

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

FORM 10-K

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

For the fiscal year ended December 31, 2021

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-36612



**ReWalk Robotics Ltd.**

(Exact name of registrant as specified in charter)

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

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

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

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Ordinary Shares, par value NIS 0.25 per share	RWLK	Nasdaq Capital Market

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

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

Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes ☐ No ☒

Indicate by a check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files).

Yes ☒ No ☐

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

Large accelerated filer ☐

Non-accelerated filer ☒

Accelerated filer ☐

Smaller reporting company ☒

Emerging growth company ☐

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

Indicate by check mark whether the registrant has filed a report on and attestation to its management’s assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 USC. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

The aggregate market value of the Ordinary Shares held by non-affiliates of the Registrant based upon the closing price of the Ordinary Shares as reported by the Nasdaq Capital Market on June 30, 2021 (the last business day of the Registrant’s most recently completed second fiscal quarter) was \$77,594,282.

As of February 24, 2022, the Registrant had outstanding 62,507,717 Ordinary Shares, par value NIS 0.25 per share.

#### **DOCUMENTS INCORPORATED BY REFERENCE**

Portions of our proxy statement for our 2022 Annual Meeting of Shareholders, which is to be filed within 120 days after the end of our 2021 fiscal year, are incorporated by reference into Part III of this annual report on Form 10-K.

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## Definitions and Introduction

Our legal and commercial name is ReWalk Robotics Ltd. We are a company limited by shares organized under the laws of the State of Israel and were founded in 2001. In September 2014, we listed our shares on the Nasdaq Global Market, and in May 2017, we transferred our listing to the Nasdaq Capital Market. We have irrevocably appointed ReWalk Robotics, Inc. as our agent to receive service of process in any action against us in any United States federal or state court. The address of ReWalk Robotics, Inc. is 200 Donald Lynch Blvd., Marlborough, Massachusetts 01752. As used herein, and unless the context clearly indicates otherwise, the terms “ReWalk”, “the Company”, “we”, “us”, “our” or “ours” refer to ReWalk Robotics Ltd. and its subsidiaries.

## Special Note Regarding Forward-Looking Statements and Risk Factors Summary

This annual report on Form 10-K (“annual report”) contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, that are based on our management’s beliefs and assumptions and on information currently available to our management. Forward-looking statements include information concerning our possible or assumed future results of operations, business strategies, financing plans, competitive position, industry environment, potential growth opportunities, potential market opportunities and the effects of competition. Forward-looking statements may include projections regarding our future performance and, in some cases, can be identified by words like “anticipate,” “assume,” “believe,” “could,” “seek,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “future,” “should,” “will,” “would” or similar expressions that convey uncertainty of future events or outcomes and the negatives of those terms. These statements may be found in the sections of this annual report titled “Part I. Item 1. Business,” “Part I. Item 1A. Risk Factors,” “Part II. Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this annual report. The statements are based on our beliefs, assumptions and expectations of future performance, taking into account the information currently available to us. These statements are only predictions based upon our current expectations and projections about future events. There are important factors that could cause our actual results, levels of activity, performance or achievements to differ materially from the results, levels of activity, performance or achievements expressed or implied by the statements.

These factors include those listed in “Part I. Item 1A. Risk Factors,” as summarized below.

- our expectations regarding future growth, including our ability to increase sales in our existing geographic markets and 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 or advance Centers for Medicare & Medicaid Services (“CMS”) coverage for our products;
- Our ability to maintain compliance with the continued requirements of the Nasdaq Capital Market and the risk that our ordinary shares will be delisted if we do not comply with such requirements;
- the adverse effect that the COVID-19 pandemic has had and continues to have on our business and results of operations;
- our ability to have sufficient funds to meet certain future capital requirements, which could impair our efforts to develop and commercialize existing and new products;
- our limited operating history and our ability to leverage our sales, marketing and training infrastructure;
- our ability to grow our business through acquisitions of businesses, products or technologies, and the failure to manage acquisitions, or the failure to integrate them with our existing business, which could have a material adverse effect on our business, financial condition, and operating results;
- our expectations as to our clinical research program and clinical results;
- our ability to obtain certain components of our products from third-party suppliers and our continued access to our product manufacturers;
- our ability to improve our products and develop new products;
- our compliance with medical device reporting regulations to report adverse events involving our products, which could result in voluntary corrective actions or enforcement actions such as mandatory recalls, and the potential impact of such adverse events on our ability to market and sell our products;

- our ability to gain and maintain regulatory approvals and to comply with any post-marketing requests
- the risk of a cybersecurity attack or breach of our information technology systems significantly disrupting our business operations;
- our ability to maintain adequate protection of our intellectual property and to avoid violation of the intellectual property rights of others;
- the impact of substantial sales of our shares by certain shareholders on the market price of our ordinary shares;
- our ability to use effectively the proceeds of our offerings of securities;
- the risk of substantial dilution resulting from the periodic issuances of our ordinary shares;
- the impact of the market price of our ordinary shares on the determination of whether we are a passive foreign investment company;
- market and other conditions; and
- other factors discussed in “Part I. Item 1A. Risk Factors.”

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.

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

#### **Where You Can Find Other Information**

Our principal executive offices are located at 3 Hatnufa Street, Floor 6, Yokneam Ilit 2069203, Israel, and our telephone number is +972 (4) 959-0123. Our website is [www.rewalk.com](http://www.rewalk.com). Information contained, or that can be accessed through, our website does not constitute a part of this annual report and is not incorporated by reference herein. We have included our website address in this annual report solely for informational purposes. Information that we furnish or file with the Securities and Exchange Commission, or the SEC, including annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to, or exhibits included in, these reports are available for download, free of charge, on our website as soon as reasonably practicable after such materials are filed or furnished with the SEC. The SEC also maintains a website at [www.SEC.gov](http://www.SEC.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. Our SEC filings, including exhibits filed or furnished therewith, are also available on this website.

## PART I

### ITEM 1. BUSINESS

#### Overview

We are an innovative medical device company that is designing, developing, and commercializing robotic exoskeletons that allow individuals with mobility impairments or other medical conditions the ability to stand and walk once again. We have developed and are continuing to commercialize our ReWalk Personal and ReWalk Rehabilitation devices for individuals with spinal cord injury (“SCI Products”), which are exoskeletons designed for individuals with paraplegia that use our patented tilt-sensor technology and an on-board computer and motion sensors to drive motorized legs that power movement.

We have also developed our ReStore device, which we began commercializing in June 2019. ReStore is a powered, lightweight soft exo-suit intended for use in the rehabilitation of individuals with lower limb disability due to stroke. During the second quarter of 2020, we finalized and moved to implement two separate agreements to distribute additional product lines in the United States. We are the exclusive distributor of the MediTouch Tutor movement biofeedback systems in the United States and have distribution rights for the MYOLYN MyoCycle FES cycles to U.S. rehabilitation clinics and personal sales through the U.S. Department of Veterans Affairs (“VA”) hospitals and other personal sales. We refer to the MediTouch and MyoCycle devices as our “Distributed Products.” These Distributed Products will improve our product offering to clinics as well as patients within the VA as they both have similar clinician and patient profile.

We are in the research stage of ReBoot, a soft exoskeleton for stroke home and community use. This product is a complementary product to ReStore as it provides ankle support including plantar flexion for gait and mobility improvement, and it received Breakthrough Device Designation from the U.S. Food and Drug Administration (“FDA”) in November 2021.

Our principal markets are the United States and Europe. In Europe, we have a direct sales operation in Germany and work with distribution partners in certain other major countries. We have offices in Marlborough, Massachusetts, Berlin, Germany and Yokneam, Israel, from where we operate our business.

We have in the past generated and expect to generate in the future revenues from a combination of third-party payors (including private and government payors) and self-pay individuals. While a broad uniform policy of coverage and reimbursement by third-party commercial payors currently does not exist in the United States for electronic exoskeleton technologies such as the ReWalk Personal, we are pursuing various paths of reimbursement and support fundraising efforts by institutions and clinics, such as the VA policy that was issued in December 2015 for the evaluation, training, and procurement of ReWalk Personal exoskeleton systems for all qualifying veterans suffering from spinal cord injury (“SCI”) across the United States.

We have also been pursuing a coverage policy with the Centers for Medicare and Medicaid Services (“CMS”), which reported in 2017 that it covers approximately 55% of the spinal cord injury population which are at least five years post their injury date. In July 2020, following a successful submission and hearing process, a code was issued for ReWalk Personal 6.0 (effective October 1, 2020), which may later be followed by a coverage policy of CMS. We are currently seeking to identify the relevant Medicare product category with CMS.

In Germany, we continue to make progress toward achieving coverage from the various government, private and worker’s compensation payors for our SCI products. In September 2017, each of German insurer BARMER GEK (“Barmer”) and national social accident insurance provider Deutsche Gesetzliche Unfallversicherung (“DGUV”), indicated that they will provide coverage to users who meet certain inclusion and exclusion criteria. In February 2018, the head office of German Statutory Health Insurance (“SHI”) Spitzenverband (“GKV”) confirmed their decision to list the ReWalk Personal 6.0 exoskeleton system in the German Medical Device Directory. This decision means that ReWalk is listed among all medical devices for compensation, which SHI providers can procure for any approved beneficiary on a case-by-case basis. During the year 2020 and 2021, we announced several new agreements with German SHIs, including TK and DAK Gesundheit, as well as the first German Private Health Insurer (“PHI”), which outline the process of obtaining our devices for eligible insured patients. We are also currently working with several additional SHIs on securing a formal operating contract that will establish the process of obtaining a ReWalk Personal 6.0 device for their beneficiaries within their system.

Additionally, to date, several private insurers in the United States and Europe are providing reimbursement for ReWalk in certain cases.

## Evolving COVID-19 Pandemic

The impact of the COVID-19 pandemic has resulted in, and will likely continue to result in, significant disruptions to the global economy and the capital markets, as well as our business. In an effort to halt the outbreak of COVID-19, a number of countries, including the United States and Germany as well as many other countries in Europe, have implemented numerous measures to contain the pandemic, such as travel bans and restrictions, shelter-in-place orders and shutdowns. In addition, a significant number of our global suppliers, vendors, distributors and manufacturing facilities are located in regions that have been affected by the pandemic. Those operations have been materially adversely affected by restrictive government and private enterprise measures implemented in response to the pandemic, which in turn, has negatively impacted our operations. Despite the distribution of COVID-19 vaccines, new and occasionally more virulent variants of the virus that causes COVID-19, including the Delta and Omicron variants, have emerged and there is significant uncertainty as to how the countries in which we do business will continue to respond to such outbreaks, including whether there will be future partial or total shutdowns, which would adversely affect our business. the Delta and recently Omicron variant are emerging.

The COVID-19 pandemic has affected our ability to engage with our SCI Products, ReStore and Distributed Products existing customers, conduct trials of candidates, deliver ordered units or repair existing systems and provide training of our products to new patients who have largely remained at home due to local movement restrictions and to rehabilitation centers, which have temporarily shifted priorities and responses to pandemic-related medical equipment. In addition, staffing shortages within the healthcare system itself has resulted in a diminished demand for our SCI Products, as the attention of healthcare workers and potential patients has turned elsewhere. As a result, our sales and results of operations have been adversely impacted. We believe that these adverse impacts may continue as long as the pandemic continues to impact our key markets which are Germany and the United States, especially as long as our ability to conduct trials of product candidates is limited or if our existing customers can't train with our SCI Products and as long as capital budgets for rehabilitation devices such as the ReStore remain reduced or on-hold. Additionally, some clinics, such as VA clinics, and many other healthcare facilities are enforcing in-clinic restrictions that affect our ability to demonstrate our devices to patients or start training for qualified potential customers. We continue to monitor our sales pipeline on a day-to-day basis in order to assess the effect of these limitations as some have short term effects and some affect our future pipeline development. While our sole manufacturer, Sanmina Corporation, has not shut down its facilities during the COVID-19 pandemic, supply chain delays, component shortages have had a limited impact on our manufacturing, and are also leading to price increases of specific parts. Other adverse impacts on our production capacity as a result of government directives or health protocols can occur. Moreover, the current limitations on our sales activities has made it difficult to effectively forecast our future requirements for systems. For more information, see "Part II, Item 1A. Risk Factors."

In addition, our future results of operations and liquidity could be adversely impacted by delays in payments of outstanding receivable amounts beyond normal payment terms, supply chain disruptions and operational challenges faced by our customers. The occurrence of new outbreaks of COVID-19 could result in a widespread health crisis that could adversely affect the economies and financial markets of many countries, resulting in an economic downturn or a global recession that could cause significant volatility or decline in the trading price of our securities, affect our ability to execute strategic business activities such as business combination, affect demand for our products and likely impact our operating results. These may further limit or restrict our ability to access capital on favorable terms, or at all, lead to consolidation that negatively impacts our business, weaken demand, increase competition, cause us to reduce our capital spend further, or otherwise disrupt our business.

During the pandemic, we have implemented remote working procedures in the United States, Germany and Israel and are establishing in-office measures to contain the spread of COVID-19 according to local regulations. With the vaccination of most of our employees we have gradually returned to work from our offices during 2021 but are currently facing another disruption with the spread of the Omicron variant. Despite this current situation and the challenges it imposes, we have developed several methods to continue to engage with our current and prospective customers with some success through video conferencing, virtual training events, and online education demos to offer our support and showcase the value of our products.

## ReWalk Personal and ReWalk Rehabilitation Products

Development of our SCI Products took over a decade and was spurred by the experiences of our founder, Dr. Amit Goffer, who became a quadriplegic due to an accident. Current ReWalk designs are intended for people with paraplegia, a spinal cord injury resulting in complete or incomplete paralysis of the legs, who have the use of their upper bodies and arms. We currently offer two products in this category: ReWalk Personal 6.0 and ReWalk Rehabilitation which is a ReWalk Personal 6.0 product sold with multiple sizes of our adjustable parts to allow different users the ability to train within a clinic

ReWalk Personal is a novel product that seeks to fundamentally change the health and life experiences of users. Designed for all-day use, the device 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. The device controls movement using subtle shifts in the user's center of gravity. A forward tilt of the upper body is sensed by the system, which initiates the first step. Repeated body shifting generates a sequence of steps that results in a functional walking speed. Because the exoskeleton supports its own weight and facilitates the user's gait, users do not expend unnecessary energy while walking. While ReWalk Personal does not allow side-to-side actuation, users are able to turn by shifting their weight to the side. The ReWalk Personal also allows users to sit, stand and depending on local regulatory approvals, climb and descend stairs. Use on stairs is currently not cleared by the FDA in the United States; 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, to operate the device independently and most are able to put on and remove the device by themselves. 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 Personal is also equipped with maintenance alarms, warnings, and backup batteries. The rechargeable batteries are easily accessible and can be recharged in any standard power outlet. Our product labeling, however, requires users to be accompanied by a trained companion at all times when using the ReWalk Personal.



- *ReWalk Personal*: intended for everyday use at home, at work or in the community with a trained companion. We began marketing ReWalk Personal in Europe with CE mark clearance at the end of 2012. We received FDA clearance to market ReWalk Personal in the United States in June 2014. ReWalk Personal units are all manufactured according to the same mechanical specifications. Each unit is then permanently sized to fit the individual user and the software is configured for the user's specifications by the rehabilitation center, clinic or distributor. We are currently offering our 6<sup>th</sup> generation device.
- *ReWalk Rehabilitation*: the current offering for clinics who wish to implement exo-skeleton training is comprised of our Personal 6.0 unit along with multiple sizing of different parts, enabling multiple patient use. The replacement of parts for different sizing is done by the clinic team and can take between 5 to 15 minutes. 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 a unique design for use in hospitals, rehabilitation centers and stand-alone training centers in the United States and Europe in 2011 and in December 2020, we decided to end the production of this unique design.



