future or what effect recently enacted federal legislation or any such additional legislation or regulation would have on our business. The pendency or approval of such proposals or reforms could result in a decrease in our stock price or limit our ability to raise capital or to enter into collaboration agreements for the further development and commercialization of our programs and products.

Risks Related to Government Regulation

The FDA previously sent us letters regarding potential regulatory action for deficiencies in our mandatory post-market surveillance study on our ReWalk Personal 6.0. While we have since initiated this post-market surveillance study with a revised FDA-approved protocol and have addressed the violations cited by the FDA, if we cannot satisfy future FDA requests promptly or if our study produces unfavorable results, we could receive additional FDA warning letters, and our labeling or marketing efforts could be materially adversely affected.

On September 30, 2015, we received a warning letter, or the September 2015 Letter, from the FDA citing deficiencies in our protocol for a post-market surveillance study of our ReWalk Personal and our failure to initiate a post-market study by the September 28, 2015 deadline. Between June 2014 and our receipt of the September 2015 Letter, we submitted our post-market study protocol to the FDA, amended the protocol in response to the FDA's subsequent request and proposed additional amendments to enhance the protocol after the FDA notified us that our subsequently-amended protocol was still deficient. While we responded to the FDA's requests throughout this period, we did not submit all of our responses on a timely basis. The September 2015 Letter warned that the FDA could take regulatory action against us for violations of Section 522 of the FFDCA based on the late post-market study and allegedly deficient protocol for that study. In February 2016, the FDA sent us an additional information request, or the February 2016 Letter, requesting additional changes to our post-market surveillance study protocol and asking that we comply within 30 days. This letter also discussed the FDA's request, as modified in our later discussions with the FDA, for a new pre-market notification for our ReWalk device linked to what the FDA viewed as changes to a computer included with the device, or the special 510(k).

In late March 2016, following our multiple discussions with the FDA, including an in-person meeting, the FDA confirmed that the agency would apply enforcement discretion to continued marketing of the ReWalk device conditioned upon our submitting a special 510(k) by April 8, 2016, and initiating our post-market surveillance study by June 1, 2016. The special 510(k) was submitted on April 8, 2016, and the FDA's substantial equivalence determination was received by us on July 22, 2016, granting us permission to continue marketing the ReWalk device. Additionally, we submitted a protocol to the FDA for the post-market surveillance study that was approved by the agency on May 5, 2016. We began the study on June 13, 2016, with Stanford University as the lead

investigational site. On August 18, 2016, the FDA sent us a letter stating that, based on its evaluation of our corrective and preventive actions in response to the September 2015 Letter, we had adequately addressed the violations cited in the September 2015 Letter. Our post-market surveillance study is currently ongoing, and we have provided the FDA with the required periodic reports on the study's progress, in a few cases with delay. We intend to continue providing the FDA with such reports on a timely basis going forward.

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We expect we will be able to respond promptly to the FDA's further requests related to the post-market surveillance study based on significant additions in staffing aimed at addressing a need for greater internal clinical and regulatory resources. However, if we are unable to satisfy this timing or if the results of our post-market surveillance study are not as favorable as we expect, the FDA may issue additional warning letters to us, may impose limitations on the labeling of our device or may require us to stop marketing the ReWalk Personal device in the United States. We derived 64% of our revenues in 2016 from sales of the ReWalk device in the United States and, if we are required to market a previous version of the ReWalk device in the United States, we expect that these sales would be adversely impacted, which could materially adversely affect our business and overall results of operations.

We are subject to extensive governmental regulations relating to the manufacturing, labeling and marketing of our products, and a failure to comply with such regulations could lead to withdrawal or recall of our products from the market.

Our medical products and manufacturing operations are subject to regulation by the FDA, the European Union, 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 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, what is known about the type of 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. For more information, see "Part I. Item 1. Business-Government Regulation" above.

In June 2014, the FDA granted our petition for "de novo" classification, which provides 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 ReWalk is intended to enable individuals with spinal cord injuries to perform ambulatory functions under supervision of a specially trained companion, and inside rehabilitation institutions. The special controls established in the de novo order include the following: compliance with medical device consensus standards; clinical testing to demonstrate safe and effective use considering the level of supervision necessary and the use environment; non-clinical performance testing, including durability testing to demonstrate that the device performs as intended under anticipated conditions of use; 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.

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 to ensure that all applicable regulatory requirements continue to be met. The process of complying with the applicable good manufacturing practices, adverse event reporting and other requirements can be costly and time consuming, and could delay or prevent the production, manufacturing or sale of the ReWalk. In addition, if we fail to comply with applicable regulatory requirements, it could result in fines or delays 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. For instance, the FDA may issue mandates, known as 522 orders, requiring us to conduct post-market studies of products for which the FDA has already granted us pre-market clearance. Failure to comply could result in enforcement of the FFDCA against us or our products. Additionally, the agency could request that we recall our ReWalk Personal 6.0 device. For more information on certain deficiencies previously identified by the FDA in our mandatory post-market surveillance study on our ReWalk Personal 6.0, see "-The FDA previously sent us letters regarding potential regulatory action for deficiencies in our mandatory post-market surveillance study on our ReWalk Personal 6.0…" above.

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If we or our third-party manufacturers or suppliers fail to comply with the FDA's Quality System Regulation, or QSR, 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, 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, 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 or refunds;
- operating restrictions or partial suspension or total shutdown of production;
- recalls, withdrawals, or administrative detention or seizure of our products;
- refusing or delaying requests for 510(k) marketing clearance or approval of pre-market approval applications relating to new products or modified products;
- reclassifying a 510(k) cleared device or withdrawing a PMA approval;
- 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 Practices Act, or the FCPA. See Item 1. "Business-Government Regulation" above. 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 or other transfers of value made to healthcare providers and teaching hospitals or funds spent on marketing and promotion of medical device products. It is widely believed that public reporting under the Sunshine Act and implementing Open Payments regulations results

in increased scrutiny of the financial relationships between industry, physicians and teaching hospitals. These anti-kickback, anti-bribery, public reporting and aggregate spending 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.

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The FCPA applies to companies, including ours, 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.

Compliance with various regulations, including those related to our status as a U.S. public company and the manufacturing, labeling and marketing of our products, may result in heightened general and administrative expenses and costs, divert management’s attention from revenue-generating activities and pose challenges for our management team, which has limited time, personnel and finances to devote to regulatory compliance.

