

ReWalk Robotics Ltd.
Form 20-F
February 27, 2015

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 20-F

☐ REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR 12(g) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

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

For the fiscal year ended December 31, 2014

OR

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

OR

☐ SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission File Number 001-36612

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

Israel
(Jurisdiction of incorporation or organization)

P.O. Box 161
Kochav Yokneam Building, Floor 6

Yokneam Ilit 20692, Israel
(Address of principal executive offices)

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(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be 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	Nasdaq Global Market

Securities registered or to be registered pursuant to Section 12(g) of the Act: None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: None

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of December 31, 2014: 11,978,554 ordinary shares, NIS 0.01 par value per share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act

Yes ☐ No ☒

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

Yes ☐ No ☒

Indicate by 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 ☒ No ☐

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 reports).

Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act (Check one):

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒

Indicate by check mark basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP <input checked="" type="radio"/>	International Financial Reporting Standards as issued by the International Accounting Standards Board <input type="radio"/>	Other <input type="radio"/>
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If “Other” has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.

Item 17 ☐ Item 18 ☐

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act):

Yes ☐ No ☒

PRELIMINARY NOTES

Terms

As used herein, and unless the context suggests otherwise, the terms “ReWalk,” “Company,” “we,” “us” or “ours” refer to ReWalk Robotics Ltd.

Special Note Regarding Forward-Looking Statements

This annual report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), Section 21E of the Securities Exchange Act of 1934, as amended (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 similar expressions that convey uncertainty about 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 forward-looking statements. The forward-looking statements are based on our beliefs, assumptions and expectations of future performance, taking into account the information currently available to us. These statements are only predictions based upon our current expectations and projections about future events. There are important factors that could cause our actual results, levels of activity, performance or achievements to differ materially from the results, levels of activity, performance or achievements expressed or implied by the forward-looking statements. In particular, you should consider the risks provided under “Item 3.D. Key Information—Risk Factors.” in this annual report on Form 20-F.

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 on Form 20-F entitled “Item 3. Key Information—Risk Factors,” “Item 4. Information on the Company,” “Item 5. Operating and Financial Review and Prospects,” “Item 10. Additional Information—Taxation—United States Federal Income Taxation—Passive Foreign Investment Company Considerations” and elsewhere in this annual report on Form 20-F.

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 on Form 20-F, to conform these statements to actual results or to changes in our expectations.

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PART I

ITEM 1: Identity of Directors, Senior Management and Advisers

Not applicable.

ITEM 2: Offer Statistics and Expected Timetable

Not applicable.

ITEM 3: Key Information

A. Selected Financial Data

The following table presents our selected historical consolidated financial data, which is derived from our consolidated financial statements, which have been prepared in accordance with U.S. Generally Accepted Accounting Principles, or U.S. GAAP. The selected consolidated statements of operations data for the years ended December 31, 2012, 2013 and 2014 and the selected consolidated balance sheet data as of December 31, 2013 and 2014 are derived from our audited consolidated financial statements included in "Item 18. Financial Statements". The selected consolidated balance sheet data as of December 31, 2012 has been derived from our audited consolidated financial statements not included in this annual report.

You should read the following selected consolidated financial data in conjunction with, and it is qualified in its entirety by, reference to our consolidated financial statements and the related notes appearing elsewhere in this annual report and other information provided in this report, including "Item 5. Operating and Financial Review and Prospects". The historical results set forth below are not necessarily indicative of the results to be expected in future periods.

	Year Ended December 31,		
	2012	2013	2014
	(in thousands, except per share data)		
Statements of Operations Data:			
Revenues	\$ 972	\$ 1,588	\$ 3,951
Cost of revenues	983	2,017	4,106
Expense related to settlement of BIRD Foundation grants	-	-	466
Gross loss	(11)	(429)	(621)
Operating expenses:			
Research and development, net	1,757	2,463	8,563
Sales and marketing, net	2,334	4,091	7,389
General and administrative	1,657	1,762	3,352
Total operating expenses	5,748	8,316	19,304
Operating loss	(5,759)	(8,745)	(19,925)
Financial expenses, net	878	3,410	1,698
Loss before income taxes	(6,637)	(12,155)	(21,623)

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Income taxes	21	22	45
Net loss	\$ (6,658)	\$ (12,177)	\$ (21,668)
Net loss per ordinary share, basic and diluted(1)	\$ (41.26)	\$ (74.53)	\$ (6.34)
Weighted average number of shares used in computing net loss per ordinary share, basic and diluted	185,688	185,688	3,766,694

	2012	As of December 31, 2013 (in thousands)	2014
Balance Sheet Data:			
Cash and cash equivalents	\$ 769	\$ 8,860	\$ 41,829
Total assets	2,094	11,059	47,665
Accumulated deficit	(14,729)	(26,906)	(48,574)
Total shareholders' equity (deficiency)	\$ (2,264)	\$ 5,631	\$ 43,853

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

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for Offer and Use of Proceeds

Not applicable.

D. Risk Factors

Our business faces significant risks. You should carefully consider all of the information set forth in this annual report and in our other filings with the United States Securities and Exchange Commission (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 (i).

Risks Related to Our Business and Our Industry

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

We currently rely, and in the future will rely, on sales of our ReWalk systems and related service contracts and extended warranties for our revenue. ReWalk is a new product, and market acceptance and adoption depend on educating people with limited upright mobility and health care providers as to the distinct features, ease-of-use, positive lifestyle impact and other benefits of ReWalk compared to alternative technologies and treatments. ReWalk may not be perceived to have sufficient potential benefits compared with these alternatives. Users may also choose other therapies due to disadvantages of ReWalk, including the time it takes for a user to put on ReWalk, the slower pace of ReWalk compared to a wheelchair, the weight of ReWalk when carried, which makes it more burdensome for a companion to transport than a wheelchair, and the requirement that users be accompanied by a trained companion.

Also, we believe that healthcare providers tend to be slow to change their medical treatment practices because of perceived liability risks arising from the use of new products and the uncertainty of third-party reimbursement. Accordingly, healthcare providers may not recommend ReWalk until there is sufficient evidence to convince them to alter the treatment methods they typically recommend, such as prominent healthcare providers or other key opinion leaders in the spinal cord injury community recommending ReWalk as effective in providing identifiable immediate and long-term health benefits.

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

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

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

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

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

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

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

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

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

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

Although we were incorporated in 2001, we did not begin selling ReWalk Rehabilitation until 2011, and we did not begin selling ReWalk Personal in Europe until 2012. We 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 the light of the potential problems, delays, uncertainties and complications encountered in connection with a newly established business. The risks include, but are not limited to, that:

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

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

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

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

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

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

Although our interim analysis of an ongoing study demonstrates improvements in secondary physical conditions such as reduction in pain and spasticity and improving bowel and urinary tract function, decreasing pain, emotional and psychosocial benefits, the health benefits of our current ReWalk products have not been substantiated by long-term

clinical data. As a result, potential customers and healthcare providers may be slower to adopt or recommend ReWalk and third-party payors may not be willing to provide coverage or reimbursement for our products. In addition, future studies or clinical experience may indicate that treatment with our current or future ReWalk products is not superior to treatment with alternative products or therapies. Such results could slow the adoption of our products and significantly reduce our sales.