Additionally, we have received regulatory approval to sell the ReWalk Personal device in other countries. In the future we intend to seek approval from the applicable regulatory agencies in other jurisdictions where we may seek to market ReWalk Personal. For more information about the safety of using our SCI products see "Part I, Item 1A. Risk Factors—Risks Related to our Business and our Industry— Defects in our products or the software that drives them could adversely affect the results of our operations.

#### *Overview of Spinal Anatomy and Spinal Cord Injury*

##### *Spinal Anatomy*

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

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

## *Spinal Cord Injury*

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

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

## *Clinical evidence*

Published clinical studies indicate ReWalk Personal's ability to deliver a functional walking speed. In addition, certain potential secondary health benefits have been reported by healthcare practitioners and ReWalk users, including study participants. Although these benefits have not been established as conclusive clinical data in randomized controlled trials, these reported secondary health benefits include:

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

We believe that using our SCI Products may have the ability to reduce the lifetime healthcare costs of individuals with spinal cord injuries, which we believe will make it economically attractive for individuals and third-party payors. While we believe that using the SCI Products could potentially offer significant advantages over competing technologies and therapies, disadvantages include the time it takes for a user to put on the device, the slower pace of the device compared to a wheelchair, the training required by the user and companion, the weight of it 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.

Current and near-term market opportunities include providing a solution for persons with spinal cord injury that can be used in the clinic and/or home settings. For persons with spinal cord injury, 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 (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 young average age at time of injury and significant remaining life expectancy, the likelihood of living at home and lifetime cost of treatment highlight the need for an out-of-hospital solution with demonstrated health and social benefits.

The NSCISC estimates according to their 2021 report that there were 296,000 people in the United States living with SCI, with an annual incidence of approximately 17,900 new cases per year. According to the VA data there are approximately 42,000 of such patients are veterans and are eligible for medical care and other benefits from the VA out of which 27,000 are receiving treatment annually. With 25 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 2015, motor vehicle crashes have been the leading cause of reported spinal cord injury cases (39%), followed by falls (32%), acts of violence (14%) and sports injuries (8%). 78% of spinal cord injuries occur among the male population. According to NSCISC data, upon hospital discharge, 87% of persons with spinal cord injuries are sent to private, non-institutional residence (in most cases, their homes prior to injury).

Based on information from a 2017 report by the NSCISC, 40.4% of the total U.S. population of SCI patients suffered injuries between levels T4 and L5. Four published ReWalk trials for SCI patients had an aggregate screening acceptance rate of 50% considering all current FDA limitations, resulting in an estimated 20.2% of the total population of SCI patients can be considered as candidates for current ReWalk Personal 6.0 product according to the device instructions for use. For important qualifying information about this determination, see “Part I, Item 1A. Risk Factors—Risks Related to our Business and our Industry—The market for medical exoskeletons, including soft suit devices, remains relatively new and unproven, and important assumptions about the potential market for our current and future products may be inaccurate.”

#### *Sales and Marketing activities*

Our initial commercialization efforts focused on penetrating rehabilitation centers, hospitals, and similar facilities that treat patients with spinal cord injuries to become an integral part of their rehabilitation programs and to develop a broad-based training network with these facilities to prepare users for home and community use. As our business has developed, we have shifted our commercialization efforts to marketing of our ReWalk Personal with insurance companies, physicians, and physical therapists as a standard of care that can be used routinely at home, at work or in the community under the supervision of a trained companion in accordance with the user assessment and training certification program.

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

As of December 31, 2021, we had placed 121 ReWalk Rehabilitation units in use at rehabilitation centers and 533 ReWalk Personal units in a home or community use, compared to 119 ReWalk Rehabilitation units and 492 ReWalk Personal units as of December 31, 2020. In the near future, we intend to continue focusing on our reimbursement efforts, pursuing insurance claims on a case-by-case basis, managing claims through the review process, and investing in efforts to expand commercial reimbursement coverage.

Although we cannot predict the time it will take to achieve higher acceptance rates of our SCI Products, we believe that further clinical evidence supporting the benefits of using the device will be a key element to accelerate it.

#### *Third-Party Reimbursements*

##### *United States*

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

In December 2015, the VA issued a national policy for the evaluation, training, and procurement of ReWalk Personal exoskeleton systems for all qualifying veterans across the United States. The VA policy is the first national coverage policy in the United States for qualifying individuals who have suffered spinal cord injury. In June 2018 the VA has updated this policy to include more training options for individuals who could not complete the training due to distance from a VA site. As of December 31, 2021, we had placed 25 units as part of the VA policy. The VA accounted for 6.97% of our total revenues for the year ended December 31, 2021. We continue to work with the VA to accelerate the pace of implementation of the VA policy including by accelerating the usage of the “Choice” program which allows training for our devices in additional sites besides the VA regional hub sites.

Successful commercialization depends in significant part on adequate coverage and reimbursement from third party payors, which may include government payors (such as Medicare and Medicaid programs in the United States), managed care organizations, and private health insurers. In general, each third-party payor decides which devices will be covered and reimbursed, establishes reimbursement and co-pay levels and sets conditions for coverage and reimbursement.

While no broad uniform policy of coverage and reimbursement for electronic exoskeleton medical technology exists among commercial insurance payors in the United States, reimbursement may be achieved on a case-by-case basis. To date, payments for the ReWalk Personal device have been made primarily through case-by-case determinations by third-party payors, including commercial insurers in the United States, by self-payors and donations and, to a lesser extent, through the use of funds from insurance and/or accident settlements.

As of December 31, 2021, we had 15 cases pending in the United States for insurance coverage decisions. For more information, see “Part I, Item 1A. Risk Factors—Risks Related to our Business and our Industry— We may fail to secure or maintain adequate insurance coverage or reimbursement for our products by third-party payors, which risk may be heightened if insurers find the products to be investigational or experimental or if new government regulations change existing reimbursement policies. Additionally, such coverage or reimbursement, even if maintained, may not produce revenues that are high enough to allow us to sell our products profitably.”

According to a 2017 report published by the Centers for Medicare and Medicaid Services, or CMS, approximately 55% of the spinal cord injury population which are at least five years post their injury date are covered by CMS.

In order to be covered and reimbursed by Medicare, the ReWalk Personal 6.0 must, among other things, be classified into an applicable Medicare benefit category. In December 2021, CMS established a new process for issuing Medicare benefit category determinations. Until CMS issues a benefit category determination for a given product, the product’s Medicare benefit category is evaluated by CMS contractors on a case-by-case basis as part of adjudicating individual Medicare claims. Medicare benefit categories include, but are not limited to, prosthetics, orthotics, and durable medical equipment. In general, each Medicare benefit category has distinct coverage and payment rules and requirements.

In December 2019, we submitted the first application for a unique code to describe the ReWalk Personal 6.0 and, in July 2020, a unique code was issued for ReWalk Personal 6.0 (effective October 1, 2020). With the issuance of a unique code, we are currently seeking clarity from CMS as the applicable Medicare benefit category. Depending on the specific Medicare benefit category determination by CMS, Medicare coverage and payment for a product could be more or less favorable. If CMS determines that no Medicare benefit category is available, this would mean that a product is not covered by Medicare. While we believe that a positive response from CMS as to the applicable Medicare benefit category for the ReWalk Personal 6.0 may broaden coverage by commercial payors, we cannot currently predict how long it would take for us to receive a decision from CMS, the outcome of any such decision or other business elements that may be decided by CMS in evaluating Medicare coverage or reimbursement such as Medicare reimbursement per unit or Medicare coverage restrictions based on product labeling. Nor can we predict how other third-party payors will respond to any decision by CMS regarding Medicare coverage and reimbursement.

For more information, see “Part I, Item 1A. Risk Factors—Risks Related to our Business and our Industry— We may fail to secure or maintain adequate insurance coverage or reimbursement for our products by third-party payors, which risk may be heightened if insurers find the products to be investigational or experimental or if new government regulations change existing reimbursement policies. Additionally, such coverage or reimbursement, even if maintained, may not produce revenues that are high enough to allow us to sell our products profitably.”

As part of our plan for growth, we intend to continue working with both national and regional commercial insurance companies, health care practitioners, physicians, researchers, and the SCI community to support efforts to demonstrate the benefits of our SCI Products. In addition, we plan to pursue potential coverage policies with third party payors based on supportive data and appeal rulings that have deemed exoskeleton devices a “medically necessary” under the standard of care for individuals with SCI. Our efforts in the future will be focused on continued education of third party payors through data application, supporting clinical trials to demonstrate the clinical benefits of using the SCI Products, working with advocacy groups, ongoing communication as well continuing to seek greater clarity regarding Medicare coverage and reimbursement standards applicable to the ReWalk Personal 6.0 device.

#### *Europe*

Reimbursement for ReWalk in Europe varies by country and historically certain third-party payors have provided reimbursement for our products in certain cases in Germany and Italy.

We initially focused our European efforts in Germany where we continue to make progress toward achieving ReWalk coverage from the various government, private, and worker’s compensation payers. Specifically:

- In September 2017, Barmer confirmed it will provide ReWalk systems to all qualifying beneficiaries. Barmer provides insurance coverage for nearly nine million people in Germany, as a member of the SHI network and one of the most significant national insurers in the country. Exoskeletons are provided to users that meet certain inclusion criteria and assessment by the German Health Insurance Medical Service (Medizinischer Dienst der Krankenversicherungen) before and after training. We remain in discussion with Barmer regarding a contract based on their 2017 decision.
- In September 2017 Germany’s national social accident insurance provider, DGUV, indicated that the DGUV’s member payers, including the health insurance association *Berufsgenossenschaft* (also known as BG) and state insurers, will approve the supply of exoskeleton systems for qualifying beneficiaries on a case-by-case basis. DGUV is comprised of 36 different insurers, which provide coverage for more than 80 million individuals in Germany. Per the agreement, eligible individuals go to BG clinics for evaluation as a part of the procurement. In May 2020 the DGUV agreed to a binding offer to the evaluation, training, and supply of the ReWalk Personal 6.0 device to qualified individuals.
- In February 2018, the GKV-Spitzenverband (Central Federal Association of (the) Statutory Health Insurance Funds) confirmed its decision to list the ReWalk Personal system in the German MDD, a comprehensive list of all medical devices which are principally and regularly reimbursed by German SHI and PHI providers. The ReWalk Personal was added to the official German list of medical aids, code number 23.29.01.2001, in June 2018. This decision means that ReWalk Personal is listed among all medical devices for compensation, which SHI providers can procure for any approved beneficiary on a case-by-case basis.

- During the year 2020 we have announced several new agreements with SHIs such as TK and DAK-Gesundheit and others as well as the first German Private Health Insurer (“PHI”) that have chosen to enter into an agreement with us that outline the process to obtaining a device for eligible insured patients.
- In March 2021 we entered into a contract with BKK Mobile Oil health insurance to supply ReWalk’s Personal 6.0 System to eligible persons in Germany.
- In June 2020, a certain SHI has appealed the decision of the State Social Court, which ordered the supply of the SHI’s insured SCI person with ReWalk. The State Social Court ruled and deemed ReWalk as the medical aid which will directly compensate the plaintiff’s disability. The SHI appealed this ruling with the Federal Social Court (*Bundessozialgericht*), which now has to decide whether an exoskeleton, as an orthopedic aid that replaces the function of the legs and enables independent walking and standing, serves to directly compensate for disability. The cost-effectiveness of an aid that serves to directly compensate for a disability is generally to be assumed and only examined if two actually equivalent but differently priced aids are available for selection. The 3rd Senate of the Federal Social Court is expected to announce the hearing date in the coming months.

Patients who are covered under these contracts and policies must be medically evaluated for their eligibility to use the ReWalk Personal device. If medically qualified, the patient, along with his or her physician, must apply for coverage of the device. If a patient is found eligible and medically fit to use our Personal 6.0 device, we first enter into a rental agreement which allows the patient the necessary period to train on how to use the device which usually takes between 3 to 6 months and then after approval from the insurer the patient receives a personal device to use at home or in the community. We are currently working with several additional SHIs and PHIs on securing a formal operating contract that will establish the process of obtaining a ReWalk Personal 6.0 device for their beneficiaries within their system.

As of December 31, 2021, there were 56 insurance cases pending in Germany. We believe that our recent coverage decisions and the existing claims will eventually lead other German insurers to provide coverage on a broader scale, but this is not guaranteed. For more information, see “Part I, Item 1A. Risk Factors—Risks Related to our Business and our Industry— We may fail to secure or maintain adequate insurance coverage or reimbursement for our products by third-party payors which risk may be heightened if insurers find the products to be investigational or experimental or if new government regulations change existing reimbursement policies. Additionally, such coverage or reimbursement, even if maintained, may not produce revenues that are high enough to allow us to sell our products profitably.”

We continue to support clinical research and academic publications, which we believe will further support the case for coverage.

We have distribution agreements in several European countries where we also had success with reimbursement by private insurers, worker’s compensation. One of the examples was achieved in March 2018, when the Italian Ministry of Labor and Social Policy’s statutory insurance corporation put in place a coverage policy that will provide exoskeleton systems for all qualifying beneficiaries. This policy, the first of its kind in Italy, will provide individuals with spinal cord injury access to obtain their own ReWalk Personal device so that they can stand and walk again. Since the initiation of coverage, we have supplied 10 units through our Italian distributor to individuals covered by this policy.

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

## ReStore

In June 2017 we unveiled our lightweight exo-suit ReStore system designed initially for rehabilitation of stroke patients. The patented soft exo-suit technology was originally developed at Harvard University's Wyss Institute for Biologically Inspired Engineering, ("Harvard") where it also underwent initial clinical testing that demonstrated potential to improve walking for stroke survivors. ReWalk and Harvard entered into a multi-year research collaboration agreement in 2016 which provides ReWalk license to intellectual property relating to lightweight exo-suit system technologies for lower limb disabilities and provides access to future innovations that emerge from this collaboration and may be relevant to additional stroke products or other therapies. The development and regulatory clearance process for ReStore took us approximately three years. In June 2019, we received FDA clearance following CE clearance in May 2019. Following the regulatory clearances, we began to commercialize the ReStore product. For more information on the collaboration with Harvard, see "Research and Development-Research and Development Collaborations."



ReStore exo-suit

The ReStore product is comprised of a soft, fabric-based design which connects to a lightweight waist pack and mechanical cables that help lift the patient's affected leg in synchronized timing with their natural walking pattern. The lightweight structure wraps around the waist and supports an actuator with a motor, computer, and cable, along with sensors attached to a stable point on the user's calf and footplate in the user's shoe. This design transfers forces in a controlled manner and provides targeted assistance to the patient ankle during forward propulsion (plantarflexion) and ground clearance (dorsiflexion), two key phases of the gait cycle. The ReStore system is designed to provide advantages to stroke rehabilitation clinics and therapists as compared to other traditional therapies and devices by improving the quality and pace of care, supplying real-time analytics to optimize session productivity, and generating ongoing data reports to assist with tracking patient progress.

