ReWalk Robotics Ltd.
Form 10-K
March 08, 2018
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, 2017

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, a smaller reporting company, or emerging growth company. See the definitions of “large accelerated filer”, “accelerated filer”, “smaller reporting company” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. x

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 Capital Market on June 30, 2017 (the last business day of the Registrant’s most recently completed second fiscal quarter) was $29,744,250.

As of March 5, 2018, the Registrant had outstanding 30,006,575 Ordinary Shares, par value NIS 0.01 per share.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of our proxy statement for our 2018 Annual Meeting of Shareholders, which is to be filed within 120 days after the end of our 2017 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, 2017

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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, and in
May 2017, we transferred our listing to the Nasdaq Capital 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 expectations as to our clinical research program and clinical results;
- our expectations as to the results of the Food and Drug Administration’s (“FDA”), potential regulatory developments with respect to our mandatory 522 postmarket surveillance study;
- the outcome of ongoing shareholder class action litigation relating to our initial public offering (“IPO”);
- our ability to repay our secured indebtedness;
- our ability to improve our products and develop new products;
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our ability to close periodic issuances of our ordinary shares to, and to form a joint venture in China with, Timwell Corporation Limited;

- the risk of substantial dilution resulting from the periodic issuances of our ordinary shares to Timwell Corporation Limited;

- the significant voting power and de facto voting control Timwell Corporation Limited will acquire;

- 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 secure capital from equity and debt financings in light of limitations under our effective registration statement on Form S-3, the price range of our ordinary shares and conditions in the financial markets, and the risk that such financings may dilute our shareholders or restrict our business;
- our ability to use effectively the proceeds of our offerings of securities;
- our ability to maintain relationships with existing customers and develop relationships with new customers;
- the impact of the market price of our ordinary shares on the determination of whether we are a passive foreign investment company; and
- our compliance with medical device reporting regulations to report adverse events involving our products and the potential impact of such adverse events on ReWalk's ability to market and sell its products

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. 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 to 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 robotic 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 designed for individuals with paraplegia that uses our patented tilt-sensor technology and an on-board computer and motion sensors to drive motorized legs that power movement. Additionally, we are developing and intend to commercialize a lightweight soft suit exoskeleton, designed to support mobility for individuals suffering from other lower limb disabilities such as stroke, multiple sclerosis, cerebral palsy, Parkinson's disease and elderly assistance.

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. 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 ReWalk.

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 that results in a 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 experience working with healthcare practitioners and ReWalk users, including reports by study participants, as well as recently released clinical data suggest that ReWalk may have the potential to provide secondary health benefits. These potential benefits may include reducing pain and spasticity, improving bowel and urinary tract function, enhancing metabolism and physical fitness, and reducing hospitalizations and dependence on medications, as well as emotional and psychological benefits. Because of these potential secondary medical benefits, we believe that ReWalk may have the ability to reduce the lifetime healthcare costs of individuals with spinal cord injuries, making it economically attractive for individuals and third-party payors. While we believe that ReWalk could potentially offer 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.

As of December 31, 2017, we had placed 116 units in use at rehabilitation centers and 317 personal units in a home or community use, compared to 112 units and 214 units, respectively, as of December 31, 2016. Furthermore, 44 of the units we placed during the year ended December 31, 2017 were paid for by insurance reimbursement compared to 51 units during the prior year period. In the near future, we intend to continue focusing on our reimbursement efforts, with our streamlined staffing, by pursuing insurance claims on a case-by-case basis, managing claims through the review process, and investing in efforts to expand commercial reimbursement coverage. As of December 31, 2017, there were 224 pending insurance claims relating to coverage for our product, compared to 199 as of December 31, 2016.

Our initial commercialization efforts focused on penetrating 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 our business has developed, we have shifted our commercialization efforts to marketing ReWalk Personal with insurance companies, physicians and physiotherapists as a standard of care that can be used routinely 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. Our principal markets are the United States and Europe. In Europe we have a direct sales operation in Germany and work with distribution partners in certain other major countries.

We have in the past generated and expect to generate in the future revenues from a combination of third-party payors, self-payors, including private and government employers, and institutions. While a broad uniform policy of coverage and reimbursement by third-party commercial payors currently does not exist in the United States 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, 2017, we had placed 17 units as part of the VA policy and continue to work with the VA to accelerate the pace of implementation of this policy. We also support users submitting requests to their commercial insurance companies to pay for the ReWalk Personal device. Additionally, to date, several private insurers in the United States and Europe have provided reimbursement for ReWalk on a case by case basis.

In 2017 we unveiled our lightweight "soft suit" exoskeleton Restore system designed for an initial indication for stroke patients, and announced our plans to begin clinical studies in the first quarter of 2018 in preparation for the later submission of applications for regulatory clearance. We created the Restore system through our ongoing collaboration with Harvard University's Wyss Institute for Biologically Inspired Engineering, pursuant to which Harvard licenses to us intellectual property relating to lightweight "soft suit" exoskeleton system technologies for lower limb disabilities, as we develop, introduce and commercialize products under the license. For more information on the Restore system, see "Future Products". For more information on the collaboration with Harvard, see "Research and Development-Research and Development Collaborations."

Recent Developments

- In early 2018, the National Association of Statutory Health Insurance Funds, the governing body of German statutory health insurance (SHI) listed the ReWalk Personal 6.0 Exoskeleton System in the German Medical Device Directory (the "MDD"), which SHI providers can procure for any approved beneficiary on a case-by-case basis.
- Secured worker's compensation reimbursement in Italy.
- Five top rehabilitation centers in the United States. received institutional review board approval for ReWalk's Restore clinical study in stroke patients, with patient enrollment planned to begin in the first quarter of 2018.
- Gross margin increased to 40% in 2017 as compared to 13% in 2016.
- On March 6, 2018, we entered into an investment agreement for a private placement of 16,000,000 of our ordinary shares to Timwell Corporation Limited, a Hong Kong entity ("Timwell"), in exchange for total aggregate proceeds of $20 million (at a price of $1.25 per share). Timwell will make the investment in three separate tranches, with the third tranche expected to close by December 31, 2018 and no later than April 1, 2019. In connection with its investment, Timwell will receive board appointment rights. Pursuant to the investment agreement, we also agreed to collaborate with an affiliate of Timwell in forming a joint venture in China for the purposes of assembly, registration, operations, sales and marketing of our products in China (including Hong Kong and Macau) and to grant to the joint venture, in accordance with the terms of an agreed form of license agreement, an exclusive license for certain Company-owned or Company-controlled patent rights marks and a non-exclusive sublicense for certain Company-controlled know-how. The closing of the various tranches is subject to specified closing conditions, including the requisite

approval of the transaction by our shareholders under rules of The NASDAQ Stock Market LLC ("Nasdaq") and Israeli law, the formation of the joint venture with an affiliate of Timwell, the signing of the license agreement and a supply agreement and the successful production of certain ReWalk products, among others. For more information, see "Part I. Item 1. Business-Timwell Investment Agreement and Related Transactions."

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

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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 2017 that there were 285,000 people in the United States living with spinal cord injury or SCI, with an annual incidence of approximately 17,500 new cases per year. Approximately 44,000 of such patients are veterans, and are eligible for medical care and other benefits from the VA. With 24 VA spinal cord injury centers, the VA has the largest single network of spinal cord injury care in the United States.

The University of Alabama-Birmingham Department of Physical Medicine and Rehabilitation operates the NSCISC, which maintains the world's largest database on spinal cord injury research. Since 2010, motor vehicle crashes have been the leading cause of reported spinal cord injury cases (38%), followed by falls (31%), acts of violence (14%) and sports injuries (9%). 81% 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 2016 report by the NSCISC, 40.6% 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."

Regarding the potential market for the lightweight soft suit exoskeleton, designed to support mobility for individuals suffering from other lower limb disabilities such as stroke and multiple sclerosis, according to American Heart Association, seven million Americans have suffered a stroke, with 795,000 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.

The Multiple Sclerosis Foundation estimates that more than 400,000 people in the United States and about 2.5 million people around the world have multiple sclerosis. About 10,000 new cases are diagnosed annually in the United States. Research indicates that approximately 75% of patients with multiple sclerosis experience clinically significant walking disturbance, and 89% of patients with moderate Expanded Disability Status Scale (EDSS) scores (4.0-5.5) had walking disability. Individuals with of less than EDSS 4.0 generally do not need a robotic mobility aid, while individuals with EDSS 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.

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 FDA 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 experience working with health care practitioners and ReWalk users, including reports by study participants, as well as recently released clinical data 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 anticipate that the next generation of ReWalk will be a structural exoskeleton similar to our existing ReWalk devices, with a range of improvements including additional functionality, more efficient drive mechanism, slimmer profile and lighter body, as well as other improvements.

Future Products

In June 2017, we unveiled the Restore, and in October 2017, we announced the start of pre-clinical testing on the system to study its safety and use in the rehabilitation setting for the mobility needs of stroke patients. We created the Restore system through our ongoing collaboration with Harvard University's Wyss Institute for Biologically Inspired Engineering. A prospective clinical trial with the Restore system is targeted to begin in the first quarter of 2018, and we aim to commercialize the system for use by stroke patients in Europe and the United States in the first half of 2019, subject to the timing and receipt of CE mark and FDA clearance, respectively. We have not yet applied for these clearances and intend to apply by the third quarter of 2018. Obtaining clearance could involve an extensive and time-consuming process and delay commercialization beyond our planned timetable, and we cannot make any assurances regarding the ultimate timing of FDA or CE mark clearance or commercialization of the products. For more information on the clearance processes, see "Part I, Item 1. Business—Government Regulation".