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

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

Many private third-party payors use coverage decisions and payment amounts determined by the Centers for Medicare and Medicaid Services, or CMS, which administers the Medicare program, as guidelines in setting their coverage and reimbursement policies. In the future, we will pursue economic benefit clinical studies for CMS, which we expect to demonstrate the secondary medical benefits and long-term cost savings potential of ReWalk. While we believe that a positive response from CMS in respect of such studies will broaden coverage by private insurers, we expect that it could take three to five years to receive a decision from CMS. Even with a positive decision from CMS regarding ReWalk Personal, future action by CMS or other government agencies may diminish possible payments to physicians, outpatient centers and/or hospitals that purchase ReWalk Rehabilitation, and possible payments to individuals who purchase ReWalk Personal. Additionally, a decision by CMS to provide reimbursement could influence other payors, including private insurers. If CMS declines to provide for reimbursements of ReWalk or if its reimbursement price is lower than that of other payors, ReWalk may not be reimbursed at a cost-effective level or at all. Those private third-party payors that do not follow the Medicare guidelines may adopt different coverage and reimbursement policies for purchase of ReWalk, or use of ReWalk Rehabilitation at a hospital or rehabilitation center. In addition, we expect that the purchase of ReWalk Rehabilitation systems will require the approval of senior management at hospitals or rehabilitation facilities, inclusion in the hospitals' or rehabilitation facilities' budget process for capital expenditures, and in the case of ReWalk Personal, fundraising and financial planning or assistance.

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

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

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

We also rely on third-party suppliers, which contract directly with Sanmina, to supply certain components of ReWalk. Sanmina does not have long-term supply agreements with most of 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.

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

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

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

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

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

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

There are several other companies developing technology and devices that compete with ReWalk. Our principal competitors in the medical exoskeleton market consist of Ekso Bionics, Rex Bionics, Cyberdyne, and Parker Hannifin.

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

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

We have incurred net losses since our inception.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- develop and introduce proposed products in sufficient quantities and in a timely manner;
- adequately protect our intellectual property and avoid infringing upon the intellectual property rights of third-parties;

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

obtain the necessary regulatory approvals for proposed products.

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

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

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

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

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

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

agreements.

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

The U.S. dollar is our functional and reporting currency. In 2014, most of our revenues were denominated in U.S. dollars and the remainder of our revenues was denominated in euros, most of our expenses were denominated in U.S. dollars and the remainder of our expenses was denominated in NIS and euros. In 2015, we expect that the denominations of our revenues and expenses will be consistent with what we experienced in 2014. 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, the rate of devaluation of the dollar against the shekel was approximately 2.3% in 2012, and approximately 7.0% in 2013, which was compounded by inflation in Israel at a rate of approximately 1.6% and 1.8%, respectively. This had the effect of increasing the dollar cost of our operations in Israel. If the dollar cost of our operations in Israel increases, 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 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 “Quantitative and Qualitative Disclosure About Market Risk—Foreign Currency Risk.”

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Government Regulation

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

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

Our products are regulated as medical devices in the United States under the Federal Food, Drug, and Cosmetic Act, or FDCA, as implemented and enforced by the FDA. Under the FDCA, 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. See “Item 4B. Business Overview — Government Regulation.”

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 compliance with medical device consensus standards; clinical study demonstrating testing to safe and effective use considering the level of supervision necessary and the use environment; non-clinical performance testing of the system's function and durability; and performance 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, delays or suspensions of regulatory clearances, closure of manufacturing sites, seizures or recalls of products and damage to our reputation. Recent changes in enforcement practice by the FDA, European Union and other agencies have resulted in increased enforcement activity, which increases the compliance risk that we and other companies in our industry are facing. In addition, governmental agencies may impose new requirements regarding registration, labeling or prohibited materials that may require us to modify or re-register ReWalk once it is already on the market or otherwise impact our ability to market ReWalk in those countries. The process of complying with these governmental regulations can be costly and time consuming, and could delay or prevent the production, manufacturing or sale of ReWalk.

If we or our third-party manufacturers or suppliers fail to comply with the FDA's Quality System Regulation, 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 and Sanmina and our suppliers are also subject to the regulations of foreign jurisdictions regarding the manufacturing process if we or our distributors market our products abroad. We continue to monitor our quality management in order to improve our overall level of compliance. Our facilities are subject to periodic and unannounced inspection by U.S. and foreign regulatory agencies to audit compliance with the QSR and comparable foreign regulations. If our facilities or those of Sanmina or our suppliers are found to be in violation of applicable laws and regulations, or if we or Sanmina or our suppliers fail to take satisfactory corrective action in response to an adverse inspection, the regulatory authority could take enforcement action, including any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications or repair, replacement or refunds;
- detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) marketing clearances or PMA approvals that have already been granted;
- refusing to provide Certificates for Foreign Government;
- refusing to grant export approval for our products; or
- pursuing criminal prosecution.

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

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

Medical device companies such as ours have faced lawsuits and investigations pertaining to alleged violations of numerous statutes and regulations, including anti-corruption laws and health care "fraud and abuse" laws, such as the federal False Claims Act, the federal Anti-Kickback Statute and the U.S. Foreign Corrupt Practices Act, or the FCPA. See "Business—Government Regulation." U.S. federal and state laws, including the federal Physician Payments Sunshine Act, or the Sunshine Act, and the implementation of Open Payments regulations under the Sunshine Act, require medical device companies to disclose certain payments 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.

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

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

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

Risks Related to Our Intellectual Property

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

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

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

time or at all.

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

In addition, we seek to protect our trade secrets, know-how and confidential information that is not patentable by entering into confidentiality and assignment agreements with our employees and certain of our contractors and confidentiality agreements with certain of our consultants, scientific advisors and other vendors and contractors. However, we may fail to enter into the necessary agreements, and even if entered into, these agreements may be breached or otherwise fail to prevent disclosure, third-party infringement or misappropriation of our proprietary information, may be limited as to their term and may not provide an adequate remedy in the event of unauthorized disclosure or use of proprietary information. Enforcing a claim that a third party illegally obtained and is using our trade secrets is expensive and time consuming, and the outcome is unpredictable.

We 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. See "Business—Competition." While we believe our tilt-sensor technology provides a more natural and superior method of exoskeleton activation, which creates a better user experience, a variety of other activation and control methods exist for exoskeletons, several of which are being developed by our competitors, or may be developed in the future. As a result, our patent portfolio and proprietary technology and processes may not provide us with a significant advantage over our competitors, and competitors may be able to design and sell alternative products that are equal to or superior to our products without infringing on our patents. In addition, upon the expiration of our current patents, we may be unable to adequately develop new technologies and obtain future patent protection to preserve our competitive advantage. If we are unable to maintain a competitive advantage, our business and results of operations may be materially adversely affected.