Published clinical trials that were conducted at Harvard using the soft-suit design on stroke patients have shown varying levels of improvements, with the main ones being improved forward propulsion, reductions in compensatory behaviors including paretic hip hiking and circumduction as well as reduction in metabolic burden associated with post stroke walking. There are currently two studies on-going with the ReStore device, that are measuring the improvement in walking speed following training with the soft suit as well as comparing the results of traditional training with soft suit training.

The main market for ReStore is rehabilitation clinics with a stroke therapy program or clinics that would like to broaden their stroke presence. This product is marketed and sold directly to rehabilitation clinics for use during the course of the treatment of their patients which is generally reimbursed by commercial and government payors. During the second half of 2019 we expanded our sales and marketing presence in the United States in order to accelerate product penetration after receiving received FDA and CE clearance. These efforts were impacted by the COVID-19 pandemic, as clinics and hospitals shifted resources and attention during the pandemic. Geographically we see our priorities as the United States and Europe.

Stroke incidence rate in the United States is 795,000 incidences per year and the survival rate is approximately 80%. Of this stroke population, 80% are left with some type of lower limb disability. This patient population seeks treatment in one of the approx. 1,600 primary and comprehensive inpatient, outpatient, and rehabilitation clinics providing therapy to stroke patients. With the clinical evidence we have to date on ReStore, its unique design and its cost-effectiveness compared to other products, we believe the ReStore soft-suit has an opportunity to be adopted in multiple clinics during their stroke patients therapy. However, we also recognize that the process to achieve that might be long and will likely only occur once national or regional healthcare providers include the device within their stroke therapy programs. We also believe that in order to accelerate adoption, further clinical evidence is required as well as continued education on the new ReStore design and its unique advantages compared to current therapies and products.

As of December 31, 2021, and December 31, 2020, we had placed 30 and 21 ReStore units, respectively.

#### *ReBoot*

We are also in the stage of research with ReBoot, a soft exoskeleton for stroke home and community use. This product is a complementary product to ReStore, and it received Breakthrough Device Designation from the FDA in November 2021. The ReBoot is a lightweight, battery-powered orthotic exo-suit intended to assist ambulatory functions in individuals with reduced ankle function related to neurological injuries, such as stroke. The ReBoot is a customizable personalized device intended for home and community use with an estimated market of 500,000 annual stroke patients who require walking assistance after being discharged home.

We are currently finalizing the design which will be followed by development of the ReBoot device and we will then potentially submit a premarket notification for regulatory clearance with the FDA and other regulatory agencies after the completion of necessary clinical studies and market assessment.

#### **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 used in the clinic and/or home settings.

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 (NASDAQ: EKS), Rex Bionics Pty, Cyberdyne (Tokyo Stock Exchange: 7779), Parker Hannifin (NYSE: PH), FREE Bionics, Hocoma, AlterG and Bioness (acquired by Bioventus (NASDAQ: BVS)). These products may also compete with the ReStore exo-suit, as well as manual forms of gait training which do not involve robotic assistive devices.

We believe that our ReWalk Personal device possesses key competitive advantages over these companies' products, such as our tilt-sensor technology that provides a self-initiated walking experience, more natural gait and faster functional walking speed, the ability to support its own weight and broad user specifications. In addition, ReWalk Personal is the first medical exoskeleton cleared by the FDA for personal use in the United States.



We believe that our ReStore soft exo-suit device has several competitive advantages over the products of our competitors, including a design that facilitates a natural, functional walking pattern through flexible materials, sensors, and powered plantarflexion as well as dorsiflexion, making it the only solution of its type of which we are aware of that supports such movements, achieving that with a lower cost and weight than rigid exoskeletal devices.

In addition, we compete with alternative devices and alternative therapies, including treadmill-based gait therapies, such as those offered by Hocoma, Tyromotion, 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.

### **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 our SCI Products, as well as for our ReStore device. 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 educate and gain support from organizations such as patient advocacy groups and clinician societies with the goal of promoting adoption of exoskeleton technology from patient, clinician, and payor communities. 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. We are also looking into ways to promote the ReStore device through different advocacy groups to accelerate adoption and support the uniqueness of this technology when compared to current therapies and products.

To date, multiple advocacy groups have issued public endorsements of the ReWalk Personal device, including leading United States-based national organizations such as the United Spinal Association and the Dana and Christopher Reeves Foundation, as well as others. In addition, the National Institute for Health and Care excellence in the United Kingdom (also known as “NICE”), has issued a public announcement regarding the ReStore device.”).

### **Services and Customer Support**

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

### **Research and Development**

We are committed to investing in a robust research and development program to support our current product line and to potentially develop our pipeline of new and complementary products, and we believe that ongoing research and development efforts are essential to our success. Our research and development team consists of both in-house and external staff, including engineers, machinists, researchers and marketing, quality, manufacturing, regulatory and clinical personnel, which we employ as efficiently as possible meet our current and future needs, and 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. Our level of research and development investment depends on our available resources, business plans, and future needs. For more information, see “Part I, Item 1A. Risk Factors — Risks Related to Our Business and Our Industry — Our future growth and operating results will depend on our ability to develop, receive regulatory clearance for, and commercialize new products and penetrate new product and geographic markets.”

We plan to focus our research and development efforts in the future by continually improving and potentially expanding our functional technological platform, by expanding the indication of use of our lightweight “soft suit” exoskeleton to other medical conditions, as well as home therapy with the ReBoot device or adding a new indication of use. Regarding our ReWalk Personal 6.0 product we are working on product improvement and expanded labeling which we plan to launch following regulatory approval, and in the longer term by developing our next generation device with design improvements. New medical indications impacting the ability to walk that we may pursue include multiple sclerosis, cerebral palsy, Parkinson’s disease, and elderly assistance.

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

Our research and development efforts have been financed, in part, through funding from the Israel Innovation Authority, or the IIA (formerly known as Office of the Chief Scientist in the Israel Ministry of Economy) (“IIA”). From our inception through December 31, 2021, we received funding totaling \$1.97 million from the IIA. For more information regarding our research and development financing arrangements, see “Part II. Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources” and “—Grants and Other Funding.”

#### ***Research and Development Collaborations***

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

The Collaboration Agreement, as amended, expires on March 31, 2022. We and Harvard might consider a new arrangement to support our research efforts in the future.

Under applicable circumstances, we may terminate the Collaboration Agreement if there is a loss of Harvard’s principal investigator or if we do not believe that we have or can secure sufficient funding to proceed. The Collaboration Agreement may also be terminated by either Harvard or us due to a material uncured breach by the other party or upon termination of the Harvard License Agreement. If the Collaboration Agreement terminates, other than in connection with a termination of the Harvard License Agreement, the Harvard License Agreement will continue in full force and effect. We may amend the Collaboration Agreement in the future depending on our commercialization focus, market conditions, spending plan, and other factors.

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

The Harvard License Agreement will continue in full force and effect until the expiration of the last-to-expire valid claim of the licensed patents, or it is terminated in accordance with its terms. We may terminate the License Agreement for any reason upon 60 days' prior written notice, while Harvard may terminate the License Agreement if we do not maintain requisite insurance or become insolvent. The Harvard License Agreement may also be terminated by Harvard or us due to the other party's material uncured breach.

The Collaboration Agreement and Harvard License Agreement contain, as applicable, customary representations and warranties and customary enforcement, indemnification, and insurance provisions. For further discussion of the Collaboration Agreement and Harvard License Agreement, see Note 9 to our consolidated financial statements for the fiscal year ended December 31, 2021.

In September 2013, we entered into a strategic alliance with Yaskawa Electric Corporation ("Yaskawa"), pursuant to which, among other arrangements, we granted Yaskawa the exclusive right to market, distribute and commercialize our products in Japan, China and other East Asian countries. In connection with the closing of the first tranche of a private placement of our ordinary shares to Timwell Corporation Limited, a Hong Kong corporation ("Timwell"), on May 15, 2018 we terminated the distribution rights granted to Yaskawa in China (including Hong Kong and Macau). We terminated all other distribution rights granted to Yaskawa effective September 24, 2020. For more information on the Timwell private placement, see "Part II. Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Timwell Private Placement."

## **Intellectual Property**

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

In addition to our portfolio of issued patents and pending patent applications, we license certain patented and patented pending technology from a third party as described above under the "Research and Development" section.

As of December 31, 2021, we have 10 issued patents in the United States and 12 issued patents outside of the United States, as well as 12 pending patent applications for our technology in the United States, China, and Europe. As such, in the United States and Europe, we have apparatus patent claims covering aspects of ReWalk and similar devices which use a plurality of sensors to empower tilt-sensor technology, as well as method patent claims covering certain methods of user activation and control of systems such as ReWalk. While our apparatus claims focus on protecting ReWalk in terms of its physical and structural characteristics, we believe that our method claims provide additional protection for our technology. We do not currently license any of the technology contained in our currently commercialized ReWalk Personal 6.0, 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 (as well as other countries) generally have a term of 20 years from their earliest effective filing date, although can be slightly longer depending upon a local jurisdiction's rules and laws. For example, the oldest of our issued patents relating to our tilt-sensor technology was filed in May 2001 in the United States and would typically expire in May 2021. However, this patent actually expires in April of 2022 due to patent term adjustment (PTA) of 689 days for delays in examination by the United States Patent and Trademark Office. The corresponding European patent to this United States patent was filed in February of 2002 and expires in February of 2022.

We currently hold a registered trademark in the United States, Europe and Israel as well as pending trademark application in the United Kingdom, for the mark "ReWalk". We currently hold a registered trademark in United States, Europe and the United Kingdom for the mark "ReStore".

We cannot be sure that our intellectual property will provide us with a competitive advantage especially as some of our older patents begin to expire, 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 “Part I, Item 1A. Risk Factors—Risks Related to Our Intellectual Property.”

## **Government Regulation**

### ***U.S. Regulation***

Our medical products and manufacturing operations are regulated by the FDA and other federal and state agencies. Our products are regulated as medical devices in the United States under the Federal Food, Drug, and Cosmetic Act, or the 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 Regulatory Requirements***

Unless an exemption applies, each medical device commercially distributed in the United States requires either FDA clearance of a 510(k) premarket notification, approval of a premarket approval application (PMA), or issuance of a de novo order. 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 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, post-market surveillance, patient registries, and FDA guidance documents. While most Class I devices are exempt from the 510(k) premarket notification requirement, most Class II devices require a 510(k) premarket notification to be marketed in the U.S. As a result, manufacturers of most Class II devices are required to submit to the FDA premarket notifications under Section 510(k) of the FDCA requesting classification of their devices in order to market or commercially distribute those devices. To obtain a 510(k), a substantial equivalence determination for their devices, manufacturers must submit to the FDA premarket notifications demonstrating that the proposed device is “substantially equivalent” to a predicate device already on the market. A predicate device is a legally marketed device that is not subject to premarket approval, or PMA, meaning, (i) a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, (ii) a device that has been reclassified from Class III to Class II or I, or (iii) a device that was found substantially equivalent through the 510(k) process. If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If the device is not “substantially equivalent” to a previously cleared device, the device is automatically a Class III device. The device sponsor must then fulfill more rigorous premarket approval requirements or can request a risk-based classification determination for the device in accordance with the “de novo” process, which is a route to market for medical devices that are low to moderate risk but are not substantially equivalent to a predicate device.

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

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

In June 2014, the FDA granted our petition for "de novo" classification, which provides a route to market for medical devices that are low to moderate risk, but are not substantially equivalent to a predicate device, and classified ReWalk as Class II subject to special controls. The ReWalk is intended to enable individuals with spinal cord injuries to perform ambulatory functions under supervision of a specially trained companion, and inside rehabilitation institutions. The special controls established in the de novo order include the following: compliance with medical device consensus standards; clinical testing to demonstrate safe and effective use considering the level of supervision necessary and the use environment; non-clinical performance testing, including durability testing, to demonstrate that the device performs as intended under anticipated conditions of use; a training program; and labeling related to device use and user training. The special controls of this de novo order also apply to competing products seeking FDA clearance.

In June 2019, the FDA issued a 510(k) clearance for ReStore which means that the device can be marketed in the U.S. ReStore is intended to be used to assist ambulatory functions in rehabilitation institutions under the supervision of a trained therapist for people with hemiplegia or hemiparesis due to stroke. ReStore complies with special controls includes the following: compliance with medical device consensus standards; clinical testing to demonstrate safe and effective use considering the level of supervision necessary and the use environment; non-clinical performance testing, including durability testing, to demonstrate that the device performs as intended under anticipated conditions of use; a training program; and labeling related to device use and user training. In order for us to market ReStore, 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 ReStore from the market, which would have a material adverse effect on our business.

For more information, see "Part I, Item 1A. Risk Factors-Risks Related to Government Regulation-We are subject to extensive governmental regulations relating to the manufacturing, labeling and marketing of our products, and a failure to comply with such regulations could lead to withdrawal or recall of our products from the market."

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;
- FDA’s Unique Device Identification requirements that call for a unique device identifier (UDI) on device labels and packages and submission of data to the FDA’s Global Unique Device Identification Database (GUDID);
- medical device reporting regulations that require manufacturers to report to the FDA if a device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; and corrections and removal reporting regulations that require manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FFDCA that may present a risk to health; and
- Post-market surveillance.

FDA required that ReWalk conduct a post-market surveillance study of the ReWalk device under Section 522 of the FFDCA. We launched our post-market surveillance study with Stanford University during the second quarter of 2016 and in March 2020 the FDA approved a protocol modification that allowed ReWalk to supplement data from the clinical study with real-world evidence. In January 2022, FDA notified ReWalk that the agency had completed its review of the postmarket surveillance report, and that ReWalk had fulfilled the 522 postmarket study requirement. In accordance with FDA’s request, ReWalk will submit a 510(k) Postmarket Surveillance Study Labeling Update to modify the device labeling to reflect the findings of the study.

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, ENISO 13485:2016.

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 post-market requirements, it has significant enforcement authority. Specifically, if the FDA determines that we failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

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

- refusing or delaying requests for approval of pre-market approval applications relating to new products or modified products;
- withdrawing PMA approval;
- refusal to grant export approvals for our products; or
- pursuing criminal prosecution.

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

#### ***Regulation outside of the U.S.***

In addition to the United States regulations, we are subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products. In the E.U., medical devices are regulated by the European Union Medical Devices Regulation (EU) 2017/745 or MDR, which became applicable on 26 May 2021 and replaced the EU Medical Devices Directive 93/42/EEC, or MDD. The MDR and its associated guidance documents and harmonized standards, govern, among other things, device design and development, preclinical and clinical or performance testing, premarket conformity assessment, registration and listing, manufacturing, labeling, storage, claims, sales and distribution, export and import and post-market surveillance, vigilance, and market surveillance.

Before a device can be placed on the market in the E.U., compliance with the MDR requirements must be demonstrated in order to affix the CE Mark to the product. 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. The Notified Body issues a CE Certificate of Conformity to confirm successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the essential requirements provided in the MDR. Under transitional provisions provided in the MDR, medical devices that had valid CE Certificates of Conformity issued under the MDD prior to 26 May 2021 may, provided related obligations are respected, continue to be placed on the EEA market for the remaining validity of the certificate, and until 27 May 2024 at the latest. After the expiry of any applicable transitional period, only devices that have been CE marked on the basis of the MDR may be placed on the market in the EEA. We comply with the E.U. requirements and have received a Notified Body Certificate of Conformity under the MDD for all of our ReWalk systems including the ReStore device which are distributed in the E.U. This allows us to continue to apply the CE mark to our products and place them on the market throughout the E.U. during the transition period until 2024 or until we have completed an appropriate conformity assessment procedure under the MDR.