As a U.S. public company, we are subject to various regulatory and reporting requirements, including those imposed by the SEC, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, or the Dodd-Frank Act, the listing requirements of the Nasdaq Global Market and other applicable securities rules and regulations. Additionally, our medical products and manufacturing operations are regulated by the FDA, the European Union and other governmental authorities both inside and outside of the United States. Compliance with the rules and regulations applicable to us as a publicly traded company in the United States and medical device manufacturer has greatly increased, and may continue to increase, our legal, general and administrative and financial compliance costs and has made, and may continue to make, some activities more difficult, time-consuming or costly. Additionally, these regulatory requirements have diverted, and may continue to divert, management’s attention from revenue-generating activities and may increase demands on management’s already-limited resources.

Our management team consists of few employees, as the majority of our employees are engaged in sales and marketing and research and development activities. As part of our previously announced plan to reduce our operating

expenses by up to 30% in 2017 as compared to 2016, in the first quarter of 2017, we reduced the number of employees to 70 worldwide, including in areas such as finance and information technology, which could affect our ability to comply with various regulations facing us as a public company. In light of such constraints on its time, personnel and finances, our management may not be able to implement programs and policies in an effective and timely manner to respond adequately to the heightened legal, regulatory and reporting requirements applicable to us. In the past, for example, we have not always been able to respond on a timely basis to requests from regulators, although we have not to date experienced any long-term material adverse consequences as a result. For more information, see "-The FDA previously sent us letters regarding potential regulatory action for deficiencies in our mandatory post-market surveillance study on our ReWalk Personal 6.0…" above. Similar deficiencies, weaknesses or lack of compliance with public company, medical device and other regulations could harm our reputation in the capital markets or for quality and safety, negatively affect our ability to maintain our public company status and to develop, commercialize or continue selling our products on a timely and effective basis, and cause us to incur sanctions, including fines, injunctions and penalties.

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In addition, complying with public disclosure rules makes our business more visible, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If such claims are successful, our business and operating results could be harmed, and even if the claims do not result in litigation or are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and harm our business and operating results.

Compliance with new regulations regarding the use of conflict minerals may be time-consuming and costly and could adversely affect our reputation.

In August 2012, under the Dodd-Frank Act, the SEC adopted new requirements for companies that use certain minerals and derivative metals, namely, tantalum, tin, gold and tungsten (referred to as "conflict minerals" regardless of their actual country of origin) in their products. These rules require us to investigate whether our products contain such "conflict minerals" and, in May 2017 (for the year ended December 31, 2016), to include on a Form SD filed with the SEC appropriate disclosures regarding our use of such minerals during the previous calendar year. There will be costs associated with these investigation and disclosure requirements, and we may be unable to complete our diligence in time. In addition, depending upon our findings, or our inability to make reliable findings, about the source of any possible conflict minerals that may be used in any products manufactured for us by third parties, our reputation could be harmed, which could cause us to lose those customers who require that all of the components of our products be certified as conflict-free. If we are not able to meet customer requirements, customer demand for our products may decline, and we may have to write off inventory in the event that it cannot be sold.

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 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. For more information, see Part I. Item 1. Business-Intellectual Property."

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 and review 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 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 may also grant our employees or consultants ownership over certain technology which they license to us for a set term. If these technologies are material to our business after the term of the license, our inability to use them could adversely affect our business and profitability.

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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 information, which could lead to the loss or impairment thereof 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.

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. For more information, see “Part I. Item 1. Business-Competition” above. 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, upon the expiration of our current patents, 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 in those countries. 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 depend on computer and telecommunications systems we do not own or control and failures in our systems or a cybersecurity attack or breach of our IT systems or technology could significantly disrupt our business operations or result in sensitive customer information being compromised which would negatively materially affect our reputation and/or results of operations.

We have entered into agreements with third parties for hardware, software, telecommunications and other information technology services in connection with the operation of our business. It is possible we or a third party that we rely on could incur interruptions from a loss of communications, hardware or software failures, a cybersecurity attack or a breach of our IT systems or technology, computer viruses or malware. We believe that we have positive relations with our vendors and maintain adequate anti-virus and malware software and controls; however, any interruptions to our arrangements with third parties, to our computing and communications infrastructure, or to our information systems or any of those operated by a third party that we rely on could significantly disrupt our business operations.

A cyber attack of our systems or networks that impairs our information technology systems could disrupt our business operations and result in loss of service to customers, including technical support for our ReWalk devices. While we have certain cybersecurity safeguards in place designed to protect and preserve the integrity of our information technology systems, we have experienced and expect to continue to experience actual or attempted cyber attacks of our IT systems or networks. However, none of these actual or attempted cyber attacks has had a material effect on our operations or financial condition.

Additionally, we have access to sensitive customer information in the ordinary course of business. If a significant data breach occurred, our reputation may be adversely affected, customer confidence may be diminished, or we may be subject to legal claims, any of which may contribute to the loss of customers and have a material adverse effect on us. For more information, see " 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." above.

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We are not 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 thus our intellectual property rights outside the United States are limited. 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.

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, published applications may issue with claims that potentially cover our products, technology or methods.

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 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 none 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.

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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 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 an Investment in Our Securities

Sales of a substantial number of ordinary shares or volatility or a reduction in the market price of our ordinary shares could have an adverse effect on our ordinary shares and on the value of the warrants offered in our follow-on offering completed in November 2016.

On November 1, 2016, we closed our follow-on public offering of 3,250,000 units, each consisting of one ordinary share and 0.75 of a warrant to purchase one ordinary share. As a result, we issued 3,250,000 ordinary shares and warrants to purchase up to 2,437,500 ordinary shares. We also granted Oppenheimer as underwriter the option to purchase 487,500 additional units for up to 30 days after October 27, 2016, which Oppenheimer did not exercise. The ordinary shares included in the units and/or the ordinary shares issuable upon exercise of the warrants included in the units will, once issued, be freely tradable without restriction or further registration under the Securities Act, subject to limitations on resales by our affiliates under Rule 144 under the Securities Act. Additionally, the warrants became immediately exercisable upon issuance. As of February 1, 2017, we did not issue any ordinary shares pursuant to the exercise of these warrants. Sales by us or our shareholders of a substantial number of ordinary shares in the public market, or the perception that these sales might occur, could cause the value of our securities to decline or could impair our ability to raise capital through a future sale of, or pay for acquisitions using, our equity securities. Additionally, while there is no established public trading market for the warrants and we do not expect one to develop, any volatility or reduction in the market price of our ordinary shares could have an adverse effect on the trading price of the warrants given that they are exercisable into ordinary shares.