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

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

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

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

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

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

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

Infringement actions and other intellectual property claims brought against us, with or without merit, may cause us to incur substantial costs and could place a significant strain on our financial resources, divert the attention of management and harm our reputation. We cannot be certain that we will successfully defend against any allegations of

infringement. If we are found to infringe another party's patents, we could be required to pay damages. We could also be prevented from selling our products that infringe, unless we could obtain a license to use the technology covered by such patents or could redesign our products so that they do not infringe. A license may be available on commercially reasonable terms or none at all, and we may not be able to redesign our products to avoid infringement. Further, any modification to our products could require us to conduct clinical trials and revise our filings with the FDA and other regulatory bodies, which would be time consuming and expensive. In these circumstances, we may not be able to sell our products at competitive prices or at all, and our business and operating results could be harmed.

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

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

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

Many of our employees were previously employed at other medical device companies, including our competitors or potential competitors, and we may hire employees in the future that are so employed. We could in the future be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. If we fail in defending against such claims, a court could order us to pay substantial damages and prohibit us from using technologies or features that are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. If any of these technologies or features that are important to our products, this could prevent us from selling those products and could have a material adverse effect on our business. Even if we are successful in defending against these claims, such litigation could result in substantial costs and divert the attention of management.

Risks Related to Our Ordinary Shares

Our share price 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 \$11.50 per share through February 20, 2015. In addition, the market price of our ordinary shares could be highly volatile and may fluctuate substantially as a result of many factors, including, but 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 by us, our insiders or other shareholders, including upon expiration of contractual lock-up agreements;

· developments with respect to intellectual property rights;

· competition from existing or new technologies and products;

· changes in key personnel;

· the trading volume of our ordinary shares;

· changes in the estimation of the future size and growth rate of our markets; and

· general economic and market conditions.

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

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

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

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

The largest beneficial owners of our shares, entities affiliated with SCP Vitalife Partners, Yaskawa Electric Corporation, Israeli Health Care Ventures II, L.P. and entities affiliated with Pontifax (Cayman) II, L.P., beneficially own in the aggregate 48.9% of our ordinary shares. As a result, these shareholders, should they chose to act together or and even if they act individually, will exert significant influence over our operations and business strategy and would together have sufficient voting power to control the outcome of matters requiring shareholder approval. These matters may include:

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

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

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

As a foreign private issuer, we are permitted to, and do, follow certain home country corporate governance practices instead of those otherwise required under the applicable rules of the Nasdaq Global Market for domestic U.S. issuers. For instance, we follow home country practice in Israel with regard to the quorum requirement for shareholder meetings. As permitted under the Israeli Companies Law, our articles of association provide that the quorum for any

meeting of shareholders shall be the presence of at least two shareholders present in person, by proxy or by a voting instrument, who hold at least 25% of the voting power of our shares, instead of 33 % of the issued share capital as required under the applicable rules of the Nasdaq Global Market. We may in the future elect to follow home country practices in Israel with regard to other matters, including the formation and composition of compensation and nominating and corporate governance committees, separate executive sessions of independent directors and non-management directors and the requirement to obtain shareholder approval for certain dilutive events (such as for the establishment or amendment of certain equity-based compensation plans, issuances that will result in a change of control of the company, certain transactions other than a public offering involving issuances of a 20% or more interest in the company and certain acquisitions of the shares or assets of another company). Following our home country governance practices as opposed to the requirements that would otherwise apply to a U.S. company listed on the Nasdaq Global Market may provide less protection to you than what is accorded to investors under the applicable rules of the Nasdaq Global Market applicable to domestic U.S. issuers.

As a foreign private issuer, we are not subject to Regulation FD or U.S. proxy rules and are exempt from filing certain Exchange Act reports.

As a foreign private issuer, we are exempt from a number of requirements under U.S. securities laws that apply to public companies that are not foreign private issuers. In particular, we are exempt from the rules and regulations under the United States Securities Exchange Act of 1934, as amended, or the Exchange Act, related to the furnishing and content of proxy statements, we are permitted to disclose limited compensation information for our executive officers on an individual basis, and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file annual and current reports and financial statements with the SEC as frequently or as promptly as U.S. domestic companies whose securities are registered under the Exchange Act and we are generally exempt from filing quarterly reports with the SEC under the Exchange Act. We are also exempt from the provisions of Regulation FD, which prohibits the selective disclosure of material nonpublic information to, among others, broker-dealers and holders of a company's securities under circumstances in which it is reasonably foreseeable that the holder will trade in the company's securities on the basis of the information. Even though we intend to comply voluntarily with Regulation FD, these exemptions and leniencies reduce the protections and the frequency and scope of information to which you would be entitled if we were not a foreign private issuer.

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

We are an "emerging growth company" and we cannot be certain whether the reduced requirements applicable to emerging growth companies will make our ordinary shares less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As a result, we may take advantage of certain exemptions from various requirements that are applicable to other public companies that are not "emerging growth companies." Most of such requirements relate to disclosures that we would only be required to make if we cease to be a foreign private issuer in the future. Nevertheless, as a foreign private issuer that is an emerging growth company, we are not required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, for up to five fiscal years after the date of our initial public offering. We will remain an emerging growth company until the earliest of: (a) the last day of our fiscal year during which we have total annual gross revenues of at least \$1.0 billion; (b) the last day of our fiscal year following the fifth anniversary of the completion of our initial public offering; (c) the date on which we have, during the previous three-year period, issued more than \$1.0 billion in non-convertible debt; or (d) the date on which we are deemed to be a "large accelerated filer" under the Exchange Act. When we are no longer deemed to be an emerging growth company, we will not be entitled to the exemptions provided in the JOBS Act discussed above. We cannot predict if investors will find our ordinary shares less attractive as a result of our reliance on exemptions under the JOBS Act. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares and our share price may be more volatile.

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

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 market price of our ordinary shares to decline or could impair our ability to raise capital through a future sale of, or pay for acquisitions using, our equity securities. If we or our existing shareholders, particularly our largest shareholders, our directors, their affiliates, or our executive officers, sell a substantial number of our ordinary shares in the public market, the market price of our ordinary shares could decrease significantly. The perception in the public market that we or these shareholders might sell our ordinary shares could also depress the market price of our ordinary shares and could impair our future ability to obtain capital, especially through an offering of equity securities.

In connection with our initial public offering, our executive officers, our directors and the pre-IPO holders of substantially all of our then-outstanding ordinary shares and vested options entered into lock-up agreements with the underwriters. Under these agreements, until March 11, 2015, subject to limited exceptions, we and they will not directly or indirectly offer, pledge, sell, contract to sell, grant any option to purchase or otherwise dispose of any ordinary shares or any securities convertible into or exercisable or exchangeable for ordinary shares, or in any manner transfer all or a portion of the economic consequences associated with the ownership of ordinary shares, or cause a registration statement covering any ordinary shares to be filed, without the prior written consent of the designated representatives of the underwriters, who may, in their sole discretion and at any time without notice, release all or any portion of the shares subject to these lock-up agreements. As a result of these agreements, on March 11, 2015, approximately 8,528,554 shares will become available for sale, approximately 5,234,904 of which are expected to be subject to volume, manner of sale and other limitations.