The Restore transmits power to key joints of the legs with motor-driven cable technologies, applying software and mechanics similar to the technologies employed in the currently-marketed ReWalk structural exoskeleton systems. The system is designed to allow a user's unimpaired leg to adjust and assist the leg with mobility impairments affected by stroke. The exoskeletal suit consists of a lightweight fabric-based structure that wraps around the waist and supports an actuator with a motor, computer and cable, along with sensors attached to a stable point on the user's calf and footplate in the user's shoe. This design transfers force in a controlled manner, enabling both powered plantarflexion, or bending to decrease the angle between the sole of the foot and the back of the leg, and powered dorsiflexion, or bending to decrease the angle between the upper surface of the foot and the front of the leg. We believe that the Restore system's soft, lightweight material will facilitate a natural walking pattern for patients using the device, and provide advantages to stroke rehabilitation clinics as compared with other traditional therapies and devices, by minimizing setup time, maximizing session productivity and reducing staffing requirements, staff fatigue and the risk for potential staff injuries. The prospective clinical trial on the Restore system, targeted for the first quarter of 2018, is intended to assess the safety of the Restore system during gait training in stroke patients in a rehabilitation setting. Based on the proposed study design, we anticipate that the study will involve 40 patients each partaking in seven training sessions at five designated stroke research centers, with first patient enrollments occurring in the first quarter of 2018.

ReWalk Restore

- ReWalk Restore : This soft suit exoskeleton is aimed for individuals who have suffered a stroke. We intend to commercialize use of the Restore system by stroke patients in Europe and the United States after receiving CE mark and FDA clearance, respectively, to market the device. In the long term, we also intend to develop and commercialize this lightweight soft suit exoskeleton for individuals suffering from other lower limb disabilities such as multiple sclerosis, cerebral palsy, Parkinson's disease and elderly assistance.

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, 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 commercial 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, commercial insurance companies do not currently cover or provide broad reimbursement policies for any personal medical exoskeleton products, including ReWalk Personal, and coverage determinations are limited to case-by-case decisions. As of December 31, 2017, we had 81 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 both national and regional commercial insurance companies, health care practitioners, physicians, researchers, and the SCI community to support efforts to demonstrate the benefits and the case to secure potential coverage policies based on supportive data and appeal rulings that have deemed exoskeleton devices a “medically necessary” standard of care for individuals with SCI. As part of this ongoing initiative, during 2017 we submitted a proposal to a large U.S. national insurance provider for a broader coverage policy for the ReWalk Personal device. While we believe there was support for a change, the insurer was unable to reach internal consensus and therefore elected not change its existing non-coverage policy. We will continue to work with this insurer and others on coverage policies. We have already submitted data to three additional U.S. commercial insurance groups for policy review and, our efforts in the future will be focused on submitting applications to a substantial number of national and regional insurance providers and workers' compensation groups for policy review.

In the future, we will pursue coverage through the Centers for Medicare and Medicaid Services, or CMS. While we believe that a positive response from CMS may broaden coverage by private insurers, we cannot currently predict how long it would take for us 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 and historically certain third-party payors have provided reimbursement for our products in certain cases in Germany and Italy.

We initially focused 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 payers. Specifically:

• In September 2017, Barmer confirmed it will provide ReWalk systems to all qualifying beneficiaries. Barmer provides insurance coverage for nearly ten million people in Germany, as a member of the German Statutory Health Insurance network and one of the most significant national insurers in the country. Exoskeletons will be provided to users that meet certain inclusion criteria and assessment by the German Health Insurance Medical Service (Medizinischer Dienst der Krankenversicherungen) before and after training. Barmer has already begun processing claims with users entering training for in-home use of an exoskeleton.

• In September 2017 Germany’s national social accident insurance provider, DGUV, signed a confirmation letter with ReWalk, stipulating that the DGUV's member payers, including the health insurance association Berufsgenossenschaft (also known as BG) and state insurers, will approve the supply of exoskeleton systems for qualifying beneficiaries on

a case-by-case basis. DGUV is comprised of 35 different insurers, which provide coverage for more than 70 million individuals in Germany. Per the agreement, eligible individuals will go to BG clinics for evaluation as a part of the procurement.

• In February 2018 the GKV, confirmed its decision to list the ReWalk Personal system in the German MDD, The MDD is a comprehensive list of all medical devices which are principally and regularly reimbursed by German social health insurance ("SHI") providers. This decision means that ReWalk Personal will be listed among all medical devices for compensation, which SHI providers can procure for any approved beneficiary on a case-by-case basis.

Patients who are covered under these policies must be medically evaluated for their eligibility to use the ReWalk Personal device. If medically qualified, the patient, along with his or her physician, must apply for coverage of the device. We expect that these payers will establish processes for patients to be evaluated, trained and procure a ReWalk Personal device over the coming months, making the process to receive a device more routine for a qualifying individual. Patients who are not covered under Barmer's or the BG's policies stated above must apply for coverage to use ReWalk. 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, 2017, there were 141 insurance cases pending in Germany, including 40 insurance cases pending with Barmer and the BG. We believe that our recent coverage decisions and the existing claims will eventually lead other German insurers to provide coverage on a broad scale. 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-payers. This includes 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 consists of both in-house and external staff, including engineers, machinists, researchers, marketing, quality, manufacturing, regulatory and clinical personnel, who work closely together to design, enhance and validate our technologies. This research and development team conceptualizes technologies and then builds and tests prototypes before refining and/or redesigning as necessary. Our regulatory and clinical personnel work in parallel with engineers and researchers, allowing us to anticipate and resolve potential issues at early stages in the development cycle.

We plan to focus our research and development efforts in the future by continually improving and expanding our functional technological platform, specifically, in the shorter term, by developing a lightweight "soft suit" exoskeleton device that will assist patients who had stroke or multiple sclerosis, and in the longer term by 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 including cerebral palsy, Parkinson's disease and elderly assistance. 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, 2017, we received funding totaling $1.77 million from the IIA and $500 thousand from the BIRD Foundation. Our research and development expenses, net were approximately $6.0 million, $9.0 million and $5.9 million for the fiscal years ended December 31, 2017, December 31, 2016 and December 31, 2015, 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 with Harvard, or Harvard License Agreement. 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, we and Harvard 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 Harvard License Agreement.

Under the Harvard 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 Harvard 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 License 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 Harvard License Agreement may also be terminated by Harvard or us due to the other party's material uncured breach.

The Collaboration Agreement and Harvard License Agreement contain, as applicable, customary representations and warranties and customary enforcement, indemnification and insurance provisions. For further discussion of the Collaboration Agreement and Harvard 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 ("Yaskawa"), pursuant to which, among other arrangements, Yaskawa can apply its expertise in product and quality improvements to ReWalk and assist in marketing, distributing and commercializing on an exclusive basis our products in Japan, China and other East Asian countries. Yaskawa is a global leader in the fields of industrial robotics and automation. While we have not engaged in joint initiatives with Yaskawa to date, we believe that this relationship may provide us with opportunities for product improvement and increased product offerings in the future. In connection with the closing of the first tranche of the private placement of our ordinary shares to Timwell, we are required to amend our exclusive distribution agreement with Yaskawa to terminate the distribution rights granted to Yaskawa in China (including Hong Kong and Macau). For more information on the Timwell private placement, see "Part I. Item 1. 1.

Business-Timwell Investment Agreement and Related Transactions," and for more information regarding our relationship with Yaskawa generally, 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 payers, 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. The VA accounted for 35.2% and 33.3% of our total revenues for the years ended December 31, 2017 and 2016, 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 Pty, Cyberdyne (Tokyo Stock Exchange: 7779), Parker Hannifin (NYSE: PH), Hocoma, AlterG, and Bioness.

We believe that our ReWalk Personal device possesses 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, the 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.

We believe that our Restore device will have key competitive advantages over the products of our competitors, including a lightweight soft-suit, of approximately 4 kilograms, a design that facilitates a natural walking pattern mimicking the movement of a healthy leg, and powered plantarflexion in addition to dorsiflexion making it the only solution of its type of which we are aware to support such movement.

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 pending patent applications, the Company licenses certain patented and patented pending technology from a third party as described above under the "Research and Development" section.

As of February 1, 2018, we have five issued patents in the United States and ten issued patents outside of the United States, as well as 28 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 and Europe, 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 currently commercialized 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 the United States and Israel for the mark “ReWalk”. We are in the process of registering the mark “Restore” in the United States and Israel.

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.”

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Government Regulation

U.S. Regulation

Our medical products and manufacturing operations are regulated 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 Regulatory Requirements

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, most Class II devices require a 510(k) premarket notification to be marketed in the U.S. 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 require modification of the study, 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 1A. 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 Regulatory Requirements

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;
- 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; and
- Post market surveillance.

ReWalk is required by an FDA order under Section 522 of the FFDCA to conduct a postmarket study of the ReWalk device. We launched our postmarket surveillance study with Stanford University during the second quarter of 2016. For more information on the post-market surveillance study, see "Part I. Item 1A. Risk Factors-Risks Related to Government Regulation."

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.

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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 the United States regulations, 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 (i.e. vigilance) 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.

In September 2017, members of the U.S. Congress introduced legislation with the announced intention to repeal and replace major provisions of the PPACA. Although this proposed legislation ultimately failed to pass, Congress succeeded in repealing the PPACA's individual mandate as part of the U.S. Tax Cuts and Jobs Act of 2017. Thus, in light of the stated policies of the new U.S. presidential administration, and actions of certain members of the U.S. Congress, 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, 2017, we had 65 employees (including full-time and hourly employees), of whom 27 are located in the United States, 26 were located in Israel and 12 were located in Germany. As of December 31, 2016, we had 94 employees, of whom 36 were located in the United States, 41 were located in Israel and 17 are located in Germany, and 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 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. The decline in total employees at the end of 2017 versus 2016 is a result of our efforts to reduce operating expenses announced in January 2017. We will continue to evaluate spending and organizational requirements as our business develops.