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Additionally, as of February 1, 2017, 570,816 ordinary shares were issuable pursuant to the exercise of outstanding warrants granted as part of our series E investment round in July 2014 and to Kreos in connection with our loan agreement with Kreos in January and December 2016, and 3,277,911 shares remained available for issuance to our and our affiliates' respective employees, non-employee directors and consultants under our equity incentive plans, including 2,234,227 ordinary shares subject to outstanding awards. Pursuant to our Amended and Restated Shareholders' Rights Agreement, dated July 14, 2014, with certain of our shareholders, as of February 1, 2017, the beneficial owners of approximately 4,203,143 of our ordinary shares were also entitled to require that we register their shares under the Securities Act for resale into the public markets. With respect to the outstanding warrants, there may be certain restrictions on the holders to sell the ordinary shares issuable thereunder to the extent they are restricted securities and/or are held by affiliates. Shares issued pursuant to our equity incentive plans may be freely sold in the public market upon issuance, subject to vesting provisions, except for shares held by affiliates who have certain restrictions on their ability to sell. All shares sold pursuant to an offering covered by such registration statement would be freely transferable. Our largest shareholders, Yaskawa Electric Corporation and certain entities, individuals affiliated with SCP Vitalife Partners and Israel Healthcare Venture Partners 2 L.P., may also have limitations under Rule 144 under the Securities Act on the resale of certain ordinary shares they hold. Despite these limitations, if we, our existing shareholders, particularly our largest shareholders, our directors, their affiliates or our executive officers, sell a substantial number of the above-mentioned ordinary shares in the public market, the market price of our ordinary shares could decrease significantly.

The exercise price and the number of ordinary shares issuable upon exercise of the warrants offered in our follow-on public offering of units, as completed in November 2016, can fluctuate under certain circumstances. If triggered, these adjustments could result in potentially material dilution to holders of our ordinary shares.

Under the terms of the warrants offered in our follow-on offering completed in November 2016, the exercise price and the number of ordinary shares for which the warrants are exercisable will be adjusted upon certain corporate events, including stock splits, reverse stock splits, combinations, stock dividends, recapitalizations and reorganizations and certain other events. Our board of directors also has discretion, pursuant to the warrants, to determine whether to make such adjustments to the exercise price and number of ordinary shares to be issued upon exercise of the warrants based on similar events, such as the granting of stock appreciation rights, phantom stock rights or other rights with equity features. Lastly, at any time, the board of directors may reduce the exercise price of the warrants to any amount and for any period of time it deems appropriate. These provisions could result in substantial dilution to holders of our ordinary shares, which may make it difficult for us to raise additional capital at prevailing market terms in the future.

We may not be able to maintain the listing of our ordinary shares on the Nasdaq Global Market, which could adversely affect our liquidity and the trading volume and market price of our ordinary shares, and decrease or eliminate your investment.

On December 14, 2016, we received a notification letter from Nasdaq advising us that we had failed to comply with the minimum $50 million market value of listed securities, or MVLS, requirement for continued listing on The Nasdaq Global Market pursuant to Nasdaq Listing Rule 5450(b)(2)(A). The letter also indicated that we did not meet the alternative total assets and total revenue standard requirements under Nasdaq Listing Rule 5450(b)(3)(A). Nasdaq stated in the letter that in accordance with Nasdaq listing rules, we had been provided a compliance period of 180 calendar days, or until June 12, 2017, to regain compliance with the MVLS continued listing requirement. The notice also states that if, at any time before June 12, 2017, the MVLS of our ordinary shares closes at $50 million or more for a minimum of 10 consecutive business days, the Nasdaq staff will provide us with written notification that we have achieved compliance with the MVLS continued listing requirement and the matter will be closed. We could also regain compliance with Nasdaq continued listing requirements by reporting stockholders' equity of $10 million or more. If we do not regain compliance by June 12, 2017, we will receive written notice that our securities are subject to delisting. At that time, we would be permitted to appeal the delisting determination to a Nasdaq Hearings Panel or, as noted above, to apply to transfer our ordinary shares to The Nasdaq Capital Market (provided that it satisfied the

requirement for continued listing on that market). In the event of an appeal, our ordinary shares would remain listed on The Nasdaq Global Market pending a decision by the panel following the hearing.

This letter is simply a notice of deficiency, not of imminent delisting, and has no immediate effect on the listing or trading of ReWalk ordinary shares on The Nasdaq Global Market at this time. However, if we fail to achieve compliance by June 12, 2017, the perception among investors that we are at heightened risk of delisting could negatively affect the market price and trading volume of our ordinary shares. Additionally, if we do not succeed in appealing a delisting determination or cannot transfer our ordinary shares to the Nasdaq Capital Market, our ordinary shares could be delisted from Nasdaq entirely, which could reduce the number of investors willing to hold or acquire our ordinary shares, increase the volatility of the price of such shares and significantly lower the shares' trading price and volume. Any of these events could also reduce our liquidity and impair our ability to raise capital.

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We may not have the ability to repurchase the warrants offered in our follow-on public offering of units.

Under certain circumstances, if a change of control (as defined in the warrants) occurs, holders of the warrants offered in our follow-on offering may require us or any successor to us to repurchase the remaining unexercised portion of such warrants for an amount of cash equal to the value of the Warrant as determined in accordance with the Black-Scholes option pricing model and the terms of the warrants. Our ability to repurchase the Warrants depends on our ability to generate cash flow in the future. To some extent, this is subject to general economic, financial, competitive, legislative and regulatory factors and other factors that are beyond our control. We cannot provide any assurances to the holders of such warrants that we will maintain sufficient cash reserves or that our business will generate cash flow from operations at levels sufficient to permit us to repurchase the warrants.

The price of our ordinary shares may be volatile, and you may lose all or part of your investment.