Prior to our initial public offering, we entered into an Amended and Restated Shareholders' Rights Agreement with certain of our shareholders. Pursuant to that agreement, at any time after the closing of our initial public offering, subject, however, to the lock-up agreements described above, the beneficial owners of up to approximately 8.2 million shares of our ordinary shares (as of February 1, 2015) are entitled to require that we register their shares under the Securities Act for resale into the public markets. All shares sold pursuant to an offering covered by such registration statement will be freely transferable. See "Item 7. Major Shareholders and Related Party Transactions—Amended and Restated Shareholders' Rights Agreement." Any sales of securities by these shareholders could have a material adverse effect on the trading price of our ordinary shares.

On October 29, 2014, we filed a registration statement on Form S-8 under the Securities Act registering the 1,396,746 shares under our share option plans. Shares included in such registration statement became available for sale in the public market immediately after such filing, subject to vesting provisions, except for shares held by affiliates who have certain restrictions on their ability to sell. Shares registered on the Form S-8 are not subject to any of the lock-up agreements described above.

As of February 1, 2015, we had outstanding options to purchase 1,504,239 shares under our share option plans and had an additional 371,649 shares available for future grants under our option plans.

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

Generally, if for any taxable year 75% or more of our gross income is passive income, or at least 50% of the average quarterly value of our assets (which may be determined in part by the market value of our ordinary shares, which is subject to change) are held for the production of, or produce, passive income, we would be characterized as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes. Passive income for this purpose generally includes, among other things, certain dividends, interest, royalties, rents and gains from commodities and securities transactions and from the sale or exchange of property that gives rise to passive income. Passive income also includes amounts derived by reason of the temporary investment of funds, including those raised in a public offering. In determining whether a non-U.S. corporation is a PFIC, a proportionate share of the income and assets of each corporation in which it owns, directly or indirectly, at least a 25% interest (by value) is taken into account. Based on our gross income and assets and the nature of our business, we do not believe that we were a PFIC for the taxable year ending December 31, 2014. There can be no assurance that we will not be considered a PFIC for 2015 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 (assuming we are treated as publicly traded for purposes of PFIC rules), a decline in the value of our ordinary shares may result in our becoming a PFIC. If we are characterized as a PFIC, our U.S. shareholders may suffer adverse tax consequences, including having

gains realized on the sale of our ordinary shares treated as ordinary income, rather than a capital gain, the loss of the preferential rate applicable to dividends received on our ordinary shares by individuals who are U.S. Holders (as defined in “Material U.S. and Israeli Tax Consequences for our Shareholders—Material U.S. Federal Income Tax Consequences”), and having interest charges apply to distributions by us and the proceeds of share sales. Certain elections exist that may alleviate some of the adverse consequences of PFIC status and would result in an alternative treatment (such as mark-to-market treatment) of our ordinary shares; however, we do not intend to provide the information necessary for U.S. holders to make qualified electing fund elections if we are classified as a PFIC. See “Material U.S. and Israeli Tax Consequences for our Shareholders—Material U.S. Federal Income Tax Consequences—Passive Foreign Investment Company Considerations.”

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

We will not be required to comply with the internal control, evaluation, and certification requirements of Section 404 of the Sarbanes-Oxley Act and the related rules adopted by the SEC and the Public Company Accounting Oversight Board until we file our Annual Report on Form 20-F for the year ending December 31, 2015. This will be the second annual report we file with the SEC after our initial public offering. In addition, unless we lose our status as an “emerging growth company” under the JOBS Act, we will not be required to obtain an auditor attestation under Section 404 of the Sarbanes-Oxley Act until 2019. Once we no longer qualify as an “emerging growth company” under the JOBS Act, however, our independent registered public accounting firm will need to attest to the effectiveness of our internal control over financial reporting under Section 404. We have not yet commenced the process of determining whether our existing internal controls over financial reporting systems are compliant with Section 404 and whether there are any material weaknesses or significant deficiencies in our existing internal controls. This process will require the investment of substantial time and resources, including by our Chief Financial Officer and other members of our senior management. We cannot predict the outcome of this determination and whether we will need to implement remedial actions in order to implement effective control over financial reporting. The determination and any remedial actions required could result in us incurring additional costs that we did not anticipate. Irrespective of compliance with Section 404, any failure of our internal controls could have a material adverse effect on our stated results of operations and harm our reputation. As a result, we may experience higher than anticipated operating expenses, as well as higher independent auditor fees during and after the implementation of these changes. If we are unable to implement any of the required changes to our internal control over financial reporting effectively or efficiently or are required to do so earlier than anticipated, it could adversely affect our operations, financial reporting and/or results of operations and could result in an adverse opinion on internal controls from our management and independent auditors.

The requirements of being a public company may strain our resources and divert management's attention.

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, the Dodd–Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Market, and other applicable securities rules and regulations. Compliance with these rules and regulations has increased and may continue to increase our legal and financial compliance costs, make some activities more difficult, time-consuming, or costly, and increase demand on our systems and resources. As a result, management’s attention may be diverted from other business concerns, which could harm our business and operating results.

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 Relating to Our Incorporation and Location in Israel

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

Our technology development and quality headquarters, which houses substantially all of our research and development and our core research and development team, including engineers, machinists, researchers, and clinical and regulatory personnel, as well as the facility of our contract manufacturer, Sanmina, are located in Israel. Many of our employees, directors and officers are residents of Israel. Accordingly, political, economic and military conditions in Israel and the surrounding region may directly affect our business. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its Arab neighbors, Hamas (an Islamist militia and political group in the Gaza Strip) and Hezbollah (an Islamist militia and political group in Lebanon). Any hostilities involving Israel or the interruption or curtailment of trade within Israel or between Israel and its trading partners could materially and adversely affect our business, financial condition and results of operations and could make it more difficult for us to raise capital. In particular, an interruption of operations at the Tel Aviv airport related to the conflict in the Gaza Strip or otherwise could prevent or delay shipments of our components or products. Although we maintain inventory in the United States and Germany, an extended interruption could materially and adversely affect our business, financial condition and results of operations. Recent political uprisings, social unrest and violence in various countries in the Middle East and North Africa, including Israel's neighbors Egypt and Syria, are affecting the political stability of those countries. This instability may lead to deterioration of the political relationships that exist between Israel and these countries and has raised concerns regarding security in the region and the potential for armed conflict. Our commercial insurance does not cover losses that may occur as a result of an event associated with the security situation in the Middle East. Any losses or damages incurred by us could have a material adverse effect on our business. In addition, Iran has threatened to attack Israel and is widely believed to be developing nuclear weapons. Iran is also believed to have a strong influence among parties hostile to Israel in areas that neighbor Israel, such as the Syrian government, Hamas in Gaza and Hezbollah in Lebanon. Any armed conflicts, terrorist activities or political instability in the region could materially and adversely affect our business, financial condition and results of operations.

