ReWalk Robotics Ltd.
Form 10-K
February 29, 2016
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, 2015

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

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

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the Ordinary Shares held by non-affiliates of the Registrant based upon the closing price of the Ordinary Shares as reported by the Nasdaq Global Market on June 30, 2015 (the last business day of the Registrant’s most recently completed second fiscal quarter) was $92,501,337.

As of February 22, 2016, the Registrant had outstanding 12,340,578 Ordinary Shares, par value NIS 0.01 per share.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of our proxy statement for our 2016 Annual Meeting of Shareholders, which is to be filed within 120 days after the end of our 2015 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, 2015

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Definitions and Introduction

Our legal and commercial name is ReWalk Robotics Ltd. We are a company limited by shares organized under the laws of the State of Israel and were founded in 2001. In September 2014, we listed our shares on the Nasdaq Global Market. We have irrevocably appointed ReWalk Robotics, Inc. as our agent to receive service of process in any action against us in any United States federal or state court. The address of ReWalk Robotics, Inc. is 33 Locke Drive, Marlborough, MA 01752. As used herein, and unless the context suggests otherwise, the terms ReWalk, the Company, we, us or ours refer to ReWalk Robotics Ltd.

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 include all statements that are not historical facts and can be identified by terms such as "anticipates," "believes," "could," "seeks," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would" or sim that convey uncertainty of future events or outcomes and the negatives of those terms. 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 and to expand to new markets;
- our ability to maintain and grow our reputation and the market acceptance of our products;
- our ability to achieve reimbursement from third-party payors for our products;
- our expectations as to our clinical research program and clinical results;
- our ability to improve our products and develop new products;
- our ability to maintain adequate protection of our intellectual property and to avoid violation of the intellectual property rights of others;
- our ability to gain and maintain regulatory approvals; and
- our ability to maintain relationships with existing customers and develop relationships with new customers.

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 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 be found in the sections of this annual report titled Item 1. "Business," Item 1A. "Risk Factors," 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. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this annual report, to conform these statements to actual results or to changes in our expectations.

Where You Can Find Other Information

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

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PART I

ITEM 1. BUSINESS

Overview

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

Current ReWalk designs are intended for people with paraplegia, a spinal cord injury resulting in complete or incomplete paralysis of the legs, who have the use of their upper bodies and arms. We currently offer two products: ReWalk Personal and ReWalk Rehabilitation. ReWalk Personal is designed for everyday use by individuals at home and in their communities, and is custom fitted for each user. ReWalk Rehabilitation is designed for the clinical rehabilitation environment where it provides valuable exercise and therapy. It also enables individuals to evaluate their capacity for using ReWalk Personal in the future. In 2011, we launched ReWalk Rehabilitation for use in hospitals and rehabilitation centers in the United States, Europe and Asia. 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. ReWalk is the first exoskeleton cleared by the FDA for personal use. In September 2013, we received clearance to sell ReWalk in Canada and, in January 2015, we received regulatory approval to distribute ReWalk systems in Australia from the Therapeutic Goods Administration, or the TGA. In the future, we will need to obtain approval from the applicable regulatory agency of any additional jurisdiction in which we seek to market ReWalk.

ReWalk is a breakthrough product that can fundamentally change the health and life experiences of users. ReWalk is currently the only commercialized exoskeleton using a tilt sensor to restore self-initiated walking. Designed for all-day use, ReWalk is battery-powered and consists of a light, wearable exoskeleton with integrated motors at the joints, an array of sensors and a computer-based control system to power knee and hip movement. ReWalk controls movement using subtle shifts in the user's center of gravity. A forward tilt of the upper body is sensed by the system, which initiates the first step. Repeated body shifting generates a sequence of steps which allows for natural gait with functional walking speed. Because the exoskeleton supports its own weight and facilitates the user's natural 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. ReWalk users are able to independently operate the devices, and most are able to put on and remove the devices by themselves. However, our safety guidelines and FDA specifications require users to be accompanied by a trained companion.

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

Development of ReWalk took over a decade and was spurred by the experiences of our founder, Dr. Amit Goffer, who became a quadriplegic due to an accident. As of December 31, 2015, we had placed 104 units in use at rehabilitation

centers and 107 in a home or community use.