Our ordinary shares were first publicly offered in our initial public offering in September 2014, at a price of $12.00 per share, and our ordinary shares have subsequently traded as high as $43.71 per share and as low as $1.95 per share through February 15, 2017. The market price of our ordinary shares could be highly volatile and may fluctuate substantially as a result of many factors. Moreover, while there is no established public trading market for the warrants offered in our follow-on public offering completed in November 2016, and we do not expect one to develop, our ordinary shares will be issuable pursuant to exercise of these warrants. Because the warrants are exercisable into our ordinary shares, volatility or a reduction in the market price of our ordinary shares could have an adverse effect on the trading price of the warrants. Factors which may cause fluctuations in the price of our ordinary shares include, but are not limited to:

- 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, warrants and debt securities by us, or sales of our ordinary shares by 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;

- changes in our quarterly or annual forecasts with respect to operating results and financial conditions; 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.

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

The trading market for our ordinary shares relies in part on the research and reports that equity research analysts publish about us and our business. The 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.

A small number of our shareholders have a significant influence over matters requiring shareholder approval, which could delay or prevent a change of control.

The largest beneficial owners of our shares, Yaskawa Electric Corporation and certain entities and individuals affiliated with SCP Vitalife Partners, beneficially own in the aggregate 19.7% of our ordinary shares as of February 1, 2017. As a result, these shareholders, should they choose 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 influence significantly 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 Second Amended and Restated Articles of Association, as amended by the First Amendment thereto, or 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.

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." For instance, we are subject to reduced compensation disclosure obligations under the JOBS Act, and we are not required to conduct votes seeking shareholder approval on an advisory basis of (i) the compensation of our named executive officers or the frequency with which such votes must be conducted or (ii) compensation arrangements and understandings in connection with merger transactions, known as "golden parachute" arrangements. Additionally, we are not required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act for up to five fiscal years after the date of our initial public offering.

We will remain an emerging growth company until the earliest of: (a) the last day of our fiscal year during which we have total annual gross revenues of at least $1.0 billion; (b) the last day of our fiscal year following the fifth anniversary of the completion of our initial public offering; (c) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt; or (d) the date on which we are deemed to be a “large accelerated filer” under the Exchange Act. 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 securities less attractive as a result of our reliance on exemptions under the JOBS Act. If some investors find our securities less attractive as a result, there may be a less active trading market for our ordinary shares and the price of our ordinary shares may be more volatile.

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U.S. investors 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 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. Based on our gross income and assets, the market price of our ordinary shares, and the nature of our business, we do not believe that we were a PFIC for the taxable year ended December 31, 2016 or that we will be considered a PFIC for the taxable year ending December 31, 2017. However, there can be no assurance that we will not be considered a PFIC for 2017 or any taxable year. PFIC status is determined as of the end of the taxable year and depends on a number of factors, including the value of a corporation's assets and the amount and type of its gross income. Further, because the value of our gross assets is likely to be determined in large part by reference to our market capitalization, a decline in the value of our ordinary shares may result in our becoming a PFIC.

If we are characterized as a PFIC, U.S. Holders (as defined below) may suffer adverse tax consequences, including, (i) having gains realized on the sale of our securities treated as ordinary income, rather than as capital gains, (ii) the loss of the preferential rate applicable to dividends received on our ordinary shares by individuals who are U.S. Holders, and (iii) having additional taxes equal to the interest charges generally applicable to underpayments of tax apply to distributions by us and the proceeds of sales of our ordinary shares and the warrants issued in our follow-on offering. A "U.S. Holder" is defined as follows: a citizen or resident of the United States; a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States or any state thereof, including the District of Columbia; an estate the income of which is subject to U.S. federal income taxation regardless of its source; or a trust if such trust has validly elected to be treated as a United States person for U.S. federal income tax purposes or if (1) a court within the United States is able to exercise primary supervision over its administration and (2) one or more United States persons have the authority to control all of the substantial decisions of such trust. 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); 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.

We are subject to ongoing costs and risks associated with determining whether our existing internal controls over financial reporting systems are compliant with Section 404 of the Sarbanes-Oxley Act, and if we fail to achieve and maintain adequate internal controls it could have a material adverse effect on our stated results of operations and harm our reputation.

We are required to comply with the internal control, evaluation, and certification requirements of Section 404 of the Sarbanes-Oxley Act and the Public Company Accounting Oversight Board. Unless we lose our status as an emerging growth company under the JOBS Act prior to the end of the fiscal year in which the fifth anniversary of our initial public offering occurred, we will not be required to obtain an auditor attestation under Section 404 of the Sarbanes-Oxley Act until the year ended December 31, 2019. However once we no longer qualify as an emerging growth company under the JOBS Act our independent registered public accounting firm will need to attest to the effectiveness of our internal control over financial reporting under Section 404.

The process of determining whether our existing internal controls over financial reporting systems are compliant with Section 404 and whether there are any material weaknesses or significant deficiencies in our existing internal controls requires the investment of substantial time and resources, including by our Chief Financial Officer and other members of our senior management. This determination and any remedial actions required could divert internal resources and take a significant amount of time and effort to complete and could result in us incurring additional costs that we did not anticipate, including the hiring of outside consultants. We could experience higher than anticipated operating expenses and higher independent auditor fees during and after the implementation of these changes.

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. 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, once we lose our emerging growth company status, our independent auditors. Further, if our internal control over financial reporting is not effective, the reliability of our financial statements may be questioned and our share price may suffer.

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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 has 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 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. Some of our executive officers and employees, as well as those of Sanmina, the manufacturer of all of our products, are required to perform annual military reserve duty in Israel and may be called to active duty at any time under emergency circumstances. 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.

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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. 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. For a discussion of our current tax obligations, see Part 2. Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations."

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, 2016, we received a total of $740,000 from the IIA. We may in the future apply to receive additional grants from the IIA to support our research and development activities. With respect to such grants we are committed to pay royalties at a rate of 3.0% 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 IIA 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 IIA. Therefore, if aspects of our technologies are deemed to have been developed with IIA funding, the discretionary approval of an IIA 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 IIA 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.

The transfer of IIA-supported technology or know-how outside of Israel may involve the payment of significant amounts to the IIA, depending upon the value of the transferred technology or know-how, the amount of IIA support, the time of completion of the IIA-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 IIA funding (such as a merger or similar transaction) may be reduced by any amounts that we are required to pay to the IIA.