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

Many Israeli citizens are obligated to perform one month, and in some cases more, of annual military reserve duty until they reach the age of 45 (or older, for reservists with certain occupations) and, in the event of a military conflict, may be called to active duty. In response to terrorist activity, there have been periods of significant call-ups of military reservists. For example, the Israeli armed forces called up a significant number of reservists to active duty in connection with the recent conflict in the Gaza Strip. It is possible that there will be additional military reserve duty call-ups in the future in connection with this conflict or otherwise. Although these call-ups have not had a material impact on our operations or on Sanmina's ability to manufacture our products, our operations and the operations of Sanmina could be disrupted by such call-ups.

Our sales may be adversely affected by boycotts of Israel.

Several countries, principally in the Middle East, restrict doing business with Israel and Israeli companies, and additional countries may impose restrictions on doing business with Israel and Israeli companies whether as a result of hostilities in the region or otherwise. In addition, there have been increased efforts by activists to cause companies and consumers to boycott Israeli goods based on Israeli government policies. Such actions, particularly if they become more widespread, may adversely impact our ability to sell our products.

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

Some of our operations in Israel, referred to as “Beneficiary Enterprises,” carry certain tax benefits under the Israeli Law for the Encouragement of Capital Investments, 5719-1959, or the Investment Law. Substantially all of our future income before taxes can be attributed to these programs. If we do not meet the requirements for maintaining these benefits or if our assumptions regarding the key elements affecting our tax rates are rejected by the tax authorities, they may be reduced or cancelled and the relevant operations would be subject to Israeli corporate tax at the standard rate, which is currently set at 26.5% for 2014 and thereafter. In addition to being subject to the standard corporate tax rate, we could be required to refund any tax benefits that we may receive in the future, plus interest and penalties thereon. Even if we continue to meet the relevant requirements, the tax benefits that our current “Beneficiary Enterprises” receive may not be continued in the future at their current levels or at all. If these tax benefits were reduced or eliminated, the amount of taxes that we pay would likely increase, as all of our Israeli operations would consequently be subject to corporate tax at the standard rate, which could adversely affect our results of operations. Additionally, if we increase our activities outside of Israel, for example, by way of acquisitions, our increased activities may not be eligible for inclusion in Israeli tax benefit programs. See “Taxation and Israeli Government Programs Applicable to Our Company—Law for the Encouragement of Capital Investments, 5719-1959” for additional information concerning these tax benefits and Note 11g to our consolidated financial statements for a discussion of our current tax obligations.

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

From our inception through December 31, 2014, we received a total of \$0.5 million from the Office of the Chief Scientist in the Israel Ministry of Economy, or OCS. We may in the future apply to receive additional grants from the OCS to support our research and development activities. With respect to such grants we are committed to pay royalties at a rate of 3% to 3.5% on sales proceeds up to the total amount of grants received, linked to the dollar and bearing interest at an annual rate of LIBOR applicable to dollar deposits. Even after payment in full of these amounts, we will still be required to comply with the requirements of the Israeli Encouragement of Industrial Research and Development Law, 1984, or the R&D Law, and related regulations, with respect to those past grants. When a company develops know-how, technology or products using OCS grants, the terms of these grants and the R&D Law restrict the transfer outside of Israel of such know-how, and the manufacturing or manufacturing rights of such products, technologies or know-how, without the prior approval of the OCS. Therefore, if aspects of our technologies are deemed to have been developed with OCS funding, the discretionary approval of an OCS committee would be required for any transfer to third parties outside of Israel of know-how or manufacturing or manufacturing rights related to those aspects of such technologies. Furthermore, the OCS may impose certain conditions on any arrangement under which it permits us to transfer technology or development out of Israel or may not grant such approvals at all.

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

In addition to the above, any non-Israeli citizen, resident or entity that, among other things, (i) becomes a holder of 5% or more of our share capital or voting rights, (ii) is entitled to appoint one or more of our directors or our chief executive officer or (iii) serves as one of our directors or as our chief executive officer (including holders of 25% or more of the voting power, equity or the right to nominate directors in such direct holder, if applicable) is required to notify the OCS and undertake to comply with the rules and regulations applicable to the grant programs of the OCS, including the restrictions on transfer described above.

We may become subject to claims for remuneration or royalties for assigned service invention rights by our employees, which could result in litigation and adversely affect our business.

A significant portion of our intellectual property has been developed by our employees in the course of their employment for us. Under the Israeli Patent Law, 5727-1967, or the Patent Law, and recent decisions by the Israeli Supreme Court and the Israeli Compensation and Royalties Committee, a body constituted under the Patent Law, employees may be entitled to remuneration for intellectual property that they develop for us unless they explicitly waive any such rights, although the validity of any such waivers remains open to judicial review. Although we enter into agreements with our employees pursuant to which they agree that any inventions created in the scope of their employment or engagement are owned exclusively by us, we may face claims demanding remuneration. As a consequence of such claims, we could be required to pay additional remuneration or royalties to our current and former employees, or be forced to litigate such claims, which could negatively affect our business.

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

Israeli corporate law regulates mergers, requires tender offers for acquisitions of shares above specified thresholds, requires special approvals for transactions involving directors, officers or significant shareholders and regulates other matters that may be relevant to such types of transactions. For example, a tender offer for all of a company's issued and outstanding shares can only be completed if the acquirer receives positive responses from the holders of at least 95% of the issued share capital. Completion of the tender offer also requires approval of a majority of the offerees that do not have a personal interest in the tender offer, unless at least 98% of the company's outstanding shares are tendered. Furthermore, the shareholders, including those who indicated their acceptance of the tender offer (unless the acquirer stipulated in its tender offer that a shareholder that accepts the offer may not seek appraisal rights), may, at any time within six months following the completion of the tender offer, petition an Israeli court to alter the consideration for the acquisition. See "Item 10B. Articles of Association — Acquisitions under Israeli Law" for additional information.

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

Furthermore, Israeli tax considerations may make potential transactions unappealing to us or to our shareholders whose country of residence does not have a tax treaty with Israel exempting such shareholders from Israeli tax. For example, Israeli tax law does not recognize tax-free share exchanges to the same extent as U.S. tax law. With respect to mergers involving an exchange of shares, Israeli tax law allows for tax deferral in certain circumstances but makes the deferral contingent on the fulfillment of a number of conditions, including, in some cases, a holding period of two years from the date of the transaction during which sales and dispositions of shares of the participating companies are subject to certain restrictions. Moreover, with respect to certain share swap transactions, the tax deferral is limited in time, and when such time expires, the tax becomes payable even if no disposition of the shares has occurred. These and other similar provisions could delay, prevent or impede an acquisition of us or our merger with another company, even if such an acquisition or merger would be beneficial to us or to our shareholders.