We are subject to labor laws and regulations within our locations mainly in the U.S. ,Germany and 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.

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, 2017, 2016, 2015:

	Year Ended December 31,		
	2017	2016	2015
Revenues based on customer's location:			
Israel	$—	$—	$—
United States	4,598	3,741	2,439
Europe	3,094	1,144	820
Asia-Pacific	61	984	487
Total revenues	$7,753	$5,869	$3,746

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.

Timwell Investment Agreement and Related Transactions

Investment Agreement

On March 6, 2018, the Company entered into an investment agreement (the "Investment Agreement") with Timwell Corporation Limited, a Hong Kong corporation ("Timwell"), pursuant to which we agreed, in return for aggregate gross proceeds to us of $20 million, to issue to Timwell an aggregate of 16,000,000 of our ordinary shares, at a price per share of $1.25, which represents a premium to the closing sale price of our ordinary shares as of March 6, 2018. Timwell will make the investment in three tranches, consisting of $5 million for 4,000,000 shares in the first tranche (the "First Tranche Closing"), $10 million for 8,000,000 shares in the second tranche (the "Second Tranche Closing") and $5 million for 4,000,000 shares in the third tranche (the "Third Tranche Closing"). On a post-transaction basis, based on 30,006,575 of our ordinary shares outstanding as of March 5, 2018 (excluding ordinary shares issuable upon conversion or exercise of derivative securities owned by other shareholders or shares issued under our equity incentive plans and assuming no changes otherwise to our capitalization), after the First Tranche Closing, the Second Tranche Closing and the Third Tranche Closing, Timwell will beneficially own 11.8%, 28.6% and 34.8% of our ordinary shares, respectively

The First Tranche Closing is subject to the Company having received the approval by our shareholders of the transaction under Rule 5635 of Nasdaq and Israeli law. The Second Tranche Closing is subject to the conditions that, by July 1, 2018, (i) the Company and an affiliate of Timwell will have formed the China JV (as defined below), and (ii) by no later than 20 days after the establishment of the China JV (or as soon thereafter as possible), the China JV and the Company will have executed the License Agreement and Supply Agreement (each as defined below). The Third Tranche Closing is subject to the conditions that, by April 1, 2019, (i) the Company will have provided to the China JV product documentation, component supply access, work instructions, know-how and training, and will have defined quality system requirements necessary for rehabilitation using the Company's Restore product, and (ii) a China-based manufacturer or agent defined by the China JV will have successfully produced the Company's Restore product to the quality requirements defined by the Company. The Third Tranche Closing is expected to occur by December 31, 2018, before the April 2019 deadline under the Investment Agreement. The transaction is also subject to other customary closing conditions. The Company plans to include the issuance of the 16,000,000 ordinary shares to Timwell as a proposal for shareholder approval at its 2018 Annual Meeting of Shareholders.

The Company intends to use the net proceeds from the issuances under the Investment Agreement (i) primarily for (a) sales, marketing activities related to market development in our existing markets as well as expanding into China and reimbursement expenses related to broadening third-party payor coverage and (b) research and development costs related to developing our lightweight “soft suit” exoskeleton technology for various lower limb disabilities, including stroke and other indications affecting the ability to walk, (ii) with respect to any remaining proceeds for general corporate purposes.

Lock-up Period

Until 18 months following the Third Tranche Closing, subject to limited exceptions, Timwell may not sell or transfer the ordinary shares purchased under the Investment Agreement (the "Purchased Shares") except to its affiliates, unless a majority of the directors of our board of directors (the "Board"), excluding any member of our Board nominated or designated by Timwell, approves the transfer. Following this 18-month lock-up period, except for transfers of up to 10% of the shares to third parties who are not competitors of the Company, any sale or transfer of the Purchased Shares must be pursuant to Rule 144 under the Securities Act of 1933 (the "Securities Act") or an underwritten public offering. This restriction will terminate if any of the JV Agreement (as defined below), the License Agreement and the Supply Agreement is not executed within 12 months after the First Tranche Closing or is terminated. Timwell may also sell its Purchased Shares pursuant to any third-party tender offer for all of the Company's ordinary shares.

Board Appointment Rights

Pursuant to the Investment Agreement, Timwell will be entitled upon the First Tranche Closing, and for so long as it maintains a 75% ownership of the Purchased Shares, to designate one nominee to our Board. Following the Third Tranche Closing and for so long as the shareholding requirements of the Purchased Shares above are satisfied, Timwell will be entitled to designate such aggregate number of members of the Board equal to the higher of (i) one, or (ii) the number of Board members affiliated with the Company's next two largest shareholders at such time.

Standstill and Voting Agreement

Subject to certain limitations set forth in the Investment Agreement, Timwell has agreed not to acquire additional equity securities of the Company and has agreed to customary "standstill" arrangements, pursuant to which it will not take certain actions related to, or knowingly encourage others to take actions related to, business combinations, mergers, tender offers or restructurings, and will refrain from taking certain actions related to the calling of meetings, proxies, proposals, director nominations, voting trusts and other actions of shareholders. Timwell has also agreed to vote its ordinary shares in accordance with the recommendations of our Board on shareholder proposals and Board proposals relating to any change of control, election of directors, amendments to the Company's organizational documents, director and officer compensation and certain other related matters, provided that the action does not have an disproportionate adverse impact on Timwell's rights as a shareholder compared to the other shareholders.

Notwithstanding the above, pursuant to the Investment Agreement, Timwell will not be restricted from purchasing shares in open-market transactions after the Third Tranche Closing, so long as Timwell and its affiliates together beneficially own not more than 35% of the outstanding shares of the Company. The standstill will remain in effect for so long as Timwell beneficially owns or has rights to at least 10% of the outstanding ordinary shares of the Company, and the voting agreement will remain in effect for so long as Timwell beneficially owns or has rights to at least 5% of the outstanding ordinary shares of the Company.

Preemptive Rights

The Investment Agreement grants Timwell certain preemptive rights. Following the First Tranche Closing and as long as Timwell holds at least 75% of the aggregate of the then-Purchased Shares at any of the First Tranche Closing, Second Tranche Closing and Third Tranche Closing through the date of determination of the preemptive right under the Investment Agreement, if any, in the event that the Company proposes to offer or sell any new securities other than in a public offering, the Company must first offer Timwell the right to purchase its then-applicable preemptive pro rata fraction of such new securities as calculated based on the terms provided in the Investment Agreement.

Registration Rights Agreement

Pursuant to the Investment Agreement, upon the First Tranche Closing, the Company and Timwell will enter into the form of registration rights agreement attached as Annex A to the Investment Agreement (the "Registration Rights Agreement"), relating to registration under the Securities Act of resales of the Purchased Shares. Pursuant to the Registration Rights Agreement, Timwell and certain permitted transferees will have certain demand and piggyback registration rights with customary indemnification provisions, subject to customary cutbacks on the number of shares to be registered or offered in an underwritten offering where the managing underwriter advises that marketing factors call for a limitation on the number of shares to be registered or offered. The registration rights will terminate upon certain customary triggers, including when Timwell and certain permitted transferees could sell all of their Purchased Shares without restriction pursuant to Rule 144 under the Securities Act.

China JV, License Agreement and Related Agreements

China JV

Pursuant to terms of the joint venture framework agreement, dated March 6, 2018 (the "JV Framework Agreement"), between the Company and RealCan Ambrum Healthcare Industry Investment (Shenzhen) Partnership Enterprise (Limited Partnership), an affiliate of Timwell ("Timwell JV Party"), the Company and Timwell JV Party intend to form a joint venture company in China for the purposes of research and development, assembly, registration, import, operations, sales and marketing of the Company's products in China (including Hong Kong and Macau) (the "China JV"). Under the JV Framework Agreement, the China JV will be owned 80% by Timwell JV Party and/or other affiliates of the Timwell and Timwell JV Party to be agreed to by the parties in the JV Agreement ("Timwell China Parties") and 20% by the Company (which ownership by the Company will not be diluted for at least the first five years after the formation of the China JV).

The parties have agreed that they will collaborate to form the China JV by negotiating and signing a JV agreement (the "JV Agreement"), consistent with the terms of the JV Framework Agreement. Pursuant to the JV Framework Agreement, the Company will not compete with the China JV in China (including Macau and Hong Kong), and Timwell JV Party will not compete with the Company anywhere in the world.

As set forth in the JV Framework Agreement, Timwell China Parties will appoint four of the China JV's directors and the Company will appoint one director. The initial chief executive officer and the initial chief financial officer of the China JV will be appointed by joint agreement of Timwell China Parties and the Company. The Company will have customary minority protection rights, including a requirement that board decisions on specified matters be unanimous, which will survive any public offering of the China JV to the extent permissible. There will also be restrictions in the JV Agreement on the parties' ability to sell or transfer their shares in the China JV other than to permitted transferees. Timwell China Parties and the Company will have a right of first refusal on proposed sales by the other party, and the Company will have a tag-along right if Timwell JV Party proposes to sell its shares in the China JV. Upon a change in control of the Company, Timwell China Parties will have the right to purchase the shares in the China JV owned by the Company at fair market value. In addition, each party will have the right to purchase the other party's shares, if the other party proposes to sell its shares to a competitor of the remaining party.