In addition to the above, any non-Israeli citizen, resident or entity that, among other things, (i) becomes a holder of 5% or more of our share capital or voting rights, (ii) is entitled to appoint one or more of our directors or our chief executive officer or (iii) serves as one of our directors or as our chief executive officer (including holders of 25% or

more of the voting power, equity or the right to nominate directors in such direct holder, if applicable) is required to notify the IIA and undertake to comply with the rules and regulations applicable to the grant programs of the IIA, including the restrictions on transfer described above.

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 the validity of any such waivers remains open to judicial review. 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.

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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.

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.

It may be difficult to enforce a judgment of a U.S. court against us, our officers and directors, to assert U.S. securities laws claims in Israel or to serve process on our officers and directors.

We are incorporated in Israel. Although the majority of our directors and executive officers reside within the United States and most of the assets of these persons are also likely located within the United States, some of our directors and executive officers reside and may have the majority of their assets outside the United States. Additionally, most of our assets are located outside of the United States. Therefore, a judgment obtained against us, or those of our directors and executive officers residing outside of the United States, 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 in the United States on those directors and executive officers residing outside of 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 be able to collect only limited, or may be unable to collect any,

damages awarded by either a U.S. or foreign court.

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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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

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	11,850
Yokneam, Israel	11,500
Berlin, Germany	775
Total	24,125

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

ITEM 3. LEGAL PROCEEDINGS

Occasionally the Company is involved in various claims, lawsuits, regulatory examinations, investigations and other legal matters arising, for the most part, in the ordinary course of business. The outcome of litigation and other legal matters is inherently uncertain. In making a determination regarding accruals, using available information, the Company evaluates the likelihood of an unfavorable outcome in legal or regulatory proceedings to which the Company is a party and records a loss contingency when it is probable a liability has been incurred and the amount of the loss can be reasonably estimated.

Where the Company determines an unfavorable outcome is not probable or reasonably estimable, the Company does not accrue for any potential litigation loss. These subjective determinations are based on the status of such legal or regulatory proceedings, the merits of our defenses and consultation with legal counsel. Actual outcomes of these legal and regulatory proceedings may materially differ from the Company's current estimates. It is possible that resolution of

one or more of the legal matters currently pending or threatened could result in losses material to the Company's consolidated results of operations, liquidity or financial condition.

As set forth below, between September 2016 and January 2017, eight substantially similar putative securities class actions were filed against the Company. Four of these actions have been dismissed on procedural grounds and four are pending, including two actions which have been consolidated and one action brought by the plaintiffs whose actions were dismissed.

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- Dismissed Actions: On September 20, November 3, November 9, and November 10, 2016, respectively, four putative class actions on behalf of alleged shareholders that purchased or acquired the Company's ordinary shares pursuant and/or traceable to the registration statement used in connection with the Company's IPO were commenced in the Superior Court of the State of California, County of San Mateo. The actions were filed against the Company, certain of the Company's current and former directors and officers, and the underwriters of the Company's IPO. We refer to these actions as the California State Actions. The complaints in the California State Actions asserted various claims under the Securities Act. Each of the California State Actions was dismissed for lack of personal jurisdiction in January 2017.
- Pending Actions:
  - On or about October 31, 2016, a class action with claims substantially similar to the California State Actions was commenced in the Massachusetts Superior Court, Suffolk County, by a different plaintiff (Civ. Action No. 16-3336), alleging claims under Section 11 of the Securities Act against the Company, certain of the Company's current and former directors and officers, and the underwriters of the Company's IPO, and alleging claims under Section 15 of the Securities Act against the Company and certain of the Company's current and former directors and officers.
  - On or about November 30, 2016, a substantially similar class action was commenced in the Massachusetts Superior Court, Suffolk County, by a different plaintiff (Civ. Action No. 16-3670) alleging claims under Sections 11 and Section 15 of the Securities Act against the same defendants as in the action commenced on October 31, 2016, and also alleging claims under Section 12(a)(2) of the Securities Act against the Company, certain of the Company's current and former directors and officers, and the underwriters of the Company's IPO. This action was ordered consolidated in the Massachusetts Superior Court, Suffolk County on January 9, 2017 with the action commenced on October 31, 2016, and the two actions are referred to as the Consolidated Massachusetts State Court Actions.
  - On or about January 24, 2017, a substantially similar class action was commenced in the United States District Court for the Northern District of California (Case No. 3:17-cv-362) alleging the same claims against the same defendants as in the action commenced on November 30, 2016, except that the Section 15 claim was not asserted against the underwriters, and the Section 11 and Section 15 claims were also asserted against certain entities referred to as the "Venture Capital Defendants", who are alleged in the complaint to have beneficially owned, directly or indirectly, approximately 51% of the Company’s stock upon the closing of the IPO. This action is referred to as the California Federal Court Action.
  - On or about January 31, 2017, a substantially similar class action was commenced in the United States District Court for the District of Massachusetts (Case No. 1:17-cv-10169) by the same plaintiffs who commenced the California State Court Actions, and one additional plaintiff, alleging claims under Section 11 and 12(a)(2) of the Securities Act against the Company, certain of the Company's current and former directors and officers, and the underwriters of the Company's IPO, and alleging claims under Section 15 of the Securities Act against certain of the Company's current and former directors and officers. This action is referred to as the Massachusetts Federal Court Action.

The plaintiffs in the Consolidated Massachusetts State Court Actions are expected to file a consolidated amended complaint on or about March 13, 2017. The Company has not yet responded to the complaints in the California Federal Court Action and the Massachusetts Federal Court Action.

The complaints in all of the actions listed above allege that the Company's registration statement used in connection with its IPO failed to disclose that the Company was unprepared or unable to comply with certain regulatory special controls and to provide the FDA with a post-market surveillance study on the Company's ReWalk Personal device, and that, as a result of such alleged omission, the plaintiffs suffered damages. The Company believes that the allegations made in the complaints are without merit and intends to defend itself vigorously against the complaints relating to the four pending actions.

Based on information currently available and the early stage of the litigation, the Company is unable to reasonably estimate a possible loss or range of possible losses, if any, with regard to these lawsuits; therefore, no litigation

reserve has been recorded in the Company's consolidated balance sheets as of December 31, 2016. The Company will continue to evaluate information as it becomes known and will record an estimate for losses at the time or times when it is probable that a loss will be incurred and the amount of the loss is reasonably estimable.