Post-Brexit the MDR does not apply in the United Kingdom (except for Northern Ireland, which under the Northern Irish Protocol is bound by certain E.U. laws). The medical device legislative framework in the United Kingdom is set out in the Medical Devices Regulations 2002. These Regulations are based on the previous medical device directives of the E.U. but have been amended so that they function properly now the United Kingdom is no longer part of the E.U. The Medical Devices Regulations 2002 have introduced several changes including (but not limited to) replacing the CE mark with a UKCA marking (although E.U. CE marks will be recognized until 30 June 2023), requiring manufacturers outside of the United Kingdom to appoint a “UK Responsible Person” if they place devices on the Great British market and more wide-ranging device registration requirements.

Sales in other jurisdictions are subject to the foreign government regulations of the relevant jurisdiction, and in most cases 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 United States or the CE mark in the E.U. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

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

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

In the United States, there are federal and state anti-kickback laws that prohibit the payment or receipt of kickbacks, bribes or other remuneration intended to induce the purchase or recommendation of healthcare products and services. Violations of these laws can lead to civil and criminal penalties, including exclusion from participation in federal healthcare programs. These laws apply to manufacturers of products, such as us, with respect to our financial relationship with hospitals, physicians and other potential purchasers or acquirers of our products. The U.S. government has published regulations that identify “safe harbors” or exemptions for certain practices from enforcement actions under the federal anti-kickback statute, and we will seek to comply with the safe harbors where possible. To qualify for a safe harbor, the activity must fit squarely within the safe harbor. Arrangements that do not meet a safe harbor are not necessarily illegal but must be evaluated on a case-by-case basis.

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

The federal civil False Claims Act (“FCA”) prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal government, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or avoiding, decreasing, or concealing an obligation to pay money to the federal government. A claim includes “any request or demand” for money or property presented to the U.S. government. The civil FCA has been used to assert liability on the basis of kickbacks and other improper referrals, improper use of Medicare provider or supplier numbers when detailing a provider of services, improper promotion of off-label uses not covered by a device’s clearance or approval, and allegations as to misrepresentations with respect to products, contract requirements, and services rendered. In addition, private payors have been filing follow-on lawsuits alleging fraudulent misrepresentation, although establishing liability and damages in these cases is more difficult than under the FCA. Intent to deceive is not required to establish liability under the civil FCA. Civil FCA actions may be brought by the government or may be brought by private individuals on behalf of the government, called “qui tam” actions. If the government decides to intervene in a qui tam action and prevails in the lawsuit, the individual will share in the proceeds from any fines or settlement funds. If the government declines to intervene, the individual may pursue the case alone. The civil FCA provides for treble damages and a civil penalty for each false claim, such as an invoice or pharmacy claim for reimbursement, which can aggregate into millions of dollars. For these reasons, since 2004, FCA lawsuits against biopharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements, as much as \$3.0 billion, regarding certain sales practices and promoting off label uses. Civil FCA liability may further be imposed for known Medicare or Medicaid overpayments that are not refunded within 60 days of discovering the overpayment, even if the overpayment was not caused by a false or fraudulent act. In addition, conviction or civil judgment for violating the FCA may result in exclusion from federal health care programs, and suspension and debarment from government contracts, and refusal of orders under existing government contracts.



The government may further prosecute conduct constituting a false claim under the criminal FCA. The criminal FCA prohibits the making or presenting of a claim to the government knowing such claim to be false, fictitious, or fraudulent and, unlike the civil FCA, requires proof of intent to submit a false claim.

The civil monetary penalties statute is another potential statute under which medical device companies may be subject to enforcement. Among other things, the civil monetary penalties statute imposes fines against any person who is determined to have knowingly presented, or caused to be presented, claims to a federal healthcare program that the person knows, or should know, is for an item or service that was not provided as claimed or is false or fraudulent.

The federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) also created federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, a healthcare benefit program, regardless of whether the payor is public or private, in connection with the delivery or payment for health care benefits, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items, or services relating to healthcare matters. Additionally, the Affordable Care Act (“ACA”) amended the intent requirement of certain of these criminal statutes under HIPAA so that a person or entity no longer needs to have actual knowledge of the statute, or the specific intent to violate it, to have committed a violation.

The ACA further created new federal requirements for reporting, by applicable drug manufacturers of covered products, payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members, including the Physician Payments Sunshine Act.

Further, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”) and its respective implementing regulations imposes certain requirements on covered entities relating to the privacy, security, and transmission of certain individually identifiable health information, known as protected health information. Among other things, HITECH, through its implementing regulations, makes HIPAA’s security standards and certain privacy standards directly applicable to business associates, defined as a person or organization, other than a member of a covered entity’s workforce, that creates, receives, maintains, or transmits protected health information on behalf of a covered entity for a function or activity regulated by HIPAA. HITECH also strengthened the civil and criminal penalties that may be imposed against covered entities, business associates, and individuals, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions. In addition, other federal and state laws may govern the privacy and security of health and other information in certain circumstances, many of which differ from each other in significant ways and may not be preempted by HIPAA, thus complicating compliance efforts.

Many states have also adopted laws similar to each of the above federal laws, which may be broader in scope and apply to items or services reimbursed by any third-party payor, including commercial insurers. Certain states also require implementation of commercial compliance programs and compliance with the medical device industry’s voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments or the provision of other items of value that may be made to healthcare providers and other potential referral sources; impose restrictions on marketing practices; or require companies to track and report information related to payments, gifts, and other items of value to physicians and other healthcare providers.

If our operations are found to be in violation of any of the laws or regulations described above or any other applicable laws, we may be subject to penalties or other enforcement actions, including criminal and significant civil monetary penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, corporate integrity agreements, suspension and debarment from government contracts, and refusal of orders under existing government contracts, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Enforcement actions can be brought by federal or state governments, or as “qui tam” actions brought by individual whistleblowers in the name of the government under the civil FCA if the violations are alleged to have caused the government to pay a false or fraudulent claim.

To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

#### ***Coverage and Reimbursement***

The commercial success of our product candidates and our ability to commercialize any approved product candidates successfully will depend in part on the extent to which governmental payor programs at the federal and state levels, including Medicare and Medicaid, private health insurers, and other third-party payors provide coverage for and establish adequate reimbursement levels for our products. Government authorities, private health insurers, and other organizations generally decide which products and services they will pay for and establish reimbursement levels for healthcare. Medicare is a federally funded program managed by CMS through local fiscal intermediaries and carriers that administer coverage and reimbursement for certain healthcare items and services furnished to the elderly and disabled. Medicaid is an insurance program for certain categories of patients whose income and assets fall below state defined levels and who are otherwise uninsured that is both federally and state funded and managed by each state.. In the United States, private health insurers and other third-party payors often provide reimbursement for products and services based on the level at which the government provides reimbursement through the Medicare or Medicaid programs for such products and services.

In the United States, the European Union, and other potentially significant markets for our products, government authorities and third-party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which often has resulted in average selling prices lower than they would otherwise be. In the United States, it is also common for government and private health plans to use coverage determinations to leverage rebates from labelers in order to reduce the plans’ net costs. These restrictions and limitations influence the purchase of healthcare services and products and lower the realization on manufacturers’ sales of products. Third-party payors are developing increasingly sophisticated methods of controlling healthcare costs. Third-party payors may limit coverage to specific therapeutic products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication or might impose high copayment amounts to influence patient choice. Third-party payors also control costs by requiring prior authorization or imposing other restrictions. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy.

Federal programs also impose price controls through mandatory ceiling prices on purchases by federal agencies and federally funded hospitals and clinics. These restrictions and limitations influence the purchase of healthcare services and products. Legislative proposals to reform healthcare or reduce costs under government programs may result in lower reimbursement for our products or exclusion of our products.

Private payors often rely on the lead of the governmental payors in rendering coverage and reimbursement determinations. Therefore, achieving favorable CMS coverage and reimbursement is usually a significant gating issue for successful introduction of a new product.

Further, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement, and utilization, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, competition from other products, judicial decisions and governmental laws and regulations related to Medicare, Medicaid, and healthcare reform, and pricing in general. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Sales of our product candidates will therefore depend substantially, both domestically and abroad, on the extent to which the costs of our products will be paid by health maintenance, managed care, and similar healthcare management organizations, or reimbursed by government health administration authorities, such as Medicare and Medicaid, private health insurers, and other third-party payors.

Moreover, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved or that significant price concessions will not be required to avoid restrictive conditions. High health plan co-payment requirements may result in patients seeking alternative therapies. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment. Legislative proposals to reform healthcare or reduce costs under government insurance programs may result in lower reimbursement for our products or exclusion of our products from coverage. The cost containment measures that healthcare payors and providers are instituting and any healthcare reform could significantly reduce our revenues from the sale of any approved product candidates.

### ***Healthcare Reform Measures***

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system. The United States government, state legislatures and foreign governments also have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the Affordable Care Act, substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Affordable Care Act is intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers, and impose additional health policy reforms.

The Affordable Care Act has been subject to challenges in the courts. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional and remanded the case to the Texas District Court to reconsider its earlier invalidation of the entire Affordable Care Act. An appeal was taken to the U.S. Supreme Court. On June 17, 2021, the Supreme Court ruled that the plaintiffs lacked standing to challenge the law as they had not alleged personal injury traceable to the allegedly unlawful conduct. As a result, the Supreme Court did not rule on the constitutionality of the ACA or any of its provisions.

Other legislative changes have been proposed and adopted since passage of the Affordable Care Act. The Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve its targeted deficit reduction of an amount greater than \$1.2 trillion for the fiscal years 2012 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions included aggregate reductions to Medicare payments to healthcare providers of up to 2.0% per fiscal year. The Bipartisan Budget Act of 2018 retained the federal budget "sequestration" Medicare payment reductions of 2%, and extended it through 2027 unless congressional action is taken, and also increased labeler responsibility for prescription costs in the Medicare Part D coverage gap. On January 2, 2013, the American Taxpayer Relief Act was signed into law, which, among other things, reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further legislative and regulatory changes under the Affordable Care Act remain possible, although the Biden Administration has signaled that it plans to build on the Affordable Care Act and expand the number of people who are eligible for subsidies under it. President Biden indicated that he intends to use executive orders to undo changes to the Affordable Care Act made by the Trump administration and would advocate for legislation to build on the Affordable Care Act. It is unknown what form any such changes or any law would take, and how or whether it may affect our business in the future. We expect that changes or additions to the Affordable Care Act, the Medicare and Medicaid programs, changes allowing the federal government to directly negotiate drug prices and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that additional federal, state and foreign healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, or additional pricing pressures.

#### **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 (“RoHS”), which restricts the use of ten 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 comply in all material respects with applicable environmental laws and regulations.

## **Manufacturing**

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

We believe that this contract manufacturing relationship allows us to operate our business efficiently by focusing our internal efforts on the development and commercialization 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 although there are instances that we purchase raw material ourselves. Components of our products and raw materials come from suppliers in the United States, 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, during the pandemic we have seen several specific parts, mainly electronic parts, suffer price increase. 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.

## Human Capital

### Employees

As of December 31, 2021, we had 51 employees (including full-time and hourly employees), of whom 22 were located in the United States, 15 were located in Israel and 14 were located in Europe. The majority of our employees are, and have been, engaged in sales and marketing activities. We do not employ a significant number of temporary or part time employees.

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

### Compensation and Benefits

We provide our employees with competitive salaries and bonuses, opportunities for equity ownership, and a robust employment package that promotes well-being across all aspects of our employees' lives, including health care, retirement planning, and paid time off. We also invest in the ongoing development of our employees through our internal training programs

### Diversity and Inclusion

We value the diversity of our employees and take pride in our commitment to diversity and inclusion across all levels of our organizational structure . We encourage a diversity of views and strive to create an equal opportunity workplace, including working with managers to develop strategies for building diverse teams and promoting the advancement of employees from diverse backgrounds.

### Financial Information about Geographic Areas and Significant Customer Information

The following table sets forth the geographical breakdown of our revenues for each of the years ended December 31, 2021, and 2020 (in thousands):

	Year Ended December 31,	
	2021	2020
Revenues based on customer's location:		
United States	\$ 2,519	\$ 1,746
Europe	3,381	2,631
Asia-Pacific	60	8
Latin America	—	6
Africa	2	2
Total revenues	<u>\$ 5,966</u>	<u>\$ 4,393</u>

Additional discussion of financial information by reportable segment and geographic area and sales in excess of 10% of total revenues to certain of our customers is contained in Note 13 to our consolidated financial statements set forth in "Part II. Item 8. Financial Statements and Supplementary Data" of this annual report.

## Recent Developments

- Annual revenue of \$6.0 million in 2021 represents 36% year over year growth;
- Fourth quarter 2021 revenues were \$1.2 million, up by 2% compared to previous year quarter;
- Strong cash position with \$88.3 million as of December 31, 2021;
- New DMEPOS rules issued in December 2021 will advance consideration of the ReWalk benefit category and pricing, and
- German court case on ReWalk Personal 6.0 direct compensation decision expected later this year.

## ITEM 1A. RISK FACTORS

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

### Risks Related to Our Business and Our Industry

***The COVID-19 pandemic has adversely affected and may continue to materially and adversely impact our business, our operations and our financial results.***

The impact of the COVID-19 pandemic has resulted in and will likely continue to result in significant disruptions to the global economy, as well as businesses and capital markets around the world. In an effort to halt the outbreak of COVID-19, a number of countries, including the United States and Germany where we have key operations, have implemented numerous measures to contain the pandemic, such as travel bans and restrictions, shelter-in-place orders and shutdowns. In addition, a significant number of our global suppliers, vendors, distributors and manufacturing facilities are located in regions that have been affected by the pandemic. Those operations have been materially adversely affected by restrictive government and private enterprise measures implemented in response to the pandemic, which in turn, has adversely affected our operations. Despite the distribution of COVID-19 vaccines, new and occasionally more virulent variants of the virus that causes COVID-19, including the Delta and Omicron variants, have emerged and there is significant uncertainty as to how the countries in which we do business will continue to respond to such outbreaks, including whether there will be future partial or total shutdowns, which would adversely affect our business.

*Sales.* The steps we have taken in response to the COVID-19 pandemic to safeguard employees and patients have curtailed direct sales activities, including our ability to train patients and rehabilitation centers on how to use our system, which has adversely impacted our sales and results of operation since 2020. The main effect we have seen that will potentially limit our results in the future is the reduction in leads and overall pipeline due to limited interaction with our customers, mainly the SCI population, which are considered high risk and will generally avoid interaction and unnecessary visits to clinics, as well as the clinics themselves that purchase our rehabilitation products which are less focused on new technologies during the pandemic. For example, we are unable to interact and test our ReWalk Personal system with potential new patients at the same levels that we had before the COVID-19 outbreak. In addition, our ReStore device which has had limited trial use and placements to date due to the outbreak of COVID-19 that occurred relatively shortly following our receipt of FDA clearance for the device in the third quarter of 2019, and currently we do not have sufficient user experience to effectively evaluate its potential market success. It may take an extended period after current restrictions end and vaccines are fully distributed in our main markets, for us to engage with potential new clients. We continue to monitor our sales pipeline on a day-to-day basis in order to assess the quarterly effect of these limitations as some have short term effects and some affect our future pipeline development.