In order for the China JV to maintain exclusive rights in China (including Macau and Hong Kong) to market and sell the Company's products and the rights to the intellectual property, the China JV will be required to make certain minimum cash payments to the Company of the following amounts: $1.25 million for the first year after formation; $4 million for the second year after formation; $8 million for the third year after formation; an amount increased annually by 15% of the preceding year's amount for the fourth, fifth and sixth years after formation; an amount increased annually by 10% of the preceding year's amount for the seventh, eighth and ninth years after formation; and an amount increased between 5% and 8% of the preceding year's amount for the tenth year after formation onward.

The Company and Timwell JV Party have agreed to use reasonable efforts to form the China JV, to negotiate and execute the JV Agreement on a date that allows reasonable time to ensure the establishment of the China JV no later than July 1, 2018, and to arrange for the China JV and the Company to execute and deliver the License Agreement and the Supply Agreement within 20 days after the establishment of the China JV.

License Agreement

In conjunction with and after formation of the China JV, the Company intends to execute a license agreement (the "License Agreement") with the China JV with terms and conditions consistent with an agreed set of key terms (the "License Key Terms"). Pursuant to the License Key Terms, the Company will grant to the China JV (a) an exclusive, royalty-bearing, non-sublicensable (except as mutually agreed), non-transferable (except as mutually agreed) license

under certain of the Company's owned intellectual property, (b) an exclusive, royalty-bearing, non-sublicensable, non-transferable sublicense under certain of the Company's controlled (but not owned) patent rights and (c) a non-exclusive, non-sublicensable, non-transferable sublicense under certain of the Company's controlled (but not owned) know-how, in each case, solely for use for certain products in the China JV's business and only in China (including Hong Kong and Macau).

The term of the License Agreement will expire upon expiration of all valid claims of the licensed patents. The License Agreement will also be terminable by the Company or the China JV due to the other party's material uncured breach and for other events, including that sublicenses under any controlled (but not owned) intellectual property will terminate upon termination of the upstream license. The License Agreement will comply with and be expressly subject and subordinate to all requirements of any upstream license agreements and requirements of applicable law and will contain customary terms and conditions mutually agreed by the parties, including diligence, confidentiality, indemnity and limitation of liability provisions.

Supply Agreement

The Company and Timwell also intend for the China JV and the Company to enter into a supply agreement consistent with an agreed form of supply agreement attached as Annex G to the Investment Agreement (the "Supply Agreement") pursuant to which the Company will sell its products to the China JV, for resale solely in China (including Macau and Hong Kong). The Supply Agreement will set a target profit margin for the Company on the sale of its products to the China JV, and also shall specify the credit terms to be afforded to the China JV on these sales. The China JV's rights under the Supply Agreement are conditioned on satisfaction of the minimum cash payments as are specified in the JV Agreement (as described above). The term of the Supply Agreement will be concurrent with the term of the License Agreement, subject to termination provisions and other terms to be agreed to by the parties in the Supply Agreement.

The Investment Agreement and JV Framework Agreement contain a number of representations and warranties that we and Timwell (and its affiliates) have made to each other that are customary in such transactions. Moreover, representations and warranties are frequently utilized in agreements as a means of allocating risks, both known and unknown, rather than to make affirmative factual claims or statements. These representations and warranties are made as of specific dates and are subject to important exceptions and limitations, including a contractual standard of materiality different from that generally applicable under federal securities laws. Accordingly, persons not party to the Investment Agreement or the JV Framework Agreement should not rely on the agreement for any characterization of factual information about us, Timwell or Timwell JV Party.

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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 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. We may not be able to achieve or maintain market acceptance of our ReWalk systems or, once approved and commercialized, our lightweight soft suit exoskeleton, or to generate sufficient revenues from these current and future products.

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. Additionally, we are developing and intend to commercialize a lightweight soft suit exoskeleton, designed to support mobility for individuals suffering from other lower limb disabilities, and aim to begin marketing an initial indication for stroke patients in the first half of 2019 after applying for and receiving mandatory regulatory clearances.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 and national insurers in the United States and Europe have provided reimbursement for ReWalk in certain cases to date, the VA maintains its coverage policy for qualifying veterans across the United States and German insurers Barmer and DGUV have issued broad coverage decisions, no broad uniform policy of coverage and reimbursement for electronic exoskeleton medical technology exists among third-party payors in the United States. Additionally, health insurance companies and other third-party payors in the future may not deliver adequate coverage or reimbursement for our products. The VA, Barmer or DGUV may cancel or materially curtail their 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 insurance reimbursements. 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;

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- adverse regulatory or legal actions relating to ReWalk or similar products or technologies; and

- problems arising from the outsourcing of our manufacturing capabilities, or our existing manufacturing and supply relationships.

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

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 $131.2 million as of December 31, 2017 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 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, 2017 regarding the substantial doubts about the Company's ability to continue as a going concern.

The Company intends to finance operating costs over the next twelve months with existing cash on hand, reducing operating spend, issuances under our at-the-market equity offering program ("ATM Offering Program"), other future public or private issuances of securities, including the recently signed private placement of ordinary shares to Timwell, or through a combination of the foregoing. However, we will need to seek additional sources of financing if we require more funds than anticipated during the next 12 months or in later periods, including if we cannot make our loan repayments under our loan agreement (the "Loan Agreement" or the "Kreos Loan Agreement") with Kreos Capital V (Expert Fund) Limited ("Kreos"), or if we cannot raise sufficient funds from equity issuances, such as the ATM Offering Program. 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, and may need to take advantage of various forms of capital-raising transactions Future equity financings, strategic transactions or borrowings may also further dilute our shareholders or place us under restrictive covenants limiting our ability to operate.
As of December 31, 2017, we had an accumulated deficit in the total amount of $131.2 million, and further losses are anticipated in the development of our business. Those factors raise substantial doubt about our ability to continue as a going concern. 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 of equity and/or debt securities, including issuances under the Company's ATM Offering Program, other future public or private issuances of securities, including the recently signed private placement of ordinary shares to Timwell, or through a combination of the foregoing. However, we will need to seek additional sources of financing if we require more funds than anticipated during the next 12 months or in later periods, including if we cannot make our loan repayments under our Kreos Loan Agreement, or if we cannot raise sufficient funds from equity issuances, such as the ATM Offering

Program. In addition, due to limitations under the rules of Form S-3, which have applied to us since we filed our Form 10-K in February 2017, we may only sell up to approximately $13.7 million in primary offerings under our effective registration statement on Form S-3 (the "Form S-3"), including our ATM Offering Program, during any 12-month period while we remain subject to these limitations. As of the date of this annual report, we have sold approximately $9.3 million in securities under our Form S-3 during the last 12 months, when we were subject to these restrictions. We will recalculate the amount of this limitation if we terminate our ongoing takedown and conduct another takedown under our Form S-3. For more information, see "Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations-Liquidity and Capital Resources-Equity Raises."

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To raise additional capital in the public markets, including taking into account the limitation above, we may be required to seek other more costly or time-consuming methods, such as additional offerings on registration statements on Form S-1. We may also conduct fundraising transactions in the form of private placements, potentially with registration rights or priced at a discount to the market value of our ordinary shares, which could require shareholder approval under the rules of Nasdaq, or other equity raise transactions such as equity lines of credit. We have in the past been, and may in the future be, required to pay advisory fees to investment banks assisting us with financing transactions. In addition to increased capital costs, any such transactions could result in substantial dilution of our shareholders' interests, transfer control to a new investor and diminish the value of an investment in our ordinary shares. We may also need to pursue strategic transactions, such as joint ventures, in-licensing transactions or the sale of our business or all or substantially all of our assets. These private financings and strategic transactions could require significant management attention, disrupt our business, adversely affect our financial results, be unsuccessful or fail to achieve the desired results. We are in discussions routinely with such possible sources of additional funding. As another alternative, we may choose to refinance up to a substantial portion of our indebtedness under our Kreos Loan Agreement, which we have considered with Kreos from time to time, or borrow additional funds. If we were to carry out these transactions using an investment bank we previously engaged to assist us on a wide range of strategic transactions, we could incur advisory fees determined as a percentage of total proceeds, subject to negotiation for other potentially-owed fees. Agreements governing any borrowing arrangement may contain covenants that could restrict our operations. In sum, if we are unable to obtain additional funds on reasonable terms, it could impair our efforts to develop and commercialize existing and new products and to repay our liabilities as they become due, materially harming our results of operations and financial condition.

The market for medical exoskeletons, including soft suit devices, is new and unproven, and important assumptions about the potential market for our current and future 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.

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, such as our Restore product for stroke patients, 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 2017 there were 285,000 people in the United States living with SCI, and that the annual incidence of SCI cases is approximately 17,500 new cases per year. Based on information from a 2016 report by the NSCISC, 40.6% 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. For more information regarding the potential market for future products, including our lightweight soft suit exoskeleton, see "Item 1. Business-Market Opportunity."

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 or CE mark clearance for such products, if received at all, may contain different limitations from the ones the FDA or EU 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.

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We may fail to secure or maintain adequate insurance coverage or reimbursement for ReWalk by third-party payors, 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. Additionally, in September 2017, German insurer Barmer and national social accident insurance provider DGUV each signed a confirmation and letter of agreement regarding the provision of ReWalk systems for all qualifying beneficiaries. However, no broad uniform policy of coverage and reimbursement for electronic exoskeleton medical technology exists among third-party payors in the United States, 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. For instance, during 2017 we submitted a proposal to a large U.S. national insurance provider for a broader coverage policy for the ReWalk Personal device. While we believe there was support for a change, the insurer was unable to reach internal consensus and therefore elected not change its existing non-coverage policy. 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.