For more information, see the information in Note 2t and Note 7e to the Company’s consolidated financial statements set forth in "Part II, Item 8. Financial Statements and Supplementary Data" of this annual report.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

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PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our ordinary shares began trading publicly on the Nasdaq Global Market on September 12, 2014 under the symbol "RWLK". The following table sets forth, for the periods indicated, the high and low sales prices of our ordinary shares as reported by the Nasdaq Global Market.

	High	Low
2016		
Fourth quarter 2016	$6.50	$2.55
Third quarter 2016	$7.85	$5.55
Second quarter 2016	$10.79	$6.00
First quarter 2016	$15.81	$7.41
2015		
Fourth quarter 2015	$17.40	$5.55
Third quarter 2015	$11.90	$7.20
Second quarter 2015	$14.65	$10.35
First quarter 2015	$22.74	$12.03
2014		
Fourth quarter 2014	$34.29	$18.01
Third quarter 2014 (beginning on September 12, 2014)	$43.71	$11.50

As of February 1, 2017, there were 31 record holders of our ordinary shares.

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. Any future determination relating to our dividend policy will be made at the discretion of our board of directors and will depend on a number of factors, including future earnings, capital requirements, financial condition and future prospects and other factors our board of 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.

Israeli Taxes Applicable to U.S. Holders

A non-Israeli resident who derives capital gains from the sale of shares in an Israeli resident company that were purchased after the company was listed for trading on a stock exchange outside of Israel will be exempt from Israeli tax so long as the shares were not held through a permanent establishment that the non-resident maintains in Israel. However, non-Israeli corporations will not be entitled to the foregoing exemption if Israeli residents (i) have a controlling interest of more than 25% in such non-Israeli corporation or (ii) are the beneficiaries of, or are entitled to, 25% or more of the revenues or profits of such non-Israeli corporation, whether directly or indirectly. Such exemption is not applicable to a person whose gains from selling or otherwise disposing of the shares are deemed to be a business income. Additionally, under the United States-Israel Tax Treaty, or the treaty, the disposition of shares by a shareholder who (i) is a U.S. resident (for purposes of the treaty), (ii) holds the shares as a capital asset, and (iii) is entitled to claim the benefits afforded to such person by the treaty, is generally exempt from Israeli capital gains tax. Such exemption will not apply if: (i) the capital gain arising from the disposition can be attributed to a permanent

establishment in Israel; (ii) the shareholder holds, directly or indirectly, shares representing 10% or more of the voting capital during any part of the 12-month period preceding the disposition, subject to certain conditions; or (iii) such U.S. resident is an individual and was present in Israel for 183 days or more during the relevant taxable year. In such case, the sale, exchange or disposition of our ordinary shares should be subject to Israeli tax, to the extent applicable; however, under the treaty, the taxpayer would be permitted to claim a credit for such taxes against the U.S. federal income tax imposed with respect to such sale, exchange or disposition, subject to the limitations under U.S. law applicable to foreign tax credits. The treaty does not relate to U.S. state or local taxes.

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In some instances where our shareholders may be liable for Israeli tax on the sale of their ordinary shares, the payment of the consideration may be subject to the withholding of Israeli tax at source. If the above exemptions from capital gains tax are not available, individuals will be subject to a 25% tax rate on real capital gains derived from the sale of shares as long as the individual is not a substantial shareholder of the corporation issuing the shares (in which case the individual will be subject to a 30% tax rate), and corporations will be subject to a 25% corporate tax rate for 2016. Under an amendment enacted in December 2016 to the Israel Income Tax Ordinance 1961-5721, or the ordinance, the corporate tax rate will decrease to 24% for 2017 and 23% for 2018 and thereafter. A substantial shareholder is generally a person who alone or together with such person's relative or another person who collaborates with such person on a permanent basis, holds, directly or indirectly, at least 10% of any of the means of control of the corporation, including the right to vote, receive profits, nominate a director or an executive officer, receive assets upon liquidation, or order someone who holds any of the aforesaid rights how to act, regardless of the source of such right. A substantial shareholder will be subject to tax at a rate of 30% in respect of capital gains derived from the sale of shares issued by a corporation in which he or she is a substantial shareholder. The determination of whether the individual is a substantial shareholder will be made on the date on which the securities are sold. In addition, the individual will be deemed to be a substantial shareholder if at any time during the 12 months preceding the date of sale he or she was a substantial shareholder.

Dividends paid on publicly traded shares, like our ordinary shares, to non-Israeli residents are generally subject to Israeli withholding tax at a rate of 25%, unless a different rate is provided under an applicable tax treaty, provided that a certificate from the Israeli Tax Authority allowing for a reduced withholding tax rate is obtained in advance. Under the treaty, the maximum rate of tax withheld at source in Israel on dividends paid to a holder of our ordinary shares who is a U.S. resident (for purposes of the treaty) is 25%. The treaty provides for reduced tax rates on dividends if (a) the shareholder is a U.S. corporation holding at least 10% of our issued voting power during the part of the tax year that precedes the date of payment of the dividend and held such minimal percentage during the whole of its prior tax year, and (b) not more than 25% of the Israeli company's gross income consists of interest or dividends, other than dividends or interest received from subsidiary corporations or corporations 50% or more of the outstanding voting shares of which is owned by the Israeli company. The reduced treaty rate, if applicable, is 15% in the case of dividends paid from income derived from Beneficiary or Preferred Enterprise or 12.5% otherwise. We cannot assure you that in the event we declare a dividend we will designate the income out of which the dividend is paid in a manner that will reduce shareholders' tax liability. If the dividend is attributable partly to income derived from a Beneficiary or Preferred Enterprise and partly to other sources of income, the withholding rate will be a blended rate reflecting the relative portions of the two types of income. U.S. residents who are subject to Israeli withholding tax on a dividend may be entitled to a credit or deduction for U.S. federal income tax purposes in the amount of the taxes withheld.