*Repairs.* We have had instances where we were unable to repair existing systems with the result that we have had to ship temporary replacement systems and parts in some cases. This situation is especially relevant when social distancing and quarantine restrictions are imposed. While these restrictions have eased in many jurisdictions, we cannot be certain that social distancing restrictions or other measures will not be reinstated in the event of a future outbreak of COVID-19 or similar outbreak as we have recently seen with the Omicron variant.

*Production and Supply Chain.* Our manufacturing was impacted mainly by parts shortages and supply chain delays, which we were able to manage to date with sufficient inventory procurement. We have also experienced an increase in cost of goods in specific areas mainly with electronic parts and batteries. There are other elements that might affect our product availability such as adverse impacts on our production capacity due to government directives, staffing shortages, transportation issues, or health protocols that might impact our production facility. In addition, given the impact of current limitations on our sales activities, it has become hard for us to effectively forecast our future requirements for systems. Accordingly, there is a greater risk that we may overproduce or under-produce compared to our actual sales.

*Regulatory and clinical trials.* Limitations on travel and business closures, along with social distancing and quarantine restrictions, recommended by federal, state, and local governments, have in the past and could in the future, among other things, impact our ability to enroll patients in clinical trials, perform other trials such as usability testing necessary for product development, recruit clinical site investigators, and obtain timely approvals from local regulatory authorities for trials we might conduct. In our post-market study that we continue to conduct, we may face decreased ability to contact patients where a patient's COVID-19 status is unknown. Regulatory oversight and actions regarding our products have been and may continue to be disrupted or delayed in regions impacted by COVID-19, including the United States and Europe, which have been and may continue to impact review and approval timelines for products in development and/or changes to existing products that require regulatory review and approval.

*Negative impacts on our suppliers and employees.* COVID-19 may impact the health of our employees, directors, partners, or customers, reduce the availability of our workforce or those of companies with which we do business, divert our attention toward non-ordinary course succession planning, or create disruptions in our supply or distribution networks. The adverse effects of such events on us may include disruption to our operations, or demand for our products in the short and/or long term.

Our future results of operations and liquidity could be adversely impacted by delays in payments of outstanding receivable amounts beyond normal payment terms, supply chain disruptions and operational challenges faced by our customers. Continued outbreaks of COVID-19 could adversely affect the economies and financial markets of many countries, resulting in an economic downturn or a global recession that could affect demand for our products and likely impact our operating results. These may further limit or restrict our ability to access capital on favorable terms, or at all, lead to consolidation that negatively impacts our business, weaken demand, increase competition, cause us to reduce our capital spend further, or otherwise disrupt our business.



***We may not have sufficient funds to meet certain future capital requirements, which could impair our efforts to develop and commercialize existing and new products, and as a result, we may in the future consider one or more capital-raising transactions, including future equity or debt financings, strategic transactions, or borrowings may also further dilute our shareholders or place us under restrictive covenants limiting our ability to operate Freely.***

We intend to finance operating costs until we reach profitable operation with existing cash on hand, continued close examination of our operating spend and potential reduction in specific areas, issuances of equity and/or debt securities, and other future public or private issuances of securities, or through a combination of the foregoing, though we may also consider additional capital raising alternatives, such as entering into a credit facility, if the foregoing are not available to us or unavailable on reasonable terms. Although we raised approximately \$79.8 million in net proceeds from equity issuances during 2021, which we believe will be sufficient to fund our planned operations through at least the next 12 months from the date of this report, if we are incorrect in our assumptions, we may need to raise additional capital sooner than expected or on less favorable terms than what might otherwise be available. Raising additional capital through one or more of these alternatives may further dilute our shareholders or place us under restrictive covenants limiting our ability to operate freely.

Raising additional capital in the public markets could also entail certain downsides. Although we are currently eligible to use our Form S-3, we could be limited to selling no more than one-third of our unaffiliated market capitalization, or public float, on Form S-3 in a 12-month period if our public float again falls below \$75 million. For more information on our inability to use Form S-3, see “Part II. Item 2, Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Equity Raises” below. Additionally, under our September 2021 purchase agreement with certain investors, we agreed for a period of one year following September 29, 2021, not to (i) issue or agree to issue equity or debt securities convertible into, or exercisable or exchangeable for, ordinary shares at a conversion price, exercise price or exchange price which floats with the trading price of the ordinary shares or which may be adjusted after issuance upon the occurrence of certain events or (ii) enter into any agreement, including an equity line of credit, whereby we may issue securities at a future-determined price, other than an at-the-market facility with the placement agent, H.C. Wainwright & Co, LLC, beginning on March 29, 2022. Such limitations may inhibit our ability to access capital efficiently. Additionally, due to these limitations on our use of Form S-3 and the use of our current at-the-market offering program with a separate bank, Piper Jaffray & Co., we may be required to seek other methods for access to capital, such as a registration statement on Form S-1. The preparation of a registration statement on Form S-1 is and has in the past been, more time-consuming and costly than using Form S-3. We may also conduct fundraising transactions in the form of private placements, potentially with registration rights or priced at a discount to the market value of our ordinary shares, which could require shareholder approval under the rules of Nasdaq, or other equity raise transactions such as equity lines of credit. In addition to entailing increased capital costs, any such transactions have historically resulted in and could result in substantial dilution of our shareholders’ interests and may also transfer control to a new investor or diminish the value of an investment in our ordinary shares.

We may also need to pursue strategic transactions, such as joint ventures, in-licensing transactions, or the sale of our business or all or substantially all of our assets if our financial stability is uncertain, and we are unable to raise additional capital effectively. These strategic transactions have in the past and could in the future require significant management attention, disrupt our business, adversely affect our financial results, be unsuccessful or fail to achieve the desired results.

Overall, if we cannot raise the required funds, or cannot raise them on terms acceptable to us or investors, we may be forced to curtail substantially our current operations or cease operations altogether.

***While we have regained compliance with the quantitative continued listing rules of the Nasdaq Capital Market, we may not be able to maintain the listing of our ordinary shares on the Nasdaq Capital Market going forward, which could adversely affect our liquidity and the trading volume and market price of our ordinary shares.***

As previously disclosed, on March 24, 2020, we received a notification letter from Nasdaq stating that we failed to comply with the closing bid price requirement of Nasdaq Rule 5550(a) (“Rule 5550(a)”). If our closing bid price is less than \$1 per share for 30 consecutive business days, we will be deficient with Rule 5550(a). On May 11, 2020, we received a notice from Nasdaq stating that we have regained compliance with Rule 5550(a) since our share price was above \$1 for 10 consecutive business days and that the matter is now closed. Our closing share price as of February 23, 2022 was \$1.05. If we become non-compliant with Rule 5550(a) or any other Nasdaq continued listing requirement in the future and we fail to regain compliance during the applicable cure period, Nasdaq will notify us that our ordinary shares are subject to delisting. In the case of non-compliance, there can be no assurance that we will be able to regain compliance with the applicable rules.

We would be permitted to appeal any delisting determination to a Nasdaq Hearings Panel, and our ordinary shares would remain listed on the Nasdaq Capital Market pending the panel’s decision after the hearing. If we do not appeal the delisting determination or do not succeed in such an appeal, our ordinary shares would be removed from trading on the Nasdaq Capital Market. Any delisting determination could seriously decrease or eliminate the value of an investment in our ordinary shares and other securities linked to our ordinary shares. While an alternative listing on an over-the-counter exchange could maintain some degree of a market in our ordinary shares, we could face substantial material adverse consequences, including, but not limited to, the following: limited availability for market quotations for our ordinary shares; reduced liquidity with respect to our ordinary shares; a determination that our ordinary shares are “penny stock” under SEC rules, subjecting brokers trading our ordinary shares to more stringent rules on disclosure and the class of investors to which the broker may sell the ordinary shares; limited news and analyst coverage, in part due to the “penny stock” rules; decreased ability to issue additional securities or obtain additional financing in the future; and potential breaches under or terminations of our agreements with current or prospective large shareholders, strategic investors and banks. The perception among investors that we are at heightened risk of delisting could also negatively affect the market price of our securities and trading volume of our ordinary shares.

***Our future growth and operating results will depend on our ability to develop, receive regulatory clearance for and commercialize new products and penetrate new product and geographic markets.***

We are currently engaged in research and development efforts to address the needs of patients with mobility impairments besides paraplegia, such as stroke, and, in the future, we may engage in efforts to address these needs in patients with other conditions such as multiple sclerosis, cerebral palsy, Parkinson's disease and elderly assistance. We also began commercializing in 2019 our first product for stroke patients, the ReStore soft suit exoskeleton. For more information, see "Part, Item 1. Business—ReStore Products" above. In addition to other research and development projects, we are collaborating with Harvard to design, research and develop lightweight exoskeleton system technologies for lower limb disabilities intended to treat stroke, multiple sclerosis, mobility limitations for the elderly and other medical applications and our current research collaboration agreement with Harvard ends on March 2022. As part of the collaboration, Harvard has also licensed to us certain of its intellectual property relating to lightweight exoskeleton system technologies for lower limb disabilities. We are obligated to use commercially reasonable efforts to develop products under the license in accordance with an agreed-upon development plan and to introduce and market such products commercially.

We expect that a portion of our revenues will be derived, in the next few years, from the ReStore soft suit exoskeleton product and, in later years, if we choose to advance the current designs, from other new products, such as potentially ReBoot, a home use device for stroke patients, or new products of ours aimed at addressing other medical indications which affect the ability to walk, including multiple sclerosis, cerebral palsy, Parkinson's disease and elderly assistance. As such, our future results will depend on our ability to successfully develop and commercialize such new products and to penetrate our targeted markets with our existing ReStore product in larger scale than we have done to date. We cannot ensure you that we will be able to introduce new products, products currently under development or products contemplated for future development for additional indications in a timely manner, or at all, as it depends on our available resources to fund such projects, as well as our ability to conduct clinical trials and testing which could be severely impacted during the COVID-19 pandemic. While we received governmental clearance to market our ReStore product on the anticipated timetable in 2019, obtaining clearance for any other soft suit exoskeleton products we may develop could be an extensive, costly and time-consuming process, which could delay any planned commercialization timelines. For more information on the clearance processes for our products, see "Part I, Item 1. Business—Government Regulation" above.

Harvard may terminate its license agreement with us if we fail to maintain the requisite insurance or become insolvent. Any such termination of this aspect of the collaboration with Harvard could impair our research and development efforts into lightweight soft suit exoskeleton system technologies for lower limb disabilities such as the ReBoot device which is intended to be used at home by people who suffered stroke. In addition, we may not be able to clinically demonstrate the medical benefits of our products for new indications. We have limited clinical data demonstrating the benefits of our products and we might not be able to support the economic benefits our products have for our potential customers. We may also be unable to gain necessary regulatory clearances or approvals to enable us to market new products for additional indications or the regulatory process may be more costly and time-consuming than expected, which could adversely impact us given our cash position and ongoing capital requirements. We might also terminate or change our research collaboration agreement with Harvard if we see limited market to the current developed products or seek to focus our available resources to other areas of the business. For more information on the collaboration with Harvard, see "Research and Development-Research and Development Collaborations".

Even if we are successful in the design and development of new products, our growth and results of operations will depend on our ability to penetrate new markets and gain acceptance by non-SCI markets such as the stroke rehabilitation market, and, in the longer term, the home use device market for stroke-caused lower limb disability, multiple sclerosis, elderly assistance and cerebral palsy patients. We may not be able to gain such market acceptance in these communities in a timely manner, or at all.

While our new products currently under development will share some aspects of the core technology platform in our current products, their design features and components may differ from our current products. Accordingly, these products will also be subject to the risks described under the Risk Factor titled "We rely on sales of our ReWalk and ReStore systems and related service contracts and extended warranties for our revenue. We may not be able to achieve or maintain market acceptance of our ReWalk or ReStore systems, or to generate sufficient revenues from these current and future products to sustain our operations." 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 rely on sales of our ReWalk and ReStore systems and related service contracts and extended warranties for our revenue. We may not be able to achieve or maintain market acceptance of our ReWalk or ReStore systems, or to generate sufficient revenues from these current and future products to sustain our operations.***

We currently rely, and expect in the future to rely, on sales of our ReWalk Personal, ReWalk Rehabilitation and ReStore systems and related service contracts and extended warranties for our revenue. We began marketing in 2019 in the United States and the EU (following the receipt of FDA and CE mark clearance) the ReStore lightweight soft suit exoskeleton, which is designed to support mobility for individuals suffering from other lower limb disabilities. Several factors could negatively affect our ability to achieve and maintain market acceptance of our ReWalk system or our ReStore system, which could in turn materially impair our business, financial condition, and operating results.

- ***ReWalk.*** We have sold only a limited number of ReWalk systems, and market acceptance and adoption depend on educating people with limited upright mobility and health care providers as to the distinct features, ease-of-use, positive lifestyle impact and other benefits of ReWalk compared to alternative technologies and treatments. ReWalk may not be perceived to have sufficient potential benefits compared with these alternatives. Users may also choose other therapies due to disadvantages of ReWalk, including the time it takes for a user to put on ReWalk, the slower pace of ReWalk compared to a wheelchair, the weight of ReWalk when carried, which makes it more burdensome for a companion to transport than a wheelchair, the required training, 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, we may be unable to sell on a profitable basis current ReWalk systems or other future products for home and community use 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. Several private and national insurers in the United States and Europe have provided reimbursement for ReWalk in certain cases. To date, VA maintains its policy of covering the cost of ReWalk devices for qualifying veterans across the United States, and German insurers such as Germany's national social accident insurance provider, Deutsche Gesetzliche Unfallversicherung (the "DGUV") indicated that its member payers will approve the supply of exoskeleton systems for qualifying beneficiaries on a case-by-case basis as the ReWalk device was issued a code in the medical device directory in Germany. In addition, in 2020 we announced that we accepted a binding offer with the DGUV to supply our ReWalk Personal 6.0 to qualified patients as well as with other payors in Germany. We have also been granted a HCPCS code by CMS and are currently in the process of identifying the relevant Medicare benefit category for the ReWalk Personal 6.0 device with CMS. with the organization. However, no broad uniform policy of coverage and reimbursement for electronic exoskeleton medical technology exists among third-party payors in the United States and Germany. Health insurance companies and other third-party payors in the future may also not deliver adequate coverage or reimbursement for our current or future products designed for home and community use. The VA, DGUV, CMS or other payors may elect not to provide coverage policy, cancel or materially curtail their current policy of providing coverage ReWalk devices in the United States and Germany for qualifying individuals who have suffered spinal cord injury, or we may not place enough units through to make our sales profitable under their policies. For more information, see "—Risks Related to our Business and our Industry— We may fail to secure or maintain adequate insurance coverage or reimbursement for our products by third-party payors, which risk may be heightened if insurers find the products to be investigational or experimental or if new government regulations change existing reimbursement policies. Additionally, such coverage or reimbursement, even if maintained, may not produce revenues that are high enough to allow us to sell our products profitably."

- **ReStore.** The ReStore system is designed to provide advantages to stroke rehabilitation clinics and therapists as compared to other traditional therapies and devices by minimizing setup time, improving patients' clinical results during therapy, supplying real-time analytics to optimize session productivity, and generating ongoing data reports to assist with tracking patient progress. Since the ReStore device is currently being used only in the rehabilitative clinical setting, its market reception will depend heavily on our ability to demonstrate to clinics and therapists the systemic and economic benefits of using the ReStore device, its clinical advantage when compared to other devices or manual therapy, the functionality of the device for a significant portion of the patients that they treat and the overall advantages that the device provides to their patients compared to other technologies. Because the ReStore system is currently being used only in clinical settings, and we received FDA approval and CE clearance in 2019, close in time to the start of the COVID-19 pandemic, the overall sales of the system have been lower than originally anticipated, as many healthcare providers and rehabilitation centers have shifted focus from the clinical setting to at-home therapies and are generally less open for introduction of new technologies such as the ReStore.