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 cannot currently predict how long it would take for us 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.

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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.

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

A key element of our long-term business strategy is the continued leveraging of our sales, marketing, training and reimbursement
infrastructure, through the training, retaining and motivating of skilled sales and marketing representatives and reimbursement personnel with industry experience and knowledge. Our ability to derive revenue from sales of our products depends largely on our ability to market the products and obtain reimbursements for them. In order to continue growing our business efficiently, we must therefore coordinate the development of our sales, marketing, training and reimbursement 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, in early 2017 we announced our plans to reduce operation expenses by up to 30% compared to 2016, in part through a realignment of and reduction in staffing to match our 2017 business goals. 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, impairing our reimbursement efforts and/or harming the quality of our customer service. For instance, the number of our staff focused on reimbursement has decreased, and in 2017, we consolidated the functions of two employees that previously focused on reimbursement into the roles of certain executive officers and employees in other departments. Additionally, our Chief Commercial Officer recently passed away in October 2017 and her position was divided between several existing management functions. Throughout 2018, we will continue to evaluate spending to reduce where possible.

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.

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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 potentially 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.

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.

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Our future growth and operating results will depend on our ability to develop, receive regulatory clearance for and commercialize new products and penetrate new product and geographic 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 cerebral palsy Parkinson's disease and elderly assistance. 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. On March 6 2018, as part of our private placement of ordinary shares to Timwell, a Hong Kong entity, we agreed to collaborate with an affiliate of Timwell in forming a joint venture in China for the purposes of assembly, registration, operations, sales, and marketing of our products in China (including Hong Kong and Macau).

We expect that a portion of our revenues will be derived, in the next few years, from new soft suit exoskeleton 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 cerebral palsy, Parkinson’s disease and elderly assistance. 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. For instance, we have not yet applied for CE mark and FDA clearances for our Restore product for stroke patients and intend to apply for such clearances by the third quarter of 2018 after beginning clinical trials in the first quarter of 2018. We aim to commercialize the system for use by stroke patients in Europe and the United States in the first half of 2019. Obtaining clearance for the Restore product or other soft suit exoskeleton products could involve an extensive and time-consuming process and delay commercialization beyond our planned timetable, and we cannot make any assurances regarding the ultimate timing of FDA or CE mark clearance or commercialization of the Restore product or any future products. For more information on the clearance processes, see “Part I, Item 1. Business-Government Regulation.”

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 soft suit 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, we do not yet have any clinical data demonstrating the benefits of our products for indications other than paraplegia and we might not be able to support the economical benefits the new product has for the customer. 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. Our competitor base may change or expand as we make efforts to develop and commercialize our soft suit exoskeleton product in the future. 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, in early 2017 we announced our plans to reduce operation expenses by up to 30% compared to 2016. During 2017 our operating expenses decreased by 20% versus 2016; additionally, our gross profit as a percentage of revenue increased to 40% as compared to 13% in 2016. Over the course of 2017, we reduced the number of employees worldwide from 94 to 65. In 2018, we will continue to evaluate spending to reduce where possible. For more information, see “Part I, Item 1. Business-Employees.”
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 Restore system. 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, 2017, 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 was initially repayable monthly over a period of 24 months commencing 12 months after the applicable drawdown date, which period would 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. In mid-2017, the Company had raised more than $20.0 million and therefore the repayment period was extended by an additional 12 months to 36 months. The outstanding principal was also reduced by $3.0 million in connection with our issuance to Kreos on June 9, 2017 of a $3.0 million secured convertible note (the "Kreos Convertible Note"). The Kreos Convertible Note may be converted into up to 2,523,660 ordinary shares of the Company at a fixed conversion price of $1.268 per share (subject to customary antidilution adjustments in connection with a share split, reverse share split, share dividend, combination, reclassification or otherwise). This amended outstanding principal amount remains subject to repayment in accordance with the terms and conditions of the Loan Agreement and an amended repayment schedule. We may in the future choose to refinance up to a substantial portion of our remaining indebtedness under the Kreos Loan Agreement, including by tying our repayment obligations and amortization schedule to the achievement of certain business milestones, which we have considered with Kreos from time to time.

Pursuant to the Loan Agreement and the Kreos Convertible Note, 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 the Kreos Convertible Note or to pay the outstanding principal amount following the termination of the Loan Agreement or the Kreos Convertible Note, 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 focus our resources on achieving reimbursement within our direct markets in the United States in response to the receipt of FDA clearance for ReWalk Personal and in Europe with the CE mark clearance, 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 and other armed groups 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.

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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. In the beginning of 2018 we updated our service policy for new devices sold to include 5 years warranty. If product returns or warranty claims are significant or exceed our expectations, we could incur unanticipated expenditures for parts and services, which could have a material adverse effect on our operating results.

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

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

When 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.

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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.

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 geographic or product 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. We also collaborate 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. Additionally, on March 6, 2018, as part of our private placement of ordinary shares to Timwell, a Hong Kong entity, we agreed to collaborate with an affiliate of Timwell in forming a joint venture in China for the purposes of assembly, registration, operations, sales, and marketing of our products in China (including Hong Kong and Macau), and to grant to the joint venture, in accordance with the terms of an agreed form of license agreement, an exclusive license for certain of our patent rights marks and a non-exclusive sublicense for certain Company-controlled know-how. For more information, see "Part I. Item 1. Business-Timwell Investment Agreement and Related Transactions."

Our arrangements with Yaskawa and Harvard, and our eventual joint venture and license arrangements with Timwell, may not be as productive or successful as we hope.We may also fail to form the joint venture with Timwell for various reasons, including if the joint venture cannot obtain required regulatory approvals.

Additionally, as we pursue these arrangements and choose to pursue other collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships in the future, we may not be in a position to exercise sole decision making authority regarding the transaction or arrangement. This 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.

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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. Since 2015 and throughout 2017, 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 remaining expenses were denominated in NIS and euros. .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 7% during the fiscal year of 2017, the rate of devaluation of the shekel against the dollar was approximately 1.5% in 2016. In 2017 and 2016, 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.

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 and discussions with the E.U. began in March 2017. While the U.K. and the E.U. are expected to reach an agreement by 2019, political changes in the U.K. following the “Brexit” referendum and other factors leave it unclear when exactly the U.K. will exit and on what terms. The impact on us from Brexit will depend, in part, on the outcome of tariff, trade, regulatory and other negotiations. Because this is an unprecedented event, it is unclear what long-term economic, financial, trade and legal implications the withdrawal of the U.K. from the E.U. would have and how such withdrawal would affect the regulation applicable to our business globally and specifically in the region.

As a result of the 2016 referendum, 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.

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Our business may be materially affected by changes to fiscal and tax policies. Potentially negative or unexpected tax consequences of these policies, or the uncertainty surrounding their potential effects, could adversely affect our results of operations and share price.

The U.S. Tax Cuts and Jobs Act of 2017 (the "TCJA") was approved by Congress on December 20, 2017 and signed into law by President Donald J. Trump on December 22, 2017. This legislation makes significant changes to the U.S. Internal Revenue Code of 1986, as amended (the "IRC"). Such changes include a reduction in the corporate tax rate from 35% to 21% and limitations on certain corporate deductions and credits, among other changes. In addition, the TCJA requires complex computations to be performed that were not previously required in U.S. tax law, significant judgments to be made in interpretation of the provisions of the TCJA and significant estimates in calculations, and the preparation and analysis of information not previously relevant or regularly produced.

While we have provided a provisional estimate on the effect of the TCJA in our Consolidated Financial Statements the application of accounting guidance for various items and the ultimate impact of the TCJA on our business are currently uncertain. In addition, the final impacts of the TCJA could be materially different from our expectations. For example, adverse changes in the underlying profitability and financial outlook of our operations or changes in tax law could lead to changes in our valuation allowances against deferred tax assets on our consolidated balance sheets, which could materially affect our results of operations. The U.S. Treasury Department, the Internal Revenue Service (the "IRS"), and other standard-setting bodies could interpret or issue guidance on how provisions of the TCJA will be applied or otherwise administered that is different from our interpretation. Finally, foreign governments may enact tax laws in response to the TCJA that could result in further changes to global taxation and materially affect our financial position and results of operations. The uncertainty surrounding the effect of the reforms on our financial results and business could also weaken confidence among investors in our financial condition. This could, in turn, have a materially adverse effect on the price of our ordinary shares.

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 following courts: (i) the Superior Court of the State of California, County of San Mateo; (ii) the Superior Court of the Commonwealth of Massachusetts, Suffolk County; (iii) the United States District Court for the Northern District of California; and (iv) 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 other defendants.

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, and the action commenced in the United States District Court for the Northern District of California has been voluntarily dismissed.

As of February 26, 2018, three actions remain pending, including (i) the two actions commenced in the Superior Court of the Commonwealth of Massachusetts, or Massachusetts State Court, which have been consolidated, and (ii) the action commenced in the United States District Court for the District of Massachusetts, or Massachusetts Federal Court, which was brought in part by certain of the plaintiffs whose actions were dismissed in the Superior Court of the State of California, County of San Mateo. The plaintiffs in the Massachusetts Federal Court action filed a consolidated amended complaint in August 2017 adding claims that certain statements we made after our IPO were materially misleading. In December 2017, the Massachusetts State Court stayed the consolidated Massachusetts State Court actions pending the outcome of the Company’s motion to dismiss in the Massachusetts Federal Court action. In January 2018, the Massachusetts Federal Court reserved judgment of the Company’s motion to dismiss the claims against it.

For more information, see Note 7e 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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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.