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

We are incorporated in Israel. The majority of our directors and executive officers reside outside of the United States, and most of our assets and most of the assets of these persons are located outside of the United States. Therefore, a judgment obtained against us, or any of these persons, including a judgment based on the civil liability provisions of

the U.S. federal securities laws, may not be collectible in the United States and may not be enforced by an Israeli court. It also may be difficult for you to effect service of process on these persons in the United States or to assert U.S. securities law claims in original actions instituted in Israel. Israeli courts may refuse to hear a claim based on an alleged violation of U.S. securities laws reasoning that Israel is not the most appropriate forum in which to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proven as a fact by expert witnesses, which can be a time-consuming and costly process. Certain matters of procedure will also be governed by Israeli law. There is little binding case law in Israel that addresses the matters described above. As a result of the difficulty associated with enforcing a judgment against us in Israel, you may not be able to collect any damages awarded by either a U.S. or foreign court.

Your rights and responsibilities as a shareholder will be governed by Israeli law which differs in some material respects from the rights and responsibilities of shareholders of U.S. companies.

The rights and responsibilities of the holders of our ordinary shares are governed by our articles of association and by Israeli law. These rights and responsibilities differ in some material respects from the rights and responsibilities of shareholders in U.S.-based corporations. In particular, a shareholder of an Israeli company has a duty to act in good faith and in a customary manner in exercising its rights and performing its obligations towards the company and other shareholders, and to refrain from abusing its power in the company, including, among other things, in voting at a general meeting of shareholders on matters such as amendments to a company's articles of association, increases in a company's authorized share capital, mergers and acquisitions and related party transactions requiring shareholder approval. In addition, a shareholder who is aware that it possesses the power to determine the outcome of a shareholder vote or to appoint or prevent the appointment of a director or executive officer in the company has a duty of fairness toward the company. There is limited case law available to assist us in understanding the nature of this duty or the implications of these provisions. These provisions may be interpreted to impose additional obligations and liabilities on holders of our ordinary shares that are not typically imposed on shareholders of U.S. corporations.

ITEM 4: Information on the Company

A. History and Development of ReWalk

Our History

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. In September 2015, we listed our shares on the Nasdaq Global Market. Our principal executive offices are located at Kochav Yokneam Building, Floor 6 P.O. Box 161, Yokneam Ilit 20692, Israel, and our telephone number is +972 (4) 959-0123. Our website address is www.rewalk.com. Information contained on, 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. 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.

We had capital expenditures of \$0.1 million, \$0.2 million and \$0.2 million in 2012, 2013 and 2014, respectively. We have financed our capital expenditures with cash generated from proceeds from sales of our equity securities. Our capital expenditures during 2012, 2013 and 2014 consisted primarily of computers and office equipment, machinery and laboratory equipment.

B. Business Overview

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

Current ReWalk designs are intended for people with paraplegia, a spinal cord injury resulting in complete or incomplete paralysis of the legs, who have the use of their upper bodies and arms. We currently offer two products: ReWalk Personal and ReWalk Rehabilitation. ReWalk Personal is designed for everyday use by individuals at home and in their communities, and is custom-fit for each user. ReWalk Rehabilitation is designed for the clinical

rehabilitation environment where it provides valuable exercise and therapy. It also enables individuals to evaluate their capacity for using ReWalk Personal in the future. In 2011, we launched ReWalk Rehabilitation for use in hospitals and rehabilitation centers in the United States and Europe. We began marketing ReWalk Personal in Europe with CE mark clearance at the end of 2012 and received FDA clearance to market it in the United States in June 2014. ReWalk is the first exoskeleton cleared by the FDA for personal use. In January 2015, we received regulatory approval to distribute ReWalk systems in Australia from the Therapeutic Goods Administration, or 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 changes in the user's center of gravity. A forward tilt of the upper body is sensed by the system, which initiates the first step. Repeated body shifting generates a sequence of steps which allows for natural gait with functional walking speed. Because the exoskeleton supports its own weight, users do not expend unnecessary energy while walking. While ReWalk does not allow side-to-side actuation, users are able to turn by shifting their weight to the side. ReWalk also allows users to sit, stand and, in some cases, climb and descend stairs. ReWalk users are able to independently operate the devices, and most are able to put on and remove the devices by themselves. However, our safety guidelines and FDA specifications require users to be accompanied by a trained companion.

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

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

Development of ReWalk took over a decade and was spurred by the experiences of our founder, Dr. Amit Goffer, himself a quadriplegic. As of December 31, 2014, we had 84 units in use at rehabilitation centers and 54 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, 87.1% of persons with spinal cord injuries are sent to private, non-institutional residences (in most cases, their homes) after hospital discharge. As a result, while the majority of our sales to date have been ReWalk Rehabilitation units, the primary focus of our commercialization efforts going forward will be marketing ReWalk Personal for routine use at home, work or in the community, and we expect sales of ReWalk Personal to account for the substantial majority of our revenues in the future.

We expect to generate revenues from a combination of self-payors and third-party payors. While no uniform policy of coverage and reimbursement by third-party payors currently exists for electronic exoskeleton technologies such as ReWalk, we plan to pursue various paths of reimbursement and support fundraising efforts by institutions and clinics.

In July 2014, the James J. Peters VA hospital (Bronx, New York) announced that it would be fully committed to supporting the procurement of ReWalk Personal and providing the staffing support needed for all eligible veterans with spinal cord injury for whom ReWalk is clinically indicated. As the first hospital to research the health-related benefits of an exoskeletal walking device for people with spinal cord injury, the Bronx VA experience supports the clinical use of ReWalk and similar FDA-approved technologies. We believe that additional VAs will adopt similar policies in the future.

As of February 25, 2015, two private insurers in the United States and four insurers in Germany have agreed to provide reimbursement in certain cases.

Our Competitive Strengths

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

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

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

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

Strategic Alliance with Yaskawa Electric Corporation. We have entered into a strategic alliance with Yaskawa Electric Corporation, a global leader in the fields of industrial robotics and automation. Pursuant to this arrangement, Yaskawa will serve as our distributor in certain Asian markets, where its name and brand recognition provide us with opportunities for growth and market penetration and can apply its expertise for product and quality improvements to ReWalk. We believe that this arrangement with such a prominent company is unique in this industry. Yaskawa also made an equity investment in our company. In addition, in the future, subject to any necessary regulatory clearance, we may market and sell in the United States and Europe certain healthcare equipment products that Yaskawa is currently developing. See "Item 7. Major Shareholders and Related Party Transactions—Series D Preferred Share Purchase Agreement" and "—Agreements with Yaskawa."