As of January 1, 2013, shareholders who are individuals with a taxable income that exceeds NIS 800,000 in a tax year (linked to the consumer price index each year, which equaled NIS 803,520 in the 2016 tax year) will be subject to an additional tax, referred to as High Income Tax, at the rate of 2% on their taxable income for such tax year that is in excess of such threshold. For this purpose, taxable income includes taxable capital gains from the sale of our shares and taxable income from dividend distributions. Under an amendment enacted in December 2016 to the ordinance, for 2017 and thereafter the rate of High Income Tax will increase to 3% and will be applicable to annual income exceeding NIS 640,000 (linked to the consumer price index each year).

If the above exemptions from capital gains tax are not available, corporations will be subject to the corporate tax rate (24% in 2017 and 23% thereafter) on capital gains derived from the sale of shares.

Stock Performance Graph

The following stock performance graph represents the cumulative total shareholder return for the period September 12, 2014 (the date upon which trading of our ordinary shares commenced) through December 31, 2016 for our ordinary shares, compared to the Nasdaq Composite Index and the Nasdaq Medical Equipment Index. The returns shown in the graph below may not be indicative of future performance.

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*$100 invested on 9/12/14 in ordinary shares of ReWalk or in the applicable indexes, including reinvestment of dividends.

The above stock performance graph shall not be deemed to be soliciting material or to be filed with the SEC under the Securities Act and the Exchange Act except to the extent that we specifically request that such information be treated as soliciting material or specifically incorporate it by reference into a filing under the Securities Act or the Exchange Act.

Recent Sales of Unregistered Securities

As described below under Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources,” on December 30, 2015, we entered into the Loan Agreement, with Kreos, pursuant to which Kreos extended a line of credit to us in the amount of $20.0 million. In connection with a drawdown of $12.0 million under the Loan Agreement, we issued to Kreos a warrant, to purchase up to 119,295 of our ordinary shares at an exercise price of $9.64 per share, which represented the average of the closing prices of our ordinary shares for the thirty-day calendar period prior to the date of the issuance of the warrant, subject to adjustment as set forth in the warrant. On December 28, 2016, we drew down the remaining $8.0 million available under the Loan Agreement. In connection with such drawdown, on December 28, 2016, we increased the amount of the warrant issued to Kreos from $1.15 million to $1.61 million, or by $460,000. In its new amount, the warrant represents the right to purchase up to 167,012 of our ordinary shares. The increase was based on the terms of the warrant, which provide that the amount of the warrant will be increased by 5.75% of any additional drawdowns.

No underwriters or underwriter discounts or commissions were involved in these issuances. We believe that each of the initial issuance of the warrant on December 30, 2015, and the issuance of the warrant with the increased principal amount on December 28, 2016, was exempt from registration under the Securities Act in reliance on Regulation S or Regulation D under the Securities Act or pursuant to Section 4(2) of the Securities Act regarding transactions by an issuer involving offers and sales of securities outside the United States or not involving a public offering. The recipient of the warrant represented its intention to acquire the warrant and the ordinary shares underlying the warrant for investment only and not with a view to, or in connection with, the sale or distribution thereof. No general advertising or solicitation was used in selling the securities and the warrant was offered only to Kreos, a non-U.S. entity, in an offshore transaction outside the United States.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

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ITEM 6. SELECTED FINANCIAL DATA

The following table presents our selected historical consolidated financial data, which is derived from our consolidated financial statements, which have been prepared in accordance with U.S. Generally Accepted Accounting Principles, or U.S. GAAP. The selected consolidated statements of operations data for the years ended December 31, 2016, 2015 and 2014 and the selected consolidated balance sheet data as of December 31, 2016 and 2015 are derived from our audited consolidated financial statements set forth in “Part II. Item 8. Financial Statements and Supplementary Data” of this annual report. The selected consolidated statement of operations data for the years ended December 31, 2013 and December 31, 2012 and the selected consolidated balance sheet data as of December 31, 2014, 2013 and 2012 has been derived from our audited consolidated financial statements not included in this annual report.

You should read the following selected consolidated financial data in conjunction with “Part II. Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and it is qualified in its entirety by, reference to our consolidated financial statements and the related notes set forth in “Part II. Item 8. Financial Statements and Supplementary Data” of this annual report. The historical results set forth below are not necessarily indicative of the results to be expected in future periods.

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	Year ended December 31 (In thousands, except share and per share data)				
	2016	2015	2014	2013	2012
Revenues	$5,869	$3,746	$3,951	$1,588	$972
Cost of revenues	5,133	3,532	4,106	2,017	983
Expense related to settlement of BIRD Foundation grants (see Note 7c)		—	466	—	—
Gross profit (loss)	736	214	(621)	(429)	(11)
Operating expenses:					
Research and development, net	9,028	5,937	8,563	2,463	1,757
Sales and marketing	13,961	13,056	7,389	4,091	2,334
General and administration	8,188	6,395	3,352	1,762	1,657
Total operating expenses	31,177	25,388	19,304	8,316	5,748
Operating loss	(30,441)	(25,174)	(19,925)	(8,745)	(5,759)
Financial expenses, net	2,059	188	1,698	3,410	878
Loss before income taxes	(32,500)	(25,362)	(21,623)	(12,155)	(6,637)
Income taxes	3	53	45	22	21
Net loss	$(32,503)	$(25,415)	$(21,668)	$(12,177)	$(6,658)
Net loss per ordinary share, basic and diluted	$(2.47)	$(2.10)	$(6.34)	$(74.53)	$(41.26)
Weighted average number of shares used in computing net loss per ordinary share, basic and diluted	13,178,107	12,115,038	3,766,694	185,688	185,688

	As of December 31, (in thousands)				
	2016	2015	2014	2013	2012
Balance Sheet Data:					
Cash and cash equivalents	$23,678	$17,869	$41,829	$8,860	$769
Total assets	31,763	25,574	47,665	11,059	2,094
Accumulated deficit	(106,492)	(73,989)	(48,574)	(26,906)	(14,729)
Total shareholders' equity	$8,260	$20,920	$43,853	$5,631	$(2,264)

(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 2r to our consolidated financial statements set forth in "Part II. Item 8. Financial Statements and Supplementary Data" of this annual report.

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ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with “Part I. Item 6. Selected Financial Data” and our consolidated financial statements and the related notes included elsewhere in this annual report. 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 “Part I. Item 1A. Risk Factors.”