Risks Related to Government Regulation

If our product may have caused or contributed to a death or a serious injury, or if our product malfunctioned and the malfunction's recurrence would be likely to cause or contribute to a death or serious injury, we must comply with medical device reporting regulations, which could result in voluntary corrective actions or agency enforcement actions against us.

Under the medical device reporting (MDR) regulations of the FDA, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, our product or a similar device marketed by us would be likely to cause or contribute to death or serious injury. In addition, all manufacturers placing medical devices in European Union markets are legally bound to report any serious or potentially serious incidents involving devices they produce or sell to the relevant authority in whose jurisdiction the incident occurred. Since 2013, we have submitted nine MDRs to report incidents in which ReWalk Personal users sustained falls or fractures; 4 of these were submitted in 2017. The FDA sent us letters requesting additional information relating to these MDRs submitted in 2017, including a request for a failure analysis. We initiated a voluntary correction for the ReWalk device that related to certain use instructions to reduce the risk of fractures and submitted a report to the FDA under 21 CFR Part 806, ("Part 806"). Under Part 806, manufacturers and importers are required to make a report to the FDA of any correction or removal of a device if the correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the FFDCA caused by the device which may present a risk to health. We are currently evaluating potential labeling and design modifications to the ReWalk to mitigate the risk of fractures, and believe the implementation of these modifications will trigger the need for a new 510(k).

Additional fractures or other events may occur in the future that may require us to report to the FDA pursuant to the MDR regulations, and/or to initiate a removal, correction, or other action. Any adverse event involving our products could result in future voluntary corrective actions, such as recalls or customer letters, or in an FDA enforcement action, such as a mandatory recall, notification to healthcare professionals and users, warning letter, seizure, injunction, or import alert. Any action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require financial resources and distract management, and may harm our reputation and financial results. In addition, failure to report such adverse events to appropriate government authorities on a timely basis, or at all, could result in enforcement action against us.

U.S. healthcare reform measures and other potential legislative initiatives could adversely affect our business.

Recent political changes in the United States could result in significant changes in, and uncertainty with respect to, legislation, regulation and government policy that could substantially impact our business and the medical device industry generally. Certain proposals, if enacted into law, could impose limitations on the prices we will be able to charge for our ReWalk system or any products we may develop and offer in the futire, or the amounts of reimbursement available for such products from governmental agencies or third-party payers. Additionally, 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 FDA's policies may also change and additional government regulations may be issued that could prevent, limit or delay regulatory approval of our future products, or impose more stringent product labeling and post-marketing testing and other requirements. For instance, in September 2017, members of the U.S. Congress introduced legislation with the announced intention to repeal and replace major provisions of the PPACA. Although this proposed legislation ultimately failed to pass, Congress succeeded in repealing the PPACA's individual mandate as part of the U.S. Tax Cuts and Jobs Act of 2017.

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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 ReWalk systems or future ReWalk products. 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.

While we addressed the observations that FDA cited in a 2015 warning letter related to our mandatory postmarket surveillance study and initiated the study, we are currently experiencing enrollment issues that make our study progress inadequate. Going forward, if we cannot meet certain FDA requirements and enrollment criteria for the study or otherwise satisfy FDA requests promptly, or if our study produces unfavorable results, we could receive additional FDA warnings, which could materially and adversely affect our labeling or marketing efforts.

We are currently conducting an ongoing mandatory FDA postmarket surveillance study on our ReWalk Personal 6.0, which began in June 2016. Before we began the current study, the FDA sent us a warning letter on September 30, 2015, or the September 2015 Warning Letter, threatening of potential regulatory action against us for violations of Section 522 of the Federal Food, Drug, and Cosmetic Act (the "FFDCA"), based on our failure to initiate a postmarket surveillance study by the September 28, 2015 deadline, our allegedly deficient protocol for that study, and the lack of progress and communication regarding the study. Between June 2014 and our receipt of the September 2015 Warning Letter, we had responded late to certain FDA's requests related to our study protocol. In February 2016, the FDA sent us an additional information request, or the February 2016 Letter, requesting additional changes to our study protocol and asking that we amend the study within 30 days. This letter also discussed the FDA's request, as further discussed in later communications with the FDA, for a new premarket notification for our ReWalk device, or a special 510(k), linked to what the FDA viewed as changes to the labeling and the device, including to a computer included with the device. In late March 2016, following multiple discussions with the FDA, including an in-person meeting, the FDA confirmed that the agency would permit the continued marketing of the ReWalk device conditioned upon our timely submitting a special 510(k) and initiating our postmarket surveillance study by June 1, 2016. The special 510(k) was timely 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 postmarket surveillance study that was approved by the FDA on May 5, 2016.

We began the study on June 13, 2016, with Stanford University as the lead investigational site. In August 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 Warning Letter, it appeared we had adequately addressed the violations cited in the September 2015 Letter. As part of our study, we have provided the FDA with the required periodic reports on the study's progress, in a few cases with delay, and we intend to continue providing the FDA with periodic reports as required. Through these reports, we have made the FDA aware that due to enrollment issues, we are currently unable to satisfy the target enrollment specified in the study protocol.

As of February 20, 2018, we had four active centers enrolling patients in the study, and there is a fifth site that should complete the process in the second half of 2018. Nine subjects have enrolled in the study, one has completed the study, and two are using the device in the community. This is substantially below the required number of patients included in our study protocol, currently leading the FDA to label our progress as "inadequate." We are in ongoing communications with the FDA regarding options to address the inadequate progress, including potential modifications to our study protocol to expand the pool of patients and/or decrease the total number of patients. Any such modifications will require approval from the FDA. However, there can be no assurance that the FDA will agree to modify our study or that we will manage to attract the required number of patients under the current requirements, or even with revised requirements. As a result, we may not be able to satisfy the postmarket study requirements. If we

cannot meet FDA requirements for the postmarket study or timely address requests from the FDA related to the study, or if the results of the study are not as favorable as we expect, the FDA may issue additional warning letters to us, impose limitations on the labeling of our device or require us to stop marketing the ReWalk Personal device in the United States. We derived 59.3% of our revenues in the fiscal year ended December 31, 2017 from sales of the ReWalk device in the United States and, if we are unable to market 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.

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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. Failure to comply with governmental requirements could result in enforcement actions against us or our products. For example, the FDA 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 “-While we addressed the observations that FDA cited in a 2015 warning letter related to our mandatory postmarket surveillance study and initiated the study, we are currently experiencing enrollment issues that make our study

progress inadequate. . . ” 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;
- rescinding a 510(k) clearance 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. Additionally, the E.U. General Data Protection Regulation (the “GDPR”), which is intended to strengthen and unify data protection and address the export of personal data outside the E.U., will become effective in May 2018. Once effective and implemented, the GDPR will impose more stringent data protection requirements and will provide for greater penalties for noncompliance. With respect to our operations in Europe, the GDPR will increase our responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the GDPR. This may be onerous and adversely affect our business, financial condition, results of operations and prospects. Additionally, if we or any of our service providers are found to be in violation of the promulgated patient privacy rules under HIPAA or, once enforced, the GDPR, we could be subject to civil or criminal penalties, which could be substantial and 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 Capital 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.

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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, During 2017 our gross profit as a percentage of revenue increased to 40% as compared to 13% in 2016 and operating expenses decreased by 20% versus 2016. During 2017, we reduced the number of employees worldwide from 94 to 65. In 2018, we will continue to evaluate spending to reduce where possible. For more information, see "Part I, Item 1. Business-Employees." 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.

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.

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 secret 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 our right to exclude others. In addition, we may fail to apply for or be unable to obtain patents necessary to protect our technology or products from competition or fail to 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 exclude others for any significant period of time or at all. Given the foregoing and in order to continue reducing operational expenses in 2018, we may invest fewer resources in filing and prosecuting new patents and on maintaining and enforcing various patents.

Litigation to establish or challenge the validity of patents, or to defend against or assert against others infringement, unauthorized use, enforceability or invalidity, can be lengthy and expensive and may result in our patents being invalidated or interpreted narrowly and restricting our ability to be granted new patents related to our pending patent

applications. Even if we prevail, litigation may be time consuming,force us to incur significant costs, and could divert management's attention from managing our business while any damages or other remedies awarded to us may not be valuable. 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.

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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 or is using our trade secrets without authorization may be expensive and time consuming, and the outcome is unpredictable. Some of our employees or consultants may own 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.

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.

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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.

In the current environment, there are numerous and evolving risks to cybersecurity and privacy, including criminal hackers, hacktivists, state-sponsored intrusions, industrial espionage, employee malfeasance and human or technological error. High-profile security breaches at other companies and in government agencies have increased in recent years, and security industry experts and government officials have warned about the risks of hackers and cyberattacks targeting businesses such as ours. Computer hackers and others routinely attempt to breach the security of technology products, services and systems, and to fraudulently induce employees, customers, or others to disclosure information or unwittingly provide access to systems or data. 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.

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, such as China, 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 may not be 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, strategic partners, 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. For instance, if our planned China JV were to infringe our licensed intellectual property in violation of the Timwell License Agreement, we could face difficulty effectively enforcing our rights in China or elsewhere. For more information on the Timwell License Agreement, see “Part I. Item 1. Business-Timwell Investment Agreement and Related Transactions.”

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.

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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 which may result in issued patents that our current or future products infringe. Also, because the claims of published patent applications can change between publication and patent grant, published applications that initially do not appear to be problematic may issue with claims that potentially cover our products, technology or methods.

Infringement actions and other intellectual property claims brought against us, whether 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 infringing products, unless we can obtain a license to use the technology covered by such patents or can 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.