As a general matter, achieving and maintaining market acceptance of our current or future products could be negatively impacted by many other factors, including, but not limited to the following: contribution to death or serious injury or malfunction, results of clinical studies relating to our or similar products; claims that our products, or any of their components, infringe on patent or other intellectual property rights of third parties; our ability to support financially and leverage our sales, marketing and training infrastructure, as well as our level of research and development efforts; our ability to enhance and broaden our research and development efforts and product offerings in response to the evolving demands of people with paraplegia and lower limb disability and healthcare providers; our estimates regarding our current or future addressable market; perceived risks associated with the use of our products or similar products or technologies; the introduction of new competitive products or greater acceptance of competitive products; adverse regulatory or legal actions relating to our products or similar products or technologies; and problems arising from the outsourcing of our manufacturing capabilities, or our existing manufacturing and supply relationships. Any or all of these factors could materially and negatively impact our business, financial condition and operating results.

***The market for medical exoskeletons, including soft suit devices, remains relatively new and unproven, and important assumptions about the potential market for our current and future products may be inaccurate.***

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

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

We obtained FDA clearance for our ReStore system in June 2019. This instructions for use permit us to market the device to be used to assist ambulatory functions in rehabilitation institutions for people with hemiplegia or hemiparesis due to stroke who can ambulate at least 1.5m (5ft) with no more than minimal to moderate levels of assistance. The FDA's clearance requires users of the device to meet the following criteria: height between 4 feet 8 inches and 6 feet 3 inches/1.42 meters and 1.92 meters and weight of less than 264 pounds/120 kilograms. Additionally, the FDA clearance mandates that persons with the following conditions should not use the Restore: serious co-morbidities that may interfere with ability to safely use ReStore, severe peripheral artery disease ("PAD"), unresolved deep vein thrombosis ("DVT"), range of motion ("ROM") restrictions at the ankle that preclude safe walking, cognitive impairments that may interfere with safe operation of the device, presence of open wounds or broken skin at device locations, urethane allergy or current pregnancy.

Future products for those with paraplegia or other mobility impairments or spinal cord injuries, may have the same or other restrictions.

Our business strategy is based, in part, on our estimates of the number of mobility-impaired individuals and the incurrence of spinal cord injuries and strokes in our target markets, and the percentage of those groups that would be able to use our current and future products. Limited sources exist to obtain reliable market data with respect to the number of mobility-impaired individuals and the incurrence of spinal cord injuries and strokes in our target markets. In addition, there are no third-party reports or studies regarding what percentage of those with limited mobility and/or spinal cord injuries would be able to use exoskeletons, in general, or our current or planned future products, in particular. Our assumptions may be inaccurate and may change.

The National Spinal Cord Injury Statistical Center (“NSCISC”) estimates that as of 2021 there were 296,000 people in the United States living with SCI, and that the annual incidence of SCI cases is approximately 17,900 new cases per year. Based on information from a 2017 report by the NSCISC, 40.4% of the total U.S. population of SCI patients suffered injuries between levels T4 and L5. Four published ReWalk trials with respect to such eligible SCI patients had an aggregate screening acceptance rate of 50% considering all current FDA limitations, resulting in an estimated 20.2% of the total population of SCI patients being qualified candidates for current ReWalk products under its medical labeling criteria. There may be other permanent or short-term factors that affect the market size such as the ability to participate in the training program, the ability to use the device in the user’s current home environment as well as available companion support. With regards to our ReStore product for stroke rehabilitation, as the indication of use is currently in rehabilitation clinics our target market is based on the number of current and future clinics who treat stroke patients. Although there are thousands of inpatient, outpatient and rehabilitation clinics providing therapy in the U.S. for example, we currently see that only a limited portion of the clinics have decided to include ReStore in their stroke rehab program. For more information on our expectations regarding these plans, see “—Our future growth and operating results will depend on our ability to develop and commercialize new products and penetrate new markets” below. For more information regarding the potential market for future products, including our lightweight soft suit exoskeleton, see “Part I, Item 1. Business—ReWalk Personal and ReWalk Rehabilitation Products—Market Opportunity” above.

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

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

We expect that in the future a significant source of payment for ReWalk systems will be private insurance plans and managed care programs, government programs such as the VA, CMS, worker’s compensation, and other third-party payors.

In December 2015, the VA issued a national reimbursement policy for the ReWalk system, which entails the evaluation, training and procurement of ReWalk Personal exoskeleton systems for all qualifying veterans across the United States. Additionally, in September 2017, German insurer Barmer signed a confirmation and letter of agreement regarding the provision of ReWalk systems for all qualifying beneficiaries and the German national social accident insurance provider DGUV indicated that its member payers will approve the supply of exoskeleton systems for qualifying beneficiaries on a case-by-case basis. However, no broad uniform policy of coverage and reimbursement for electronic exoskeleton medical technology exists among third-party payors in the United States, although reimbursement may be achieved on a case-by-case basis. To date, payments for our products, which are largely for our ReWalk systems, have been made primarily through case-by-case determinations by third-party payors (including several private insurers in the United States), by self-payors and, to a lesser extent, through the use of funds from insurance and/or accident settlements.

Generally, private insurance companies in the United States do not cover or provide reimbursement for any medical exoskeleton products for personal use, including ReWalk Personal, and may ultimately provide no coverage at all. Additionally, there is limited clinical data related to the ReWalk and ReStore systems, and third-party payors may consider use of them to be experimental and therefore refuse to cover any or all of them. Additionally, the majority of independent medical review decisions to date made following the denial of ReWalk coverage have determined that ReWalk is experimental and/or investigational, citing a lack of clinical data.

Many private third-party payors use coverage decisions and payment amounts determined by the Center for Medicare and Medicaid Services (the “CMS”), which administers the Medicare program, as guidelines in setting their coverage and reimbursement policies. We have started the process of obtaining reimbursement coverage from CMS, and in July 2020, CMS issued a Healthcare Common Procedure Coding System Level II Code for ReWalk Personal 6.0 (effective October 1, 2020). These codes are used to identify medical products and supplies and to facilitate insurance claim submissions and processing for these items. However, while we believe that any ultimate positive reimbursement response by CMS will broaden coverage by private insurers, we cannot currently predict how long it would take for us to receive a coverage decision from CMS for any of our products nor can we predict other business elements that will be decided by CMS such as the price per unit or product labeling requirements. Even with a positive decision from CMS regarding a product of ours, future action by CMS or other government agencies may diminish possible payments to physicians, outpatient centers and/or hospitals that purchase our products for use by their patients and possible payments to individuals who purchase the ReWalk Personal for their own use. Additionally, a decision by CMS to provide reimbursement could influence other payors, including private insurers. If CMS declines to provide for reimbursements of our products or if its reimbursement price is lower than that of other payors, our products 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 our products or their use in a hospital or rehabilitative setting. In addition, we expect that the purchase of ReWalk Rehabilitation systems and the ReStore system, as it is currently being sold for use in rehabilitative settings, 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 our products on a profitable basis if third-party payors deny coverage or provide insufficient levels of reimbursement.

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

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

The design, manufacture and marketing of our products involve certain inherent risks. Manufacturing or design defects, unanticipated use of ReWalk or ReStore, or inadequate disclosure of risks relating to the use of our products 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 our products (either voluntary or required by the FDA or similar governmental authorities in other countries), and could result, in certain cases, in the removal of our products 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 clearances or approvals.

When an exoskeleton is used by a paralyzed individual to walk, the individual relies completely on the exoskeleton to hold him or her upright. Between 2013 and 2020, we submitted medical device reports, or MDRs, to the FDA (and equivalent authorities outside of the United States) relating to reports of falls and fractures of individuals using the ReWalk Personal system. We conducted a voluntary correction related to certain use instructions in the device's labeling, which the FDA classified as a Class II recall. The recall was closed in November 2019, and the FDA cleared our updated 510(k) containing revised instruction for use in May 2020.

In addition, our products incorporate 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 our product's hardware or software were to fail, the user could experience death or serious injury. For example, ReWalk recently submitted medical device reports to the FDA and medical device vigilance reports to the European regulatory authorities and initiated a correction in response to two complaints regarding battery thermal runaway events. The correction that includes clarification of previous instructions and additional information on battery operation and storage is closed in Europe and in the United States. ReWalk has separately initiated a design project to improve power management and battery operation during charge and discharge. Additionally, users may not use or maintain our products in accordance with safety, storage, and training protocols, which could enhance the risk of death or injury. Any such occurrence could cause delay in market acceptance of our products, 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 any of our products which has resulted in an injury or death. 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. Any alleged defect that has resulted in an adverse event involving our products could result in future voluntary corrective actions, such as recalls or customer letters, or in an FDA enforcement action, such as a mandatory recall, notification to healthcare professionals and users, warning letter, seizure, injunction or import alert. In addition, failure to report such adverse events to appropriate government authorities on a timely basis, or at all, could result in enforcement action against us. Any action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require financial resources and distract management, and may harm our reputation and financial results.

***We have a limited operating history and sales experience upon which you can evaluate our business plan and prospects in comparison to larger, more established companies developing products to treat spinal cord injuries or rehabilitative treatments for lower limb disability due to stroke.***

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, after receiving FDA clearance to do so in June 2014. We began selling our ReStore product in the United States and Europe in June 2019 following receipt of FDA and CE mark clearance, respectively. However, due to a shift to at-home therapies brought on by the ongoing COVID-19 pandemic and the challenges associated with marketing and selling our products during the pandemic, as described elsewhere in this report, we have had a limited ability to engage with potential SCI Product and ReStore purchasers over the past two years, which has resulted in lower sales than originally anticipated. In addition, we are actively working toward, but have not yet achieved, meaningful reimbursement for our SCI products from third party payors, which is generally a barrier to wider market acceptance. Due to the challenges brought on by the COVID-19 pandemic and those associated with entry into the markets in which we operate, although we have been a revenue generating company since 2011, we have a limited operating history and sales experience upon which you can evaluate our business plan and prospects in comparison to other larger or more established companies developing products to treat spinal cord injuries or rehabilitative treatments for lower limb disability due to stroke. Our business plan and prospects must be considered in light of the potential problems, delays, uncertainties and complications encountered in connection with a more newly established business in comparison to larger or more established companies that operate in our targeted markets. The risks include, but are not limited to, that:

- a market will not sufficiently 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 nor will we get sufficient reimbursement coverage;
- we will not be able to establish brand recognition and competitive advantages for our products;
- we will not receive necessary regulatory clearances or approvals for our products; and
- our competitors market an equivalent or superior product or hold proprietary rights that preclude us from marketing our products.

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

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

A key element of our long-term business strategy is the continued leveraging of our sales, marketing, training, and reimbursement infrastructure, through the training, retaining and motivating of skilled sales and marketing representatives and reimbursement personnel with industry experience and knowledge. Our ability to derive revenue from sales of our products depends largely on our ability to market the products and obtain reimbursements for them. In order to continue growing our business efficiently, we must therefore coordinate the development of our sales, marketing, training and reimbursement infrastructure with the timing of regulatory approvals, decisions regarding reimbursements, limited resources consideration and other factors in various geographies. Managing and maintaining our sales and marketing infrastructure is expensive and time consuming, and an inability to leverage such an organization effectively, or in coordination with regulatory or other developments, could inhibit potential sales and the penetration and adoption of our products into both existing and new markets. However, certain decisions we make regarding staffing in these areas in our efforts to maintain an adequate spending level could have unintended negative effects on our revenues, such as by weakening our sales infrastructure, impairing our reimbursement efforts and/or harming the quality of our customer service.

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

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

Although study participants and other ReWalk users have reported the secondary health benefits of our ReWalk products such as a reduction in pain and spasticity, improved bowel and urinary tract functions and emotional and psychosocial benefits, among others, currently there is no conclusive clinical data establishing any secondary health benefits of ReWalk. There is also a lack of conclusive clinical data for such health benefits of the ReStore specifically its long-term benefits following the usage of the product within the clinic as the trials conducted to date using this product are limited.



As a result, potential customers and healthcare providers may be slower to adopt or recommend ReWalk or ReStore 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 products is not superior to treatment with alternative products or therapies. Such results could slow the adoption of our products and significantly reduce our sales.

***We depend on a single third party to manufacture our products, and we rely on a limited number of third-party suppliers for certain components of our products.***

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

Our results of operations and liquidity could be adversely impacted by supply chain disruptions and operational challenges faced by our manufacturer or suppliers. Sanmina generally uses a small number of suppliers for ReWalk and ReStore. Depending on a limited number of suppliers exposes us to risks, including limited control over pricing, availability, quality, and delivery schedules. Such risks are heightened in light of the interruptions in supply chains and distribution networks related to the COVID-19 pandemic. For example, as a result of the ongoing COVID-19 pandemic, we have seen several components, mainly electronic parts, suffer price increases. 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 or accept price increase as we have seen during the pandemic. 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.

All manufacturing and assembly of our products is conducted at a single facility run by Sanmina 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 such as a local shutdown as we have seen during the pandemic, our business, financial condition and results of operations could be materially adversely affected. In particular, this facility is located in the north of Israel within range of rockets that have from time to time been fired into the country during armed conflicts with Hezbollah and other armed groups in Lebanon, Syria or other countries in the region. Although our manufacturing and assembly operations could be transferred elsewhere, either in-house or to an alternative Sanmina facility, the process of relocating these operations would cause delays in production. Lost sales or increased costs that we may experience during the disruption, or a forced relocation, of operations may not be recoverable under our insurance policies, and longer-term business disruptions could result in a loss of customers. If this were to occur, our business, financial condition and operations could be materially negatively impacted. Additionally, our reliance on Sanmina as a contract manufacturer or any other contract manufacturer makes us vulnerable to possible capacity constraints and reduced control over component availability, delivery schedules, manufacturing yields and costs.

***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 our products. Our principal competitors in the medical exoskeleton market consist of Ekso Bionics, Parker Hannifin, FREE Bionics, Rex Bionics, Cyberdyne, and others. These companies have products currently available for institutional use and in some cases personal use. We expect some of such products to become available for personal use in the next few years especially as we continue to expand coverage by different payors and geographies. In addition, we compete with alternative devices and alternative therapies, including treadmill-based gait therapies, such as those offered by DIH (formerly known as Hocoma), AlterG, Aretech, Reha Technology and Bioness. Our competitor base may change or expand as we continue to develop and commercialize our soft suit exoskeleton product in the future. These or other medical device or robotics companies, academic and research institutions, or others, may develop new technologies or therapies that provide a superior walking and usage experience, are more effective in treating the secondary medical conditions that we target or are less expensive than ReWalk, ReStore 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 our products seek 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 or ReStore, particularly if it competes with or has the potential to compete with or diminish the need/utilization of products or treatments supported through these existing relationships. If we are not able to compete effectively, our business and results of operations will be negatively impacted.

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

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

While we expect that the percentage of our sales generated from independent distributors will decrease over time as we continue to focus our resources on achieving reimbursement within our direct markets in the United States and Europe, we believe that some 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 may receive a significant number of warranty claims or our ReWalk and ReStore systems may require significant amounts of service after sale.***

Sales of ReWalk generally include a five-year warranty for parts and services, other than for normal wear and tear. Some of our active devices were delivered prior to 2018 with two years warranty so we provide these customers with the option to purchase an extended warranty for up to an additional three years. Our ReStore product offering includes a two-year warranty for parts and services. 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.