Our commercialization strategy is to penetrate rehabilitation centers, hospitals and similar facilities that treat patients with spinal cord injuries to become an integral part of their rehabilitation programs and to develop a broad based training network with these facilities to prepare users for home and community use. According to the National Spinal Cord Injury Statistical Center, 87% of persons with spinal cord injuries are sent to private, non-institutional residences (in most cases, their homes) after hospital discharge. As a result, while almost half of our sales to date have been for use in a Rehabilitation setting, the primary focus of our commercialization efforts going forward will be marketing ReWalk Personal for routine use at home, work or in the community, and we expect sales of ReWalk Personal to account for the substantial majority of our revenues in the future.

We expect to generate revenues from a combination of third-party payors, self-payors and institutions. While no uniform policy of coverage and reimbursement by third-party payors currently exists for electronic exoskeleton technologies such as ReWalk, we plan to pursue various paths of reimbursement and support fundraising efforts by institutions and clinics. In 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, which is exclusive to ReWalk Robotics exoskeleton systems, is the first national coverage policy in the United States for qualifying individuals who have suffered spinal cord injury. Additionally, to date several private insurers in the United States and Europe have provided reimbursement for ReWalk in certain cases.

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.

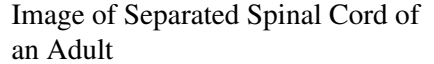

Image of Separated Spinal Cord of an Adult

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

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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 NSCISC estimates as of 2014 that there were 276,000 people in the United States living with spinal cord injury, with an annual incidence of approximately 12,500 new cases per year. Approximately 42,000 of such patients are veterans, and are eligible for medical care and other benefits from the VA. With 24 VA spinal cord injury centers, the VA has the largest single network of spinal cord injury care in the United States.

The University of Alabama-Birmingham Department of Physical Medicine and Rehabilitation operates the NSCISC, which maintains the world's largest database on spinal cord injury research. Between September 2005 and March 2015, motor vehicle crashes have been the leading cause of reported spinal cord injury cases (39%), followed by falls (30%), acts of violence (14%) and sports injuries (8%). Nearly 80% of spinal cord injuries occur among the male population. According to NSCISC data, upon hospital discharge, 87% of persons with spinal cord injuries are sent to private, non-institutional residence (in most cases, their homes prior to injury).

Three published ReWalk trials for SCI patients had an aggregate screening acceptance rate of 81%, when exclusions due to logistics, scheduling and weight were removed. The weight exclusion can be considered potentially short term addressable, as focus was on determining medical exclusions such as insufficient bone material density. This indicates that approximately 80% of the SCI population could be candidates for current or future ReWalk products. 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.

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

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

Over five million Americans have suffered a stroke, with 780,000 new incidences expected each year. Physical limitations after stroke vary from case to case, but approximately 60% of these individuals will have lower limb disability, which could require them to seek additional assistance in walking.

Our Solutions

ReWalk is a breakthrough product that can fundamentally change the quality of life for individuals with lower limb disability through the creation and development of market leading robotic technologies. Published clinical studies demonstrate ReWalk's ability to deliver a natural gait and functional walking speed. ReWalk's patented tilt-sensor technology and an on-board computer and motion sensors drive motorized legs that power knee and hip movement and allow self-initiated walking. ReWalk controls movement using subtle changes in the user's center of gravity. A forward tilt of the upper body is sensed by the system, which initiates the first step. Repeated body shifting generates a sequence of steps, which allows natural ambulation with functional walking speed. While ReWalk does not allow side-to-side actuation, users are able to turn by shifting their weight to the side. ReWalk also allows users to sit, stand and, depending on local regulatory approvals, climb and descend stairs. Use on stairs is not cleared by the FDA in the United States.

Designed for all-day use and worn over the clothes of users, ReWalk consists of a light wearable exoskeleton with integrated motors at the joints, an array of sensors and a backpack 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.

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 Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations."

ReWalk Personal 6.0

- ReWalk Personal: intended for everyday use at home, at work or in the community. We began marketing ReWalk Personal in Europe with CE mark clearance at the end of 2012. We received clearance to market ReWalk Personal in the United States in June 2014. ReWalk Personal units are all manufactured according to the same 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, Europe and Asia in 2011. ReWalk Rehabilitation units are all manufactured according to the same specifications and are equipped with adjustable sizing for multi-patient use.

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

We intend to continue to develop future generations of ReWalk, with a range of improvements including additional functionality, more efficient drive mechanism, slimmer profile and lighter body, as well as other improvements. We plan to expand the designs and indications that we address beyond paraplegia to include other disabilities affecting gait and ability to walk, such as multiple sclerosis, stroke and cerebral palsy.