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 in the United States and are in the process of registering the trademark “Restore” in the United States and in Israel. 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.

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Risks Related to the Timwell Investment Agreement and Related Transactions

Existing shareholders will experience substantial dilution from the periodic issuances of ordinary shares to Timwell.

As of March 5, 2018, we had 30,006,575 ordinary shares outstanding. On March 6, 2018, we entered into an investment agreement for a private placement of 16,000,000 of our ordinary shares to Timwell in exchange for total aggregate proceeds of $20 million (at a price of $1.25 per share). Timwell will make the investment in three separate tranches, with the Third Tranche Closing expected to occur by December 31, 2018 and no later than April 1, 2019, subject to specified closing conditions, including the requisite approval of the transaction by our shareholders under Nasdaq rules and Israeli law, the formation of a joint venture, the signing of a license agreement and a supply agreement and the successful production of certain ReWalk products, among others. For more information, see “Part I. Item 1. Business-Timwell Investment Agreement and Related Transactions.” If the applicable closing conditions are met at any or all of the three tranche closings, our existing shareholders will experience substantial incremental dilution, which will significantly diminish the value and voting power of our shareholders’ investment in our ordinary shares.

A small number of our shareholders currently have significant influence over matters requiring shareholder approval, and Timwell, after the issuance of the periodic agreed-upon ordinary shares to it, will have increasing influence over and ultimately possible de facto control over such matters. This could discourage takeover or merger attempts or other actions the shareholders may consider favorable.

As of December 31, 2017, the largest beneficial owners of our shares were Yaskawa, certain entities and individuals affiliated with Vitalife, and Kreos, which is deemed a beneficial owner of our ordinary shares pursuant to its right to acquire ordinary shares upon the exercise of warrants and the conversion of the Kreos Convertible Note, which may be converted at any time, subject to its terms. These holders beneficially owned in the aggregate approximately 18% of our ordinary shares as of December 31, 2017 (taking into account Kreos’s beneficial ownership in the total number of ordinary shares outstanding). As a result, Yaskawa and Vitalife, and, if it were to convert all ordinary shares underlying its convertible note, Kreos, 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.

In addition, pursuant to the Investment Agreement, we agreed to sell 16,000,000 ordinary shares to Timwell in three separate tranches, subject to specified closing conditions. For more information, see “Part I. Item 1. Business-Timwell Investment Agreement and Related Transactions.” On a post-transaction basis, using the total number of ordinary shares outstanding as of March 6, 2018 (excluding ordinary shares issuable upon conversion or exercise of derivative securities owned by other shareholders or shares issued under our equity incentive plans, and assuming no changes otherwise to our capitalization), after each of the First Tranche Closing, the Second Tranche Closing and the Third Tranche Closing, Timwell will beneficially own 11.76%, 28.57% and 34.78% of our ordinary shares, respectively. Additionally, under the terms of the Investment Agreement, Timwell will be entitled after the First Tranche Closing, subject to maintaining 75% ownership of the Purchased Shares, to designate one nominee to our board. Following the

Third Tranche Closing and for so long as the shareholding requirements above are satisfied, Timwell will be entitled to designate such aggregate number of members of the board equal to the higher of (i) one, or (ii) the number of board members affiliated or associated with the Company's next two largest shareholders at such time. Timwell has agreed to customary "standstill" restrictions and to vote its ordinary shares in accordance with the recommendation of our board on certain matters, provided it maintains a certain percentage of beneficial ownership in our ordinary shares. However, based solely on its board representation and significant ownership position, Timwell will, after each of the various closings, alone possess sufficient voting power to influence significantly, or potentially have de facto control over, the outcome of the above-listed matters requiring shareholder approval.

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The concentration of ownership of our ordinary shares among Vitalife, Yaskawa and Kreos currently, and by Timwell in the future, could delay or prevent proxy contests, mergers, tender offers, open-market purchase programs or other purchases of our ordinary shares that might otherwise give public float shareholders 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.

The closings of the three tranches of ordinary shares under the Investment Agreement are subject to various conditions, many of which are outside our control. In addition, we may experience difficulties in forming the China JV. The failure to close issuances under the Investment Agreement and to form the China JV could adversely impact our liquidity and our financial condition.

The contemplated issuance of 16,000,000 ordinary shares to Timwell in exchange for proceeds of $20 million, under the Investment Agreement, represents a significant source of liquidity for the Company. For more information on the Company's liquidity position, see "Risks Related to Our Business and Our Industry-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, and may need to take advantage of various forms of capital-raising transactions…." Additionally, we expect that, once formed, the minimum payments owed by the China JV to us will provide us with a source of ongoing income to supplement our other then-available capital resources. The issuance under the Investment Agreement, which will occur in three tranches, is subject to specified closing conditions, including the requisite approval of the transaction by our shareholders under Nasdaq rules and Israeli law, the formation of a joint venture, the signing of a license agreement and a supply agreement and the successful production of certain ReWalk products, among others. For more information, see "Part I. Item 1. Business-Timwell Investment Agreement and Related Transactions." While we intend to pursue actively the steps necessary to fulfill all closing conditions to each of the three tranches under the Investment Agreement, some of the conditions are outside of our control and it is possible that certain or all of the closing conditions will not be satisfied. We may not receive the requisite shareholder approval of the Investment Agreement needed to complete the First Tranche Closing for proceeds of $5 million. Even if we do receive such approval, we may experience delays and difficulties working to form the China JV, as required for the Second Tranche Closing for proceeds of $10 million. Additionally, after the Second Tranche Closing, regulatory, competitive and marketing factors may hinder the ability of a China-based manufacturer or agent to successfully produce our Restore product to certain quality requirements, as required for the Third Tranche Closing for proceeds of $5 million. The failure to close any or all of the three tranches could adversely and materially impact our liquidity and financial condition. If the China JV were to fail to incorporate or to operate at a level necessary to make the minimum payments owed to us, we would also lose an additional source of income, which could adversely affect our business and financial condition.

The use of proceeds from the Timwell issuances will be allocated as determined by the Board without shareholder approval.

The proposed use of proceeds from the Timwell issuances described in "Part I. Item 1. Business-Timwell Investment Agreement and Related Transactions" is based on the current expectations of the Company; however, there may be circumstances where, for business reasons, a reallocation of funds may be necessary as determined at the discretion of the Board, and there can be no assurance as to how those funds may be reallocated. Accordingly, shareholders will have to rely upon the judgment of the Board with respect to the use of the proceeds, with only limited information concerning the Board's specific intentions.

Risks Related to an Investment in Our Ordinary Shares

Sales of a substantial number of ordinary shares by us, our large shareholders and holders of our warrants and other derivative securities, certain of whom may have registration rights, could have an adverse effect on our ordinary

shares.

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 ordinary shares to decline or could impair our ability to raise capital through a future sale of, or pay for acquisitions using, our equity securities.

As of December 31, 2017, 403,804 ordinary shares were issuable pursuant to the exercise of outstanding warrants granted as part of our Series E Preferred investment round in July 2014 at an exercise price of $10.08 and 2,437,500 ordinary shares were issuable pursuant to the exercise of warrants issued in our follow-on offering of ordinary shares and warrants in November 2016, with an exercise price of $4.75. There were also 167,012 ordinary shares issuable pursuant to the exercise of warrants granted to Kreos in connection with the Loan Agreement in January and December 2016, with an exercise price of $9.64, and 2,523,660 ordinary shares issuable pursuant to the conversion of the Kreos Convertible Note at a conversion price of $1.268 per share (subject to customary anti-dilution adjustments).

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Additionally, pursuant to our Amended and Restated Shareholders' Rights Agreement, dated July 14, 2014, with certain of our shareholders, as of December 31, 2017, Yaskawa, as the beneficial owner of approximately 1,561,968 of our ordinary shares, was entitled to require that we register its shares under the Securities Act for resale into the public markets. In our Kreos Convertible Note, we separately undertook to prepare and file with the SEC a registration statement to enable the resale by Kreos of up to 2,523,660 ordinary shares to be issued upon conversion of the note, unless they can otherwise be freely sold using Rule 144 under the Securities Act. We have also agreed to enter into a registration rights agreement with Timwell, after the closing of the first tranche of 4,000,000 shares, to register under the Securities Act its 16,000,000 privately-placed ordinary shares.
All shares sold pursuant to an offering covered by a registration statement would be freely transferable. With respect to the outstanding warrants, there may be certain restrictions on the holders to sell the underlying ordinary shares to the extent they are restricted securities, held by "affiliates" or would exceed certain ownership thresholds. Certain of our largest shareholders,, may also have limitations under Rule 144 under the Securities Act on the resale of certain ordinary shares they hold unless they are registered for resale under the Securities Act. Despite these limitations, if we, our existing shareholders or their affiliates sell a substantial number of the above-mentioned ordinary shares in the public market, the market price of our ordinary shares could decrease significantly. Any such decrease could impair the value of your investment in us.

A decline in the value of our ordinary shares could result in our being characterized as a passive foreign investment company, which would cause adverse tax consequences for U.S. investors.

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 an 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, 2017. However, there can be no assurance that we will not be considered a PFIC for 2018 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, there is a significant risk that a decline in the value of our ordinary shares could result in our becoming a PFIC. For more information on our share price, see "Price Range of Ordinary Shares and Dividend Policy."

If we are characterized as a PFIC, U.S. Holders (as defined below) may suffer adverse tax consequences, including the following: (i) having gains realized on the sale of our securities treated as ordinary income, rather than as capital gains; (ii) losing 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 issued in this offering and other offerings. 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.