***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 are working to enhance and broaden our research and development efforts and product offerings in response to the evolving demands of people with paraplegia, paralysis, other medical conditions and healthcare providers, as well as competitive technologies. We are also currently involved in ongoing research and development efforts directed to the needs of patients with other mobility impairments, such as stroke, and began commercializing our ReStore product for stroke patients in 2019. Depending on our future resources and business focus, we plan to address these needs in patients with other conditions or devices for stroke patients to be used at home, improving our current products, or developing products to address additional medical conditions such as multiple sclerosis, Parkinson's disease or cerebral palsy and support elderly assistance. We may decide to invest our business development resources in partnerships, licensing agreements, business acquisition and other ways that will provide us new product offerings without significant research and development activities. We may not be successful in developing, obtaining regulatory approval for, or marketing our currently proposed products, or our approved products for additional indications, products proposed to be created in the future or products that will be available for us through business acquisitions. 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;
- identify the product features that people with stroke, multiple sclerosis or other similar indications require while the products are used at home as well as what items are valuable to the clinics that provide them rehabilitation;
- 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 clearances and approvals for proposed products.

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

***We may enter into collaborations, in-licensing arrangements, joint ventures, strategic alliances, business acquisitions 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, we may enter into collaborations, in-licensing arrangements, joint ventures, strategic alliances, business acquisitions, partnerships or other arrangements to develop our products and to pursue new geographic or product markets. Proposing, negotiating, and implementing collaborations, in-licensing arrangements, joint ventures, strategic alliances, or partnerships may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing, sales, technology or other business resources, may compete with us for these opportunities or arrangements. 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 agreements with MediTouch and Myolyn for the distribution of their products in the U.S. These distribution arrangements with MediTouch and Myolyn may not be as productive or successful as we hope.

On May 16, 2016, we entered into the Collaboration Agreement and License Agreement with Harvard. Pursuant to the Collaboration Agreement, we have agreed to collaborate with Harvard for the research, design, development, and commercialization of lightweight exoskeleton system technologies for lower limb disabilities, aimed to treat stroke, multiple sclerosis, mobility limitations for the elderly and other medical applications. It is possible that neither the Collaboration Agreement nor the Harvard License Agreement will result in any meaningful product developments, or if they do, that we will be able to successfully commercialize or market any such products. For more information on the collaboration with Harvard, see “Research and Development-Research and Development Collaborations”.

Additionally, as we pursue these arrangements and choose to pursue other collaborations, in-licensing arrangements, joint ventures, strategic alliances, or partnerships in the future, we may not be in a position to exercise sole decision-making authority regarding the transaction or arrangement. This could create the potential risk of creating impasses on decisions, and our collaborators may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. It is possible that conflicts may arise with our collaborators. Our collaborators or any future collaborators may act in their self-interest, which may be adverse to our best interest, and they may breach their obligations to us. Disputes between us and our collaborators or any future collaborators may 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. Our collaborators or any future collaborators may allege that we have breached our agreement with them, and accordingly seek to terminate such agreement, which could adversely affect our competitive business position and harm our business prospects.

#### **Risks Related to Government Regulation**

***Although the FDA granted Breakthrough Device Designation status to our new ReBoot device, this designation does not guarantee regulatory clearance or approval, or a speedier clearance or approval timeline.***

In November 2021, the FDA granted Breakthrough Device Designation status to ReBoot, a soft exoskeleton for stroke home and community use.

The Breakthrough Devices Program is a voluntary program for certain medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. It is available for devices and device-led combination products which are subject to review under a PMA, (510(k), or de novo request. The Breakthrough Devices Program offers manufacturers an opportunity to interact with the FDA’s experts through several different program options to efficiently address topics as they arise during the premarket review phase, which can help them receive feedback from the FDA and identify areas of agreement in a timely way. The program also provides manufactures prioritized review of their submission.

However, achieving Breakthrough Device Designation status does not guarantee regulatory clearance or approval or a speedier clearance or approval timeline. We have not yet submitted an application with the FDA or any other regulatory agency for clearance or approval of ReBoot.

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

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

In January 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the 2.3% excise tax imposed on manufacturers and importers for certain sales of medical devices through December 31, 2019. Absent further legislative action, the device excise tax was to be reinstated on medical device sales starting January 1, 2020. The Further Consolidated Appropriations Act, 2020 H.R. 1865 (Pub.L.116-94), signed into law on December 20, 2019, repealed the medical device excise tax previously imposed by Internal Revenue Code Section 4191.

In addition, the Affordable Care Act has been subject to challenges in the courts. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional and remanded the case to the Texas District Court to reconsider its earlier invalidation of the entire Affordable Care Act. An appeal was taken to the U.S. Supreme Court. On June 17, 2021, the Supreme Court ruled that the plaintiffs lacked standing to challenge the law as they had not alleged personal injury traceable to the allegedly unlawful conduct. As a result, the Supreme Court did not rule on the constitutionality of the ACA or any of its provisions. It is unclear what effect this decision and other efforts to repeal and replace the ACA will have on our business.

In January 2021, CMS issued a rule creating a new pathway for Medicare coverage of medical devices designed by FDA as breakthrough. This pathway, the “Medicare Coverage of Innovative Technology (MCIT),” provided for national coverage for on-label uses of such devices for four years. However, in September 2021, CMS reversed course, and proposed to rescind the rule due primarily to clinical evidence concerns.

Other legislative changes have been proposed and adopted since passage of the Affordable Care Act. The Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve its targeted deficit reduction of an amount greater than \$1.2 trillion for the fiscal years 2012 through 2021, triggering the legislation’s automatic reductions to several government programs. These reductions included aggregate reductions to Medicare payments to healthcare providers of up to 2.0% per fiscal year. The Bipartisan Budget Act of 2018 retained the federal budget “sequestration” Medicare payment reductions of 2%, and extended it through 2027 unless congressional action is taken, and also increased labeler responsibility for prescription costs in the Medicare Part D coverage gap. On January 2, 2013, the American Taxpayer Relief Act was signed into law, which, among other things, reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further legislative and regulatory changes under the Affordable Care Act remain possible, although the Biden Administration has signaled that it plans to build on the Affordable Care Act and expand the number of people who are eligible for subsidies under it. President Biden indicated that he intends to use executive orders to undo changes to the Affordable Care Act made by the Trump administration and would advocate for legislation to build on the Affordable Care Act. It is unknown what form any such changes or any law would take, and how or whether it may affect our business in the future. We expect that changes or additions to the Affordable Care Act, the Medicare and Medicaid programs, changes allowing the federal government to directly negotiate drug prices and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry.

The implementation of cost containment measures or other healthcare reforms may thus prevent us from being able to generate revenue, attain profitability or further commercialize our existing ReWalk systems or future ReWalk products. We are currently unable to predict what additional legislation or regulation, if any, relating to the health care industry may be enacted in the future or what effect recently enacted federal legislation or any such additional legislation or regulation would have on our business. The pendency or approval of such proposals or reforms could result in a decrease in our stock price or limit our ability to raise capital or to enter into collaboration agreements for the further development and commercialization of our programs and products.

***Our devices are subject to the FDA's regulations pertaining to marketing and promotional communications, among others. Failure to comply with such regulations may give rise to a number of potential FDA enforcement actions, any of which could have a material adverse effect on our business.***

Our sales and marketing efforts, as well as promotions, are subject to various laws and regulations. Medical device promotions must be consistent with and not contrary to labeling, be truthful and not false or misleading, and be adequately substantiated. In addition to the requirements applicable to 510(k)-cleared products, we may also be subject to enforcement action in connection with any promotion of an investigational new device. A sponsor or investigator, or any person acting on behalf of a sponsor or investigator, may not represent in a promotional context that an investigational new device is safe or effective for the purposes for which it is under investigation or otherwise promote the device.

Our marketing and promotional materials are subject to FDA scrutiny to ensure that the device is being marketed in compliance with these requirements. If the FDA investigates our marketing and promotional materials and finds that any of our current or future commercial products were being marketed for unapproved or unclear uses or in a false or misleading manner, we could be subject to FDA enforcement and/or false advertising consumer lawsuits, each of which could have a material adverse effect on our business.

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

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

Our products are regulated as medical devices in the United States under the FFDCA as implemented and enforced by the FDA. Under the FFDCA, medical devices are classified into one of three classes (Class I, Class II or Class III) depending on the degree of risk associated with the medical device, what is known about the type of device, and the extent of control needed to provide reasonable assurance of safety and effectiveness. Classification of a device is important because the class to which a device is assigned determines, among other things, the necessity and type of FDA review required prior to marketing the device. For more information, see "Part I, Item 1. Business—Government Regulation" above.

In June 2014, the FDA granted our petition for "*de novo*" classification, which provides a route to market for medical devices that are low to moderate risk, but are not substantially equivalent to a predicate device, and classified ReWalk as Class II subject to certain special controls. The ReWalk is intended to enable individuals with spinal cord injuries to perform ambulatory functions under supervision of a specially trained companion, and inside rehabilitation institutions. The special controls established in the *de novo* order include the following: compliance with medical device consensus standards; clinical testing to demonstrate safe and effective use considering the level of supervision necessary and the use environment; non-clinical performance testing, including durability testing to demonstrate that the device performs as intended under anticipated conditions of use; a training program; and labeling related to device use and user training. In order for us to market ReWalk, we must comply with both general controls, including controls related to quality, facility registration, reporting of adverse events and labeling, and the special controls established for the device. Failure to comply with these requirements could lead to an FDA enforcement action, which would have a material adverse effect on our business.

In June 2019, the FDA issued a 510(k) clearance for our ReStore device. ReStore is intended to be used to assist ambulatory functions in rehabilitation institutions under the supervision of a trained therapist for people with hemiplegia or hemiparesis due to stroke who have a specified amount of ambulatory function. In order for us to market ReStore, 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 that include clinical testing, non-clinical performance testing, and a training program. Failure to comply with these requirements could lead to an FDA enforcement action, which would have a material adverse effect on our business.

In the E.U. we are subject to directives and standards regulating the design, manufacture, clinical trials, labeling and adverse event (i.e., vigilance) reporting for medical devices. Devices that comply with the requirements of a relevant directive are entitled to bear the CE mark, indicating that the device conforms to the essential requirements of the applicable directive and, accordingly, can be commercially distributed throughout the European Economic Area (i.e., the E.U. Member States plus Norway, Iceland, and Lichtenstein). We comply with the E.U. requirements and have received the CE mark for all of our ReWalk systems including the ReStore device which are distributed in the E.U. A new Medical Device Regulation went into effect in May 2021, and includes additional premarket and post-market requirements, as well as potential product reclassifications or more stringent commercialization requirements that could adversely affect our CE mark. Failure to comply with these new requirements could lead to substantial penalties, including fines, revocation or suspension of CE mark and criminal sanctions.

Following the introduction of a product, the governmental agencies will periodically review our manufacturing processes and quality controls, 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 our devices. In addition, if we fail to comply with applicable regulatory requirements, it could result in fines or delays of regulatory clearances, closure of manufacturing sites, seizures or recalls of products and damage to our reputation, as well as enforcement actions against us.

For example, the FDA could request that we recall our ReWalk Personal 6.0 or ReStore device in case of product defects. FDA also has the authority to require us to conduct post-market surveillance studies, and if we fail to conduct such studies to FDA's satisfaction, we could be subject to FDA enforcement action. Such post-market surveillance studies could have unfavorable results or identify new safety concerns. For more information on certain deficiencies previously identified by the FDA in our mandatory post-market surveillance study on our ReWalk Personal 6.0, see “—Risks Related to Government Regulation—While we addressed the observations that FDA cited in a 2015 warning letter related to our mandatory post-market surveillance study and initiated the study, we are currently experiencing enrollment issues that make our study progress inadequate. Going forward, if we cannot meet certain FDA requirements and enrollment criteria for the study or otherwise satisfy FDA requests promptly, or if our study produces unfavorable results, we could receive additional FDA warnings, which could materially and adversely affect our commercial success.”

In addition, governmental agencies may impose new requirements regarding registration or labeling that may require us to modify or re-register our products or otherwise impact our ability to market our products in those countries, such as the May 2021 Medical Device Regulation changes. 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 our products. In the European Union, for example, a new Medical Device Regulation includes additional premarket and post-market requirements, as well as potential product reclassifications or more stringent commercialization requirements that could adversely affect our CE mark. Penalties for regulatory non-compliance with the Medical Device Regulation could also be substantial, including fines, revocation or suspension of CE mark and criminal sanctions.

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

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

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications or repair, replacement, or refunds;
- operating restrictions or partial suspension or total shutdown of production;
- recalls, withdrawals, or administrative detention or seizure of our products;
- refusing or delaying requests for approval of pre-market approval applications relating to new products or modified products;
- withdrawing a PMA approval;
- refusing to provide Certificates for Foreign Government;
- refusing to grant export approval for our products; or
- pursuing criminal prosecution.

Any of these sanctions could impair our ability to produce our products 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" above.

U.S. federal and state laws, including the federal Physician Payments Sunshine Act, or the Sunshine Act, and the implementation of Open Payments regulations under the Sunshine Act, require medical device companies to disclose certain payments or other transfers of value made to healthcare providers and teaching hospitals or funds spent on marketing and promotion of medical device products. It is widely believed that public reporting under the Sunshine Act and implementing Open Payments regulations results in increased scrutiny of the financial relationships between industry, physicians and teaching hospitals. Further, some state laws require medical device companies to report information related to payments to physicians and other health care providers or marketing expenditures. 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 or ReStore. 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, including those with marketers and sales agents. We may face significant costs in attempting to comply with these laws and regulations. If we are found to be in violation of any of these requirements or any actions or investigations are instituted against us, those actions could be costly to defend and 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, and damage to our reputation or business.



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

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

There are a number of federal, state and foreign laws protecting the confidentiality of certain patient health information, including patient records, and restricting the use and disclosure of that protected information. In particular, the U.S. Department of Health and Human Services, or HHS, promulgated patient privacy rules under the Health Insurance Portability and Accountability Act of 1996, or HIPAA. These privacy rules protect medical records and other personal health information by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting of their own health information and limiting most use and disclosures of health information to the minimum amount reasonably necessary to accomplish the intended purpose. Additionally, the E.U. General Data Protection Regulation (the “GDPR”), which took effect in 2018, imposes more stringent data protection requirements and will provide for greater penalties for noncompliance. Thus, with respect to our operations in Europe, the GDPR may increase our responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the GDPR. This may be onerous and adversely affect our business, financial condition, results of operations and prospects. Additionally, if we or any of our service providers are found to be in violation of the promulgated patient privacy rules under HIPAA or, once enforced, the GDPR, we could be subject to civil or criminal penalties, which could be substantial and could increase our liabilities, harm our reputation and have a material adverse effect on our business, financial condition and operating results.

In addition, a number of U.S. states have enacted data privacy and security laws and regulations that govern the collection, use, disclosure, transfer, storage, disposal, and protection of sensitive personal information, such as social security numbers, financial information and other personal information. For example, several U.S. territories and all 50 states now have data breach laws that require timely notification to individual victims, and at times regulators, if a company has experienced the unauthorized access or acquisition of sensitive personal data. Other state laws include the California Consumer Privacy Act (“CCPA”) which, among other things, contains new obligations for businesses that collect personal information about California residents and affords those individuals new rights relating to their personal information that may affect our ability to use personal information or share it with our business partners. Meanwhile, other states have considered privacy laws like the CCPA. We will continue to monitor and assess the impact of state law developments, which may impose substantial penalties for violations, impose significant costs for investigations and compliance, allow private class-action litigation and carry significant potential liability for our business.