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

Experienced Management Team and Employees with Personal Experience with Paralysis. Our senior management team has significant experience in the medical device, technology and robotics industries, with an average of over 20 years of experience. The experiences of Dr. Amit Goffer, our founder, President and Chief Technology Officer, and

the inventor of ReWalk, who has been paralyzed since 1997, have been one of the greatest drivers in the development and refinement of ReWalk. Additionally, certain of our sales and marketing and research and development employees are paraplegic, which provides us with invaluable perspective to advance the development of our products.

Our Growth Strategies

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

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

Expand Geographic Coverage. We intend to increase our presence in the United States in response to receipt of FDA clearance for ReWalk Personal. We also plan to expand into new geographies throughout Europe and Asia.

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

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

Overview of Spinal Anatomy and Spinal Cord Injury

Spinal Anatomy

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

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

Spinal Cord Injury

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

Image of Separated Spinal Cord of an Adult

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

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

Market Opportunity

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

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

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

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

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

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

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

Our Solutions

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

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

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

- **ReWalk Personal:** intended for everyday use at home, at work or in the community. We began marketing ReWalk Rehabilitation Personal in Europe with CE mark clearance at the end of 2012. We received clearance to market ReWalk Personal in the United States in June 2014. ReWalk Personal units are all manufactured according to the same specifications. Each unit is then permanently sized to fit the individual user and the software is configured for the user's specifications by the rehabilitation center, clinic or distributor.
- **ReWalk Rehabilitation:** designed for the clinical rehabilitation environment, ReWalk Rehabilitation has adjustable sizing enabling multiple patient use. ReWalk Rehabilitation provides a valuable means of exercise and therapy. It also enables individuals to evaluate their capacity for using ReWalk Personal in the future. We began marketing ReWalk Rehabilitation for use in hospitals, rehabilitation centers and stand-alone training centers in the United States and Europe in 2011. ReWalk Rehabilitation units are all manufactured according to the same specifications and are equipped with adjustable sizing for multi-patient use.

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

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

ReWalk users must have healthy hands and shoulders, weigh less than 220 pounds (100 kilograms) and be between 5 feet 1 inch and 6 feet 3 inches (1.55 meters and 1.87 meters). Based on U.S. Census Bureau data, the spinal cord injury population gender and age statistics and data from the Spinal Cord Model Systems report, we estimate that approximately 80% of persons with spinal cord injury in the United States comply with these restrictions and other requirements for current and future ReWalk products. ReWalk systems have an estimated useful life of five years and come with a two year warranty covering all elements beyond normal wear and tear. As part of the warranty, users receive software upgrades and an annual inspection. We offer extended warranties for purchase and, outside of the warranty program, provide repairs and service on a fee-for-service basis. ReWalk batteries, which are covered by our warranties, have an estimated life of approximately 600 charges, which for a typical user lasts two to three years.

ReWalk-Q

We are currently developing our next generation of ReWalk, with a more efficient drive mechanism, slimmer profile and lighter body, as well as other improvements. We are also developing ReWalk-Q for individuals with quadriplegia who are unable to hold crutches, which will include attached

crutches with wheels. We expect to complete the development of ReWalk-Q in the near future, at which time we will begin clinical testing and apply for regulatory clearances. We plan to expand the designs and indications that we address beyond paraplegia and quadriplegia to include other disabilities affecting gait and ability to walk, such as multiple sclerosis, stroke and cerebral palsy.

Reimbursements and Other Funding Sources

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

Third-Party Reimbursements

United States

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

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

Private insurance companies do not currently cover or provide reimbursement for any personal medical exoskeleton products, including ReWalk Personal, 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 30 such cases pending in Germany, and we believe that these will result in eventual coverage. We plan to continue to pursue this case-by-case strategy and expect that once the precedent for coverage is established, seeking coverage will become easier and more routine. We continue to support clinical research and academic publications, which we believe will further support the case for coverage.

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

Other Funding Sources

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

Research and Development

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

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

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

Our research and development efforts have been financed, in part, through funding from the OCS and from the BIRD Foundation. From our inception through December 31, 2014, we received funding totaling \$0.5 million from the OCS and \$0.5 million from the BIRD Foundation. For more information regarding these arrangement, see "Item 5. Operating and Financial Review and Prospects—Liquidity and Capital Resources" and "—Grants and Other Funding."

In September 2013, we entered into a strategic alliance with Yaskawa Electric Corporation, pursuant to which, among other arrangements, Yaskawa can apply its expertise product and quality improvements to ReWalk. Yaskawa is a global leader in the fields of industrial robotics and automation, and we believe that this relationship provides us with opportunities for product improvement and increased product offerings in the future. For more information regarding our relationship with Yaskawa, see "—Sales and Marketing" and "Item 7. Major Shareholders and Related Party Transactions."

Clinical Studies

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

- The first study, published in The Journal of Spinal Cord Medicine in 2012, included six participants and was designed to assess the safety and tolerance of use of ReWalk by patients with a spinal cord injury. The participants were all able to walk 100 meters with ReWalk. The study found no adverse safety events (which included falls, status of the skin, status of the spine and joints, blood pressure, pulse and electrocardiography) and concluded that use of ReWalk was well-tolerated by participants with no increase in pain and a moderate level of fatigue after use. The participants generally had positive feedback regarding ReWalk. No adverse effects were noted.
- The second study included 24 participants and was designed to assess the safety and performance of ReWalk in enabling individuals with paraplegia to carry out routine ambulatory functions. Results with respect to a 12-participant subset were published in the American Journal of Physical Medicine & Rehabilitation in 2012. The

results from this subset demonstrated that all participants were able to independently walk, without assistance from another person, for at least 50 meters and at least five minutes. Some participants reported improvements in pain, bowel function, bladder function and spasticity. All participants had strong positive feedback regarding the emotional and psychosocial benefits of using ReWalk. ReWalk was found to hold significant potential as a safe ambulatory powered orthotic for spinal cord injury patients. Significant performance variability was noted between participants. There were no serious adverse events reported. Five participants reported mild to moderate adverse effects, consisting of skin abrasions, lightheadedness and edema of the lower limbs. These adverse effects were managed by the appropriate use of padding, caffeine intake and adjustment of blood pressure medication, elastic stockings and rest.

- The third study, published in The Journal of Spinal Cord Medicine in 2013, included six participants and found that participants with spinal cord injury, walking independently with ReWalk, demonstrated a stance and gait similar to that of an able-bodied individual. No adverse effects were noted.
- The fourth study, which is ongoing and includes 30 participants, was designed to assess the mobility skills and levels of training and assistance needed to use and benefit from ReWalk. Results with respect to a seven-participant subset have been finalized and were presented at the STO Human Factors and Medicine Panel Symposium, Milan, Italy, in 2013. The results from this subset demonstrated that over the course of the training, all of the participants learned to move from sitting to standing and standing to sitting and to walk 50 to 166 meters in six minutes. Some assistance was needed for participants with the most limiting spinal cord injuries. Four of the participants were able to climb and descend stairs. The study concluded that ReWalk assisted walking can be performed independently by individuals with certain cases of spinal cord injury and that future technological advances and ongoing training could 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.