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Certain U.S. holders of our ordinary shares may suffer adverse tax consequences if we or any of our non-U.S. subsidiaries are characterized as a "controlled foreign corporation" under Section 957(a) of the IRC.

A non-U.S. corporation is considered a "controlled foreign corporation" (a "CFC") if more than 50 percent of (1) the total combined voting power of all classes of stock of such corporation entitled to vote, or (2) the total value of the stock of such corporation, is owned, or is considered as owned by applying certain constructive ownership rules, by United States shareholders who own stock representing 10 percent or more of the vote or, for the taxable year of a non-U.S. corporation beginning after December 31, 2017 and for taxable years of shareholders with or within which such taxable years of such non-U.S. corporation ends, 10 percent or more of the value on any day during the taxable year of such non-U.S. corporation ("10% U.S. Shareholder"). Generally, 10% U.S. Shareholders of a CFC are required to include currently in gross income such 10% U.S. Shareholder's share of the CFC's "Subpart F income", a portion of the CFC's earnings to the extent the CFC holds certain U.S. property, and certain other new items under the TCJA. Such 10% U.S. Shareholders are subject to current U.S. federal income tax with respect to such items, even if the CFC has not made an actual distribution to such shareholders. "Subpart F income" includes, among other things, certain passive income (such as income from dividends, interests, royalties, rents and annuities or gain from the sale of property that produces such types of income) and certain sales and services income arising in connection with transactions between the CFC and a person related to the CFC.

Certain changes to the CFC constructive ownership rules introduced by the TCJA may cause us and our German subsidiary to be treated as CFCs, and may affect holders of our ordinary shares that are United States shareholders. For 10% U.S. Shareholders, this may result in negative U.S. federal income tax consequences, such as current U.S. taxation of Subpart F income and of any such shareholder's share of our accumulated non-U.S. earnings and profits (regardless of whether we make any distributions), taxation of amounts treated as global intangible low-taxed income under Section 951A of the IRC with respect to such shareholder, and being subject to certain reporting requirements with the IRS. Any 10% U.S. Shareholders should consult their own tax advisors regarding the U.S. tax consequences of acquiring, owning, or disposing our ordinary shares and the impact of the TCJA, especially the changes to the rules relating to CFCs.

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

As previously disclosed, the Company received a notice of deficiency (the "Deficiency Notice") from Nasdaq on November 10, 2017 indicating that the Company did not comply with the minimum $2.5 million stockholders' equity requirement for continued listing on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(b) ("Rule 5550(b)"), and did not meet the alternative $35.0 million market value of listed securities standard ("MVLS") and $500 thousand net income standard requirements under Rule 5550(b). In the Deficiency Notice, Nasdaq instructed the Company to submit a compliance plan, and stated that, following the submission, Nasdaq could extend the Company's time to regain compliance with Rule 5550(b) for up to 180 days from November 10, 2017. The Company submitted a compliance plan in December 2017. In a letter to the Company dated January 11, 2018 (the "Update Letter"), Nasdaq agreed to extend the Company's period to evidence compliance with Rule 5550(b) on the following terms: (i) the Company must file its annual report on Form 10-K for the year ended December 31, 2017 by March 30, 2018, demonstrating compliance as of December 31, 2017; (ii) the Company must show compliance as of March 30, 2018 when it files its quarterly report on Form 10-Q for the quarter ended March 30, 2018 (the "Q1 2018 Form 10-Q"); and (iii) if the Company does not show compliance as of either or both dates, Nasdaq will notify the Company that its ordinary shares will be delisted. As a means of proving its compliance with the shareholders' equity requirement as of March 30, 2018, the Company would be allowed to show to Nasdaq the effect of transactions subsequent to March 30, 2018 on a pro forma basis. The Company would be permitted to appeal the delisting determination to a Nasdaq Hearings Panel (the "Panel"), and the Company's ordinary shares would remain listed on The Nasdaq Capital Market pending a decision by the Panel after the hearing.

Given its stockholders' equity of $3.7 million as of December 31, 2017, the Company is in compliance with the stockholders' equity requirement as of December 31, 2017. While we believe that, based on information we submitted

to Nasdaq in our compliance plan, including our plans for 2018, the Company will show compliance as of March 30, 2018, we can give no assurances regarding our ability to comply as of that date.

Additionally, we face risks regarding our compliance with Nasdaq rules due to the market price of our ordinary shares. Along with meeting the above-discussed requirements of Rule 5550(b), we must satisfy Nasdaq Listing Rule 5550(a)'s ("Rule 5550(a)") closing bid price per share requirement (as well as certain other requirements). Under Rule 5550(a), if the closing bid price of our ordinary shares for 30 consecutive business days is less than $1.00 per share, Nasdaq will send us a notification of deficiency and may provide us a cure period, after which, if we cannot show compliance, we will become subject to delisting proceedings. Since the first quarter of 2017, our ordinary shares have traded periodically between $1.00 and $2.00, reaching an all-time low of $1.05 throughout the fourth quarter of 2017 and the first quarter of 2018. In the event our share price falls below $1.00, we may be unable to meet the closing bid price per share requirement of Rule 5550(a).

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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 maintaining the listing requirements , 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 and trigger potential breaches under our agreements with current or prospective large shareholders. Any of these events could also reduce our liquidity and impair our ability to raise capital.

Future grants of ordinary shares under our equity incentive plans to our employees, non-employee directors and consultants, or sales by these individuals in the public market, could result in substantial dilution, thus decreasing the value of your investment in our ordinary shares, and certain grants may also require shareholder approval.

We have historically used, and continue to use, our ordinary shares as a means of both rewarding our employees, non-employee directors and consultants and aligning their interests with those of our shareholders. As of December 31, 2017, 3,148,318 ordinary shares remained available for issuance to our and our affiliates' respective employees, non-employee directors and consultants under our equity incentive plans, including 1,846,797 ordinary shares subject to outstanding awards (consisting of outstanding options to purchase 1,277,726 ordinary shares and 569,071 ordinary shares underlying unvested restricted share units ("RSUs")). For more information, See Note 8b to our consolidated financial statements set forth in "Part II. Item 8. Financial Statements and Supplementary Data" of this annual report. Additionally, the number of ordinary shares available for issuance under our 2014 Incentive Compensation Plan, or our 2014 Plan, may increase each year due to the operation of an "evergreen" provision previously approved by our shareholders. Pursuant to this provision, the 2014 Plan's reserve increases on January 1 of each calendar year during the plan's term by the lesser of (i) 972,000, (ii) 4% of the total number of shares outstanding on December 31 of the immediately preceding calendar year and (iii) an amount determined by our board of directors.

We previously signed an agreement with a non-employee consultant, who agreed to assist us in commercially promoting and expanding insurance coverage of our ReWalk devices. Although this agreement terminated in May 2017 and was not extended, if we may choose to compensate this consultant for services in an amount equal to those provided for in the expired agreement, the consultant may receive up to ten percent of the increase in our market capitalization following the dates when coverage becomes active under national insurance policies that the consultant secures for us, subject to certain monetary limits. For more information, see Note 8c to our audited consolidated financial statements set forth in "Part II. Item 8. Financial Statements and Supplementary Data" of this annual report. If we opt to pay the consultant in ordinary shares, we may need to seek shareholder approval pursuant to the rules of Nasdaq, potentially due to the size of an issuance or an insufficient number of ordinary shares available for issuance under our 2014 Plan. Any such issuance, or the perception that we will make issuances when we solicit shareholder approval, could substantially dilute existing shareholders and materially decrease the value of an investment in our ordinary shares. Additionally, to the extent registered on a Form S-8, ordinary shares granted or issued under our equity incentive plans will, subject to vesting provisions, lock-up restrictions and Rule 144 volume limitations applicable to our "affiliates," be available for sale in the open market immediately upon registration. Sales of a substantial number of the above-mentioned ordinary shares in the public market could result in a significant decrease in the market price of our ordinary shares and have a material adverse effect on an investment in our ordinary shares.

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.

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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 $1.05 per share through February 8, 2018. 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. Additionally, we may fail to meet publicly announced financial guidance or other expectations about our business, which would cause our ordinary shares to decline in value.

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. During 2017, certain of our regular analysts stopped producing reports and commentary about our business. From time to time, we have also faced difficulty accurately projecting our earnings and have missed certain of our publicly announced guidance. If our financial results for a particular period do not meet our guidance or if we reduce our guidance for future periods, the market price of our ordinary shares may decline.

We are an "emerging growth company" and "smaller reporting company," and we cannot be certain whether the reduced requirements applicable to emerging growth companies and smaller reporting 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 $1.07 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.

We are also a "smaller reporting company" under the rules of the Securities Act and the Exchange Act. As a result, in addition to the exemptions available to us as an "emerging growth company," we may choose to take advantage of certain scaled disclosure requirements available specifically to smaller reporting companies. For example, we are not required to provide market risk disclosures, a contractual obligations table in our management's discussion and analysis of our financial condition and results of operations or selected financial data in our annual report. Additionally, even if we cease to be an emerging growth company as noted above, as long as we continue to be a smaller reporting company, we will not be obligated to follow the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and may continue to use the reduced compensation disclosure obligations (but not the exemptions relating to shareholder voting) available to emerging growth companies. We will remain a smaller reporting company until the last day of the fiscal year in which the aggregate market value of ordinary shares held by non-affiliated persons and entities (known as our "public float") was at least $75.0 million as of the last business day of the second quarter of that year.

We cannot predict or otherwise determine if investors will find our securities less attractive as a result of our reliance on exemptions under the JOBS Act or as a smaller reporting company. 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.

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.

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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.

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), Hezbollah (an Islamist militia and political group in Lebanon) and other armed groups. 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 area