Overview

We are an innovative medical device that derives revenue from selling the ReWalk Personal and ReWalk Rehabilitation exoskeleton devices that allow individuals with paraplegia the ability to stand and walk once again. Since obtaining FDA clearance in June 2014 we have continued to increase our focus on selling the Personal device through third party payors in the U.S. and Germany, and through distributors in other parts of the world.

We expect to generate revenues from a combination of third-party payors, self-payors and institutions. 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 to obtain broad commercial and government reimbursement coverage. In December 2015, the VA issued a national policy for the evaluation, training and procurement of ReWalk Personal exoskeleton systems for all qualifying veterans across the United States. The VA policy, is the first national coverage policy in the United States for qualifying individuals who have suffered spinal cord injury. Additionally, to date several private insurers in the United States have provided reimbursement for ReWalk in certain cases. For more information regarding reimbursement of our products, see “Part I. Item 1. Business—Third Party Reimbursement and “Part I. Item 1. Business — Other Funding Sources.”

We have incurred net losses and negative cash flows from operations since inception and anticipate this to continue in the near term. As previously announced, we have set a goal to reduce total operating expenses in 2017 by up to 30% as compared to 2016. These reductions will be achieved through a combination of targeted savings, including the completion of specific projects focused on quality improvement initiatives and efforts to reduce overall product cost, a realignment of and reduction in staffing to match the Company’s 2017 business goals, and a reduction in other corporate spending. The Company plans to focus its resources mainly on reimbursement efforts, clinical studies to expand data on the effectiveness of the Spinal Cord Injury products, field sales, service and training efforts for the ReWalk system and the commercialization pathway for the Stroke Softsuit program.

Components of Our Statements of Operations

Revenues

We currently rely, and in the future will rely, on sales and rentals of our ReWalk systems and related service contracts and extended warranties for our revenue. Our revenue is generated from a combination of third-party payors, institutions and self-payors. Payments for our products by third party payors have been made primarily through case-by-case determinations. Third-party payors include, without limitation, private insurance plans and managed care programs, government programs including the US Department of Veterans Affairs, worker's compensation and Medicare and Medicaid. We expect that third-party payors will be an increasingly important source of revenue in the future. In December 2015, the VA issued a national policy for the evaluation, training and procurement of ReWalk Personal exoskeleton systems for all qualifying veterans across the United States. The VA policy is the first national coverage policy in the United States for qualifying individuals who have suffered spinal cord injury.

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.

Revenues are presented net of the amounts of any provision we record for expected future product returns.

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Cost of Revenues and Gross Profit (Loss)

Cost of revenue consists primarily of systems purchased from our outsourced manufacturer, Sanmina, salaries, personnel costs including non-cash share based compensation, associated with manufacturing and inventory management, training and inspection, warranty and service costs, shipping and handling and manufacturing startup and transition costs. Prior to the first quarter of 2014, when we completed the manufacturing transition to Sanmina, cost of revenues also included costs of components, compensation related costs associated with manufacturing and costs to transition manufacturing to Sanmina. Cost of revenues also includes royalties and expenses related to royalty-bearing research and development grants and sales and marketing grants.

In the future we expect our unit cost to decrease as our sales increase due to product cost improvements including economies of scale realized in connection with larger quantities and increased efficiency.

Our gross profit (loss) and gross margin as a percentage of sales is influenced by a number of factors, including primarily the volume and price of our products sold and fluctuations in our cost of revenues. Certain one-time expenses also impact gross margins including a 2014 expense relating to the early settlement, at a discount, of a royalty-bearing grant to the BIRD Foundation and 2015 and 2016 costs to transition manufacturing to the ReWalk Personal 6.0 model. We expect gross profit (loss) as a percentage of sales will improve in the future as we increase our sales volumes and decrease the product manufacturing costs.

Operating Expenses

Research and Development Expenses, Net

Research and development expenses, net, consist primarily of salaries, related personnel costs including share-based compensation, supplies, materials and expenses related to product design and development, clinical studies, regulatory submissions, 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.

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 Israel Innovation Authority, or “IIA”, (formerly known as the Office of the Chief Scientist). Certain of those grants require us to pay royalties on sales of ReWalk systems, which are recorded as cost of revenues. We may receive additional funding from these entities or others in the future. See “Grants and Other Funding” below.

Sales and Marketing Expenses

Our sales and marketing expenses, consist primarily of salaries, related personnel costs including share-based compensation for sales, marketing and reimbursement personnel, travel, marketing and public relations activities and consulting costs. Also included in the sales and marketing expenses are the costs associated with our reimbursement activities in the United States and Germany.

General and Administrative Expenses

Our general and administrative expenses consist primarily of salaries, related personnel costs including share-based compensation for our administrative, finance, and general management personnel, professional services and insurance.

Financial Income (Expenses), Net

Financial income and expenses consist of bank commissions, foreign exchange gains and losses, interest earned on investments in short term deposits, and revaluation of the fair value of warrants to purchase our preferred shares and expenses related to our convertible loans, which were issued in 2013 and are no longer outstanding.

Warrants to purchase our convertible preferred shares were classified as a liability on our consolidated balance sheet at fair value. The warrants were 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. All such warrants were exercised, expired or converted into warrants to purchase ordinary shares in connection with our initial public offering, and therefore as of December 31, 2014 and for periods beginning with the fourth quarter of 2014, we 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 consists of interest earned on our cash and cash equivalent balances. Interest expense consists of interest accrued on, and certain other costs with respect to any indebtedness. Foreign currency exchange changes reflect gains or losses related to transactions denominated in currencies other than the U.S. dollar.

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As described above in Item 5. “Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities – Unregistered Sales of Equity Securities”, on December 30, 2015 we entered into the Loan Agreement with Kreos pursuant to which Kreos extended a line of credit to us in the amount of $20.0 million. In connection with the Loan Agreement we issued to Kreos a warrant to purchase up to 119,295 of our ordinary shares at an exercise price of $9.64 as we drew down $12 million under the Loan Agreement, which amount was increased to167,012 ordinary shares upon an additional drawdown of $8 million. For further discussion of the Loan Agreement with Kreos, see “-Liquidity and Capital Resources” below and also Note 6 to our audited consolidated financial statements below.

Taxes on Income

As of December 31, 2016, we had not yet generated taxable income in Israel. As of that date, our net operating loss carry forwards for Israeli tax purposes amounted to approximately $83.8 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.

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.