Third-Party Reimbursements

United States

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

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, which is exclusive to ReWalk Robotics exoskeleton systems, is the first national coverage policy in the United States for qualifying individuals who have suffered spinal cord injury.

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

Private insurance companies do not currently cover or provide reimbursement for any personal medical exoskeleton products, including ReWalk Personal, and are limited to case-by-case decisions.

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

Western Europe

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

We are initially focusing our efforts in Europe in Germany, which has a single-payer system and where we believe we have made significant progress toward achieving ReWalk coverage from the government. Because ReWalk is not currently covered in Germany, a patient who wishes to use ReWalk must apply for coverage and receive an official denial. He or she must then appeal the decision in court, relying on supporting documentation from a health care provider and other medical evidence. There are approximately 61 such cases pending in Germany, and we believe that these will result in eventual coverage. We plan to continue to pursue this case-by-case strategy and expect that once the precedent for coverage is established, seeking coverage will become easier and more routine. We continue to support clinical research and academic publications, which we believe will further support the case for coverage.

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

Other Funding Sources

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. Self-payers also include individuals who purchase ReWalk with funds from legal settlements with insurance companies or third parties.

Research and Development

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

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

We conduct our research and development efforts at our facility in Yokneam, Israel. We believe that the close interaction among our research and development, marketing and manufacturing groups allows for timely and effective realization of our new product concepts.

Our research and development efforts have been financed, in part, through funding from the Office of the Chief Scientist in the Israel Ministry of Economy, or the OCS, and from the BIRD Foundation. From our inception through December 31, 2015, we received funding totaling $740,000 from the OCS and $500,000 from the BIRD Foundation. Our research and development expenses, net were approximately $5.9 million, $8.6 million and $2.5 million for the fiscal years ended December 31, 2015, December 31, 2014 and December 31, 2013, respectively. For more information regarding our research and development financing arrangements and expenses, see 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.”

In September 2013, we entered into a strategic alliance with Yaskawa Electric Corporation, pursuant to which, among other arrangements, Yaskawa can apply its expertise in product and quality improvements to ReWalk. Yaskawa is a global leader in the fields of industrial robotics and automation, and we believe that this relationship provides us with opportunities for product improvement and increased product offerings in the future. For more information regarding our relationship with Yaskawa, see “—Sales and Marketing” and Item 13. “Certain Relationships and Related Transactions, and Director Independence.”

Clinical Studies

There have been multiple clinical studies to establish the effectiveness and benefits of ReWalk for individuals with spinal cord injuries that have resulted in publications in peer-reviewed journals, as follows:

- The first study, published in The Journal of Spinal Cord Medicine in 2012, included six participants and was designed to assess the safety and tolerance of use of ReWalk by patients with a spinal cord injury. The participants were all able to walk 100 meters with ReWalk. The study found no adverse safety events (which included falls, status of the skin, status of the spine and joints, blood pressure, pulse and electrocardiography) and concluded that use of ReWalk was well-tolerated by participants with no increase in pain and a moderate level of fatigue after use. The participants generally had positive feedback regarding ReWalk. No adverse effects were noted.
- The second study included 24 participants and was designed to assess the safety and performance of ReWalk in enabling individuals with paraplegia to carry out routine ambulatory functions. Results with respect to a 12-participant subset were published in the American Journal of Physical Medicine & Rehabilitation in 2012. The results from this subset demonstrated that all participants were able to independently walk, without assistance from another person, for at least 50 meters and at least five minutes. Some participants reported improvements in pain, bowel function, bladder function and spasticity. All participants had strong positive feedback regarding the emotional and psychosocial benefits of using ReWalk. ReWalk was found to hold significant potential as a safe ambulatory powered orthotic for spinal cord injury patients. Significant performance variability was noted between participants. There were no serious adverse events reported. Five participants reported mild to moderate adverse effects, consisting of skin abrasions, lightheadedness and edema of the lower limbs. These adverse effects were managed by the appropriate use of

padding, caffeine intake and adjustment of blood pressure medication, elastic stockings and rest.