The interpretation and enforcement of the laws and regulations described above are uncertain and subject to change and may require substantial costs to monitor and implement compliance with any additional requirements. Failure to comply with U.S. or international data protection laws and regulations could result in government enforcement actions (which could include substantial civil and/or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.

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

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

Our management team consists of few employees, as the majority of our employees are engaged in sales and marketing and research and development activities. For more information, see "Part I, Item 1. Business—Employees" above. In light of such constraints on its time, personnel and finances, our management may not be able to implement programs and policies in an effective and timely manner to respond adequately to the heightened legal, regulatory and reporting requirements applicable to us. In the past, for example, we have not always been able to respond on a timely basis to requests from regulators, although we have not to date experienced any long-term material adverse consequences as a result. Similar deficiencies, weaknesses, or lack of compliance with public company, medical device and other regulations could harm our reputation in the capital markets or for quality and safety, negatively affect our ability to maintain our public company status and to develop, commercialize or continue selling our products on a timely and effective basis, and cause us to incur sanctions, including fines, injunctions, and penalties.

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

## **Risks Related to Our Intellectual Property and Information Technology**

***We depend on computer and telecommunications systems we do not own or control and failures in our systems or a cybersecurity attack or breach of our IT systems or technology could significantly disrupt our business operations or result in sensitive customer information being compromised which would negatively materially affect our reputation and/or results of operations.***

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

In the current environment, there are numerous and evolving risks to cybersecurity and privacy, including criminal hackers, hacktivists, state-sponsored intrusions, industrial espionage, employee malfeasance and human or technological error. High-profile security breaches at other companies and in government agencies have increased in recent years, and security industry experts and government officials have warned about the risks of hackers and cyberattacks targeting businesses such as ours. Computer hackers and others routinely attempt to breach the security of technology products, services, and systems, and to fraudulently induce employees, customers, or others to disclose information or unwittingly provide access to systems or data. A cyberattack of our systems or networks that impairs our information technology systems could disrupt our business operations and result in loss of service to customers, including technical support for our ReWalk devices. While we have certain cybersecurity safeguards in place designed to protect and preserve the integrity of our information technology systems, we have experienced and expect to continue to experience actual or attempted cyberattacks of our IT systems or networks. However, none of these actual or attempted cyberattacks has had a material effect on our operations or financial condition.

Additionally, we have access to sensitive customer information in the ordinary course of business. If a significant data breach occurred, our reputation may be adversely affected, customer confidence may be diminished, or we may be subject to legal claims, any of which may contribute to the loss of customers and have a material adverse effect on us. For more information, see “—Risks Related to Government Regulation—If we are found to have violated laws protecting the confidentiality of patient health information, we could be subject to civil or criminal penalties, which could increase our liabilities and harm our reputation or our business.” above.

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

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

The patent position of robotic and exoskeleton inventions can be highly uncertain and involves many new and evolving complex legal, factual, and technical issues. Patent laws and interpretations of those laws are subject to change and any such changes may diminish the value of our patents or narrow the scope of our right to exclude others. In addition, we may fail to apply for or be unable to obtain patents necessary to protect our technology or products from competition or fail to enforce our patents due to lack of information about the exact use of technology or processes by third parties. Also, we cannot be sure that any patents will be granted in a timely manner or at all with respect to any of our patent pending applications or that any patents that are granted will be adequate to exclude others for any significant period of time or at all. Given the foregoing and in order to continue reducing operational expenses in the future, we may invest fewer resources in filing and prosecuting new patents and on maintaining and enforcing various patents, especially in regions where we currently do not focus our market growth strategy.

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

In addition, we seek to protect our trade secrets, know-how, and confidential information that is not patentable by entering into confidentiality and assignment agreements with our employees and certain of our contractors and confidentiality agreements with certain of our consultants, scientific advisors, and other vendors and contractors. However, we may fail to enter into the necessary agreements, and even if entered into, these agreements may be breached or otherwise fail to prevent disclosure, third-party infringement, or misappropriation of our proprietary information, may be limited as to their term and may not provide an adequate remedy in the event of unauthorized disclosure or use of proprietary information. Enforcing a claim that a third party illegally obtained or is using our trade secrets without authorization may be expensive and time consuming, and the outcome is unpredictable. Some of our employees or consultants may own certain technology which they license to us for a set term. If these technologies are material to our business after the term of the license, our inability to use them could adversely affect our business and profitability.

We also have taken precautions to initiate reasonable safeguards to protect our information technology systems. However, these measures may not be adequate to safeguard our proprietary information, which could lead to the loss or impairment thereof or to expensive litigation to defend our rights against competitors who may be better funded and have superior resources. In addition, unauthorized parties may attempt to copy or reverse engineer certain aspects of our products that we consider proprietary or our proprietary information may otherwise become known or may be independently developed by our competitors or other third parties. If other parties are able to use our proprietary technology or information, our ability to compete in the market could be harmed. Further, unauthorized use of our intellectual property may have occurred, or may occur in the future, without our knowledge.

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

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

Robotics and exoskeleton technologies have been developing rapidly in recent years. We are aware of several other companies developing competing exoskeleton devices for individuals with limited mobility and we expect the level of competition and the pace of development in our industry to increase. For more information, see "Part I, Item 1. Business—Competition" above. While we believe our tilt-sensor technology provides a more natural and superior method of exoskeleton activation, which creates a better user experience, as well as that our licensed technology used in our ReStore device is unique and provides better results when compared to other products, 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, as our current patents begin to expire, we may lose a competitive advantage over our competitors as we will no longer be able to keep our competitors from practicing the technology covered by the claim of the expired patents. We may also be unable to adequately develop new technologies and obtain future patent protection to preserve a 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 and Europe are limited. In addition, the laws of some foreign countries, especially developing countries, such as China, do not protect intellectual property rights to the same extent as federal and state laws in the United States. Also, it may not be possible to effectively enforce intellectual property rights in some countries at all or to the same extent as in the United States and other countries. Consequently, we are unable to prevent third parties from using our inventions in all countries, or from selling or importing products made using our inventions in the jurisdictions in which we do not have (or are unable to effectively enforce) patent protection. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop, market or otherwise commercialize their own products, and we may be unable to prevent those competitors from importing those infringing products into territories where we have patent protection, but enforcement may not be as strong as in the United States. These products may compete with our products and our patents and other intellectual property rights may not be effective or sufficient to prevent them from competing in those jurisdictions. Moreover, strategic partners, competitors, or others in the chain of commerce may raise legal challenges against our intellectual property rights or may infringe upon our intellectual property rights, including through means that may be difficult to prevent or detect.

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

Infringement actions and other intellectual property claims brought against us, whether with or without merit, may cause us to incur substantial costs and could place a significant strain on our financial resources, divert the attention of management, and harm our reputation. We cannot be certain that we will successfully defend against any allegations of infringement. If we are found to infringe another party's patents, we could be required to pay damages. We could also be prevented from selling our infringing products, unless we can obtain a license to use the technology covered by such patents or can redesign our products so that they do not infringe. A license may be available on commercially reasonable terms or none at all, and we may not be able to redesign our products to avoid infringement. Further, any modification to our products could require us to conduct clinical trials and revise our filings with the FDA and other regulatory bodies, which would be time consuming and expensive. In these circumstances, we may not be able to sell our products at competitive prices or at all, and our business and operating results could be harmed.

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

We rely on trademark protection to distinguish our products from the products of our competitors. We have registered the trademark “ReWalk” in Israel and in the United States. The trademark “ReStore” is registered in Europe, United States and United Kingdom. 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 Ownership of Our Ordinary Shares**

***Sales of a substantial number of ordinary shares by us or our large shareholders, certain of whom may have registration rights, or dilutive exercises of a substantial number of warrants by our warrant-holders could adversely affect the value 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 value of our ordinary shares to decline or could impair our ability to raise capital through a future sale of our equity securities. Additionally, dilutive exercises of a substantial number of warrants by our warrant-holders, or the perception that such exercises may occur, could put downward price on the market price of our ordinary shares.

As of February 24, 2022, 19,414,215 ordinary shares were issuable pursuant to the exercise of warrants, with exercise prices ranging from \$1.25 to \$9.375 per warrant, issued in private and registered offerings of ordinary shares and warrants in November 2016, November 2018, February 2019, April 2019, June 2019, February 2020, July 2020, December 2020, February 2021 and September 2021. We have registered with the SEC all of these warrants and/or the resale of the shares issuable upon their exercise. There were also 6,679 ordinary shares issuable pursuant to the exercise of warrants granted to Kreos Capital V (Expert Fund) Limited (“Kreos”), in connection with the December 30, 2015 signed loan agreement (the “Loan Agreement”) in January and December 2016, with an exercise price that is now set to \$7.50 per warrant. For more information, see “Part I, Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Loan Agreement with Kreos and Related Warrant to Purchase Ordinary Shares” and “Part I, Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Equity Raises”, in each case below.

All shares sold pursuant to an offering covered by a registration statement would be freely transferable. With respect to the outstanding warrants, there may be certain restrictions on the holders to sell the underlying ordinary shares to the extent they are restricted securities, held by “affiliates” or would exceed certain ownership thresholds. Certain of our largest shareholders, may also have limitations under Rule 144 under the Securities Act on the resale of certain ordinary shares they hold unless they are registered for resale under the Securities Act. Despite these limitations and the liquidity we may gain from cash exercises of outstanding warrants, if we, our existing shareholders, or their affiliates sell a substantial number of the above-mentioned ordinary shares in the public market, the market price of our ordinary shares could decrease significantly. Shareholders may also incur substantial dilution if holders of our warrants exercise their warrants to purchase ordinary shares, which could lower the market price of our ordinary shares. Any such decrease could impair the value of your investment in us.

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

We have historically used, and continue to use, our ordinary shares as a means of both rewarding our employees, non-employee directors, and consultants and aligning their interests with those of our shareholders. As of December 31, 2021, 1,652,073 ordinary shares remained available for issuance to our and our affiliates’ respective employees, non-employee directors, and consultants under our equity incentive plans, including 1,418,116 ordinary shares subject to outstanding awards (consisting of outstanding options to purchase 61,832 ordinary shares and 1,356,284 ordinary shares underlying unvested RSUs, and we may seek to increase the number of shares available under our equity incentive plans in the future. For more information, see Note 8c to our consolidated financial statements for the year ended December 31, 2021, below.

Additionally, to the extent registered on a Form S-8, ordinary shares granted or issued under our equity incentive plans will, subject to vesting provisions, lock-up restrictions, and Rule 144 volume limitations applicable to our “affiliates,” be available for sale in the open market immediately upon registration. Further, as of December 31, 2021, there were 19,518,390 ordinary shares underlying issued and outstanding warrants, which if exercised for ordinary shares, could decrease the net tangible book value of our ordinary shares and cause dilution to our existing shareholders. Sales of a substantial number of the above-mentioned ordinary shares in the public market could result in a significant decrease in the market price of our ordinary shares and have a material adverse effect on an investment in our ordinary shares.

***If we do not meet the expectations of equity research analysts, if any, if the sole remaining equity analyst following our business does not continue to publish research or reports about our business or if the analyst issues unfavorable commentary or downgrade our ordinary shares, the price of our ordinary shares could decline. Additionally, we may fail to meet publicly announced financial guidance or other expectations about our business, which would cause our ordinary shares to decline in value.***

There is currently one equity analyst publishing research reports about our business and we are currently seeking to attract additional coverage. If our results of operations are below the estimates or expectations of our sole analyst or consensus assuming we have some 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 analysts issue other unfavorable commentary or stop publishing research or reports about us or our business (as has occurred over time, with a decrease in the number of analysts following us from five in 2014 to one in 2021). Given that there is only one analyst that currently covers our business, we face an increased risk that such analyst’s evaluation of our business, if less than positive, will cause a larger decline in our stock price than would otherwise be the case if we had multiple analysts covering our business.

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

***We are a “smaller reporting company” and the reduced reporting requirements applicable to such companies may make our ordinary shares less attractive to investors.***

We are a “smaller reporting company” as defined in Item 10(f)(1) of Regulation S-K, which allows us to take advantage of certain scaled disclosure requirements available specifically to smaller reporting companies. For example, we may continue to use reduced compensation disclosure obligations, and, provided we are also a “non-accelerated filer,” we will not be obligated to follow the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. We will remain a smaller reporting company until the last day of the fiscal year in which we have at least \$100 million in revenue and at least \$700 million in aggregate market value of ordinary shares held by non-affiliated persons and entities (known as “public float”), or, alternatively, if our revenues exceed \$100 million, until the last day of the fiscal year in which our public float was at least \$250.0 million (in each case, with respect to public float, as measured as of the last business day of the second quarter of such fiscal year). For the year ended December 31, 2021, we recorded revenue of approximately \$6 million.

We cannot predict or otherwise determine if investors will find our securities less attractive as a result of our reliance on exemptions as a smaller reporting company and/or “non-accelerated filer.” If some investors find our securities less attractive as a result, there may be a less active trading market for our ordinary shares and the price of our ordinary shares may be more volatile.

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

We are required to comply with the internal control, evaluation, and certification requirements of Section 404 of the Sarbanes-Oxley Act and the Public Company Accounting Oversight Board, which requires us to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. Once we no longer qualify as a “smaller reporting company” and “non-accelerated filer,” our independent registered public accounting firm will need to attest to the effectiveness of our internal control over financial reporting under Section 404. When our independent registered public accounting firm is required to undertake an assessment of our internal control over financial reporting, the cost of our compliance with Section 404 will correspondingly increase. Our compliance with applicable provisions of Section 404 will require that we incur substantial accounting expense and expend significant management time on compliance-related issues as we implement additional corporate governance practices and comply with reporting requirements. Moreover, if we are not able to comply with the requirements of Section 404 applicable to us in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

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

Irrespective of compliance with Section 404, any failure of our internal controls could have a material adverse effect on our stated results of operations and harm our reputation. If we are unable to implement any of the required changes to our internal control over financial reporting effectively or efficiently or are required to do so earlier than anticipated, it could adversely affect our operations, financial reporting and/or results of operations and could result in an adverse opinion on internal controls from our management and our independent auditors. Further, if our internal control over financial reporting is not effective, the reliability of our financial statements may be questioned, and our share price may suffer.



***U.S. holders of our ordinary shares may suffer adverse U.S. tax consequences if we are characterized as a passive foreign investment company, or a PFIC, under Section 1297(a) of the Code.***

Generally, if for any taxable year 75% or more of our gross income is passive income, or at least 50% of the average quarterly value of our assets (which may be determined in part by the market value of our ordinary shares, which is subject to change) are held for the production of, or produce passive income, we would be characterized as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes. Passive income for this purpose generally includes, among other things, certain dividends, interest, royalties, rents, and gains from commodities and securities transactions and from the sale or exchange of property that gives rise to passive income. Passive income also includes amounts derived by reason of the temporary investment of funds, including those raised in an offering. In determining whether a non-U.S. corporation is a PFIC, a proportionate share of the income and assets of each corporation in which it owns, directly or indirectly, at least a 25% interest (by value) is taken into account.

The determination of whether we are a PFIC will depend on the nature and composition of our income and the nature, composition, and