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

Community Engagement and Education

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

Sales and Marketing

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

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

We also maintain arrangements with third-party distributors in Europe and Asia-Pacific.

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

In September 2013, we entered into a strategic alliance with Yaskawa Electric Corporation, in connection with which Yaskawa has agreed to be our exclusive distributor in certain Asian markets. We believe that this relationship provides us with a significant opportunity for growth in Asia. Our arrangement with Yaskawa also provides that in the future, subject to any necessary regulatory clearance, we may market and sell certain of Yaskawa's healthcare equipment products currently under development in the United States and Europe. For more information regarding our relationship with Yaskawa, see "Item 7. Major Shareholders and Related Party Transactions."

Services and Customer Support

Our centers of operations in Marlborough, Massachusetts and Berlin, Germany coordinate all service functions for North America and Europe, respectively, through dedicated technical service personnel and customer service call centers. We aim to provide high-level support to our customers to build long-standing relationships. The following are the main categories of service and customer support functions that we provide:

- Training. We provide on-site, hands-on, basic and advanced technical training for health care providers. These providers, who then train individual users, are subject to rigorous training and certification requirements. We have also implemented a rigorous, multi-level training and licensure program for users and their companions. We believe that these training programs serve an important safety and support function.
- Communications Centers. We operate communications centers in our U.S. and Germany locations, which provide support hotlines, installation, maintenance, and periodic, preventive servicing. Outside of our direct markets, service functions are generally coordinated through our third-party distributors.
- Spare Parts and Logistics Channels. We operate warehouses in the U.S., Germany and Israel, which house our inventory, parts and accessories.

Competition

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

We are aware of a number of other companies developing competing technology and devices, and some of these competitors may have greater resources, greater name recognition, broader product lines, or larger customer bases than we do. Our principal competitors in the medical exoskeleton market consist of Ekso Bionics (OTC: EKS0), Rex

Bionics (London Stock Exchange: RXB), Cyberdyne (Tokyo Stock Exchange: 7779), and Parker Hannifin (NYSE: PH). We believe we have key competitive advantages over these companies, such as our tilt-sensor technology that provides a self-initiated walking experience, more natural gait and functional walking speed, slimmer and lighter design, ReWalk's ability to support its own weight and broad user specifications. Additionally, we are not aware of any medical exoskeleton product that is cleared or in the process of seeking clearance from the FDA for personal use. ReWalk Personal is the first medical exoskeleton cleared by the FDA for personal use in the United States.

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

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

Intellectual Property

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

As of February 25, 2015, we have four issued patents in the United States and one issued patent in Europe, as well as six pending patent applications in various countries around the world for our technology. As such, we have apparatus patent claims in the United States and Europe covering aspects of ReWalk and similar devices which use a plurality of sensors to empower tilt-sensor technology. In addition, in the United States, we have method patent claims covering certain methods of user activation and control of systems such as ReWalk, including by sensing the users' torso lean or weight shifts. While our apparatus claims focus on protecting ReWalk in terms of its physical and structural characteristics, we believe that our method claims, which protect the process behind how ReWalk is controlled by the user, provide additional protection for our tilt sensor technology. We do not currently license any of the technology contained in our products other than with respect to technology that is generally publicly available, but we may do so in the future.

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

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

The employment agreement of our founder, Dr. Amit Goffer, provides that a patent pending relating to a standing wheelchair is his individual property and that he may independently engage in the development of a standing wheelchair. The agreement also provides that we and any of our affiliates or successors have the royalty-free right to the exclusive use in the field of exoskeletons of any intellectual property developed by Dr. Goffer, alone or jointly with others (whether or not as part of the development of a standing wheelchair and whether or not developed through a company), while he is our employee, consultant or board member and for three years thereafter. See "'Item 7. Major Shareholders and Related Party Transactions — Arrangements with Founder.'"

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

Government Regulation

U.S. Regulation

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

Premarket Regulation

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

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

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

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

In June 2014, the FDA granted our petition for “de novo” classification, which provides a route to market for medical devices that are low to moderate risk, but are not substantially equivalent to a predicate device, and classified ReWalk as Class II subject to special controls. The ReWalk is intended to enable individuals with spinal cord injuries to perform ambulatory functions under supervision of a specially trained companion, and inside rehabilitation institutions. The special controls established in the de novo order include compliance with medical device consensus standards; clinical study demonstrating testing to safe and effective use considering the level of supervision necessary and the use environment; non-clinical performance testing of the system’s function durability and performance 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.

Postmarket Regulation

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

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

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

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

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

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

refusal to grant export approvals for our products; or

criminal prosecution.

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

Foreign Regulation

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

In Australia, the TGA is responsible for administering the Australian Therapeutics Goods Act. The Office of Devices, Blood and Tissues is the department within the TGA responsible for devices. The TGA recognizes five classes of medical devices and ReWalk falls under the category of Class II for low-medium risk medical devices.

The Australian Register of Therapeutic Goods, or ARTG, is the register of information about therapeutic goods for human use that may be imported, supplied in, or exported from Australia. Medical devices cannot generally be imported, supplied in, or exported from Australia unless they are included in the ARTG. To clinically investigate a product that is not included in the ARTG, or to use a registered or listed product in a clinical trial beyond the conditions of its marketing approval, the sponsor must receive approval of an application from the TGA under the Clinical Trial Exemption Scheme, or must submit a notification to the Human Research Ethics Committee under the Clinical Trial Notification Scheme and receive approval from the institution or organization at which the trial will be conducted.

In January 2015, we received regulatory approval to sell ReWalk systems commercially in Australia from the TGA, and as such, are subject to regulation in Australia.

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

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

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

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

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

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, the PPACA. The PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them. In addition, the PPACA provides that the government may assert that a claim that includes items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act. The PPACA also imposes new reporting and disclosure requirements on device manufacturers for any “transfer of value” made or distributed to physicians and teaching hospitals. Device manufacturers will also be required to report and disclose any investment interests held by physicians and their immediate family members during the preceding calendar year. A number of provisions of PPACA also reflect increased focus on and funding of healthcare fraud enforcement.

Environmental Matters

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

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

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

registration of certain chemicals we use and ship. We believe we are in compliance in all material respects with applicable environmental laws and regulations.

Manufacturing

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

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

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

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

Suppliers

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

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

Employees

As of December 31, 2014, we had 66 employees, of whom 20 are located in the United States, 33 are located in Israel and 13 are located in Germany. As of December 31, 2013, we had 45 employees, of whom 10 were located in the United States, 27 were located in Israel and eight were located in Germany, and as of December 31, 2012, we had 28 employees, of whom eight were located in the United States and 20 were located in Israel. 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.

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

The employees of our U.S. and German subsidiaries are subject to local labor laws and regulations.

C. Organizational Structure

The following is a list of our significant subsidiaries, including the name and country of incorporation or residence. Each of our significant subsidiaries is wholly-owned by us.

Name of Subsidiary	Place of Incorporation
ReWalk Robotics, Inc.	