- The third study, published in The Journal of Spinal Cord Medicine in 2013, included six participants and found that participants with spinal cord injury, walking independently with ReWalk, demonstrated a stance and gait similar to that of an able-bodied individual. No adverse effects were noted.
- The fourth study, which is ongoing and includes 30 participants, was designed to assess the mobility skills and levels of training and assistance needed to use and benefit from ReWalk. Results with respect to a seven-participant subset

have been finalized and were presented at the STO Human Factors and Medicine Panel Symposium, Milan, Italy, in 2013. The results from this subset demonstrated that over the course of the training, all of the participants learned to move from sitting to standing and standing to sitting and to walk 50 to 166 meters in six minutes. Some assistance was needed for participants with the most limiting spinal cord injuries. Four of the participants were able to climb and descend stairs. The study concluded that ReWalk assisted walking can be performed independently by individuals with certain cases of spinal cord injury and that future technological advances and ongoing training could improve mobility and independence. Certain participants reported adverse effects in the form of mild to moderate skin abrasions, which were resolved with equipment adjustments, additional padding, and, in certain cases, allowing the skin to heal.

- The fifth study, published in International Journal of Physical Therapy and Rehabilitation in November 2014 reported on 16 patients who had undergone gait training using the ReWalk Rehabilitation device. These subjects demonstrated significant increases in joint range of motions for the hip and ankle joints. No adverse results were reported.
- A sixth study, which was a continuation of the fourth study mentioned above, was presented at a scientific session of the 2015 American Academy of Physical Medicine and Rehabilitation. This study demonstrated improvements in quality of life measurements for pain reduction, fatigue, and improved sleep. Restoration of physiological loading to the legs. Improvements in bowel function, seated balance and reduction in fat mass were also documented.
- A seventh study published in the Journal of Rehabilitation Research and Development in 2015 assessed heart rate and oxygen demand of powered exoskeleton-assisted walking in person with paraplegia. As part of an ongoing clinical study, eight non-ambulatory persons with paraplegia were trained to ambulate with a powered exoskeleton. Measurements of oxygen uptake and heart rate were recorded for six minutes each during each maneuver while sitting, standing, and walking. The average value of oxygen uptake and heart rate response during walking were significantly higher than for sitting and standing. Persons with paraplegia were able to ambulate efficiently using the powered exoskeleton for over-ground ambulation, providing the potential for functional gain and improved fitness. This report is the first to determine energy expenditure of powered exoskeletal-assisted walking by use of the ReWalk system in persons with SCI. Although the results of this study did not address long-term changes in oxygen demand with habitual use, routine use of the device to increase activity energy expenditure would be expected to have positive cardiopulmonary and metabolic benefits.
- An eighth study published in Topics in Spinal Cord Injury Rehabilitation in April 2015 assessed in-hospital walking velocity and level of assistance in a powered exoskeleton for persons with SCI. Twelve individuals that had SCI for 1.5 years or more who were wheelchair-users participated, and seven were able to ambulate greater than 0.4 meters per second, which is a velocity that may be conductive to outdoor activity related community ambulation. The maximum velocity recorded was 0.74 meters per second.
- A ninth publication is a case report on the effects of training with the ReWalk exoskeleton on quality of life in incomplete spinal cord injury. The study was carried out at a hospital for neurological rehabilitation in Germany. One patient, initially unable to walk independently after suffering a traumatic spinal cord injury, was recruited for this study one year after suffering such injury. The progress of the first six months of training was documented and as a primary outcome measure the quality of life was measured using the industry-standard SF-36 questionnaire. At the end of the six-month study period the patient was able to walk independently supervised by one person. Quality of life, mobility, risk of falling, motor skills and control of bladder and bowel functions were improved. A positive effect of robot-assisted gait training on various areas of quality of life was shown.

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

Community Engagement and Education

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

Sales and Marketing

We market and sell our products directly to third party payors, institutions, including rehabilitation centers, individuals and through third-party distributors. We sell our products directly in Germany and the United States and primarily through

distributors in our other markets. In our direct markets, we have established relationships with rehabilitation centers and the spinal cord injury community, and in our indirect markets, our distributors maintain these relationships. Sales of ReWalk Personal are generated primarily from the patient base at our rehabilitation centers, referrals through the spinal cord injury community and direct inquiries from potential users. One customer accounted for 14.8% and 15.0% of our total revenues for the years ended December 31, 2015 and 2014, respectively.

We have established centers of operations in Marlborough, Massachusetts, Berlin, Germany and Yokneam, Israel, to manage sales in North America, Europe, and the rest of world, respectively.

Services and Customer Support

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

Competition

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

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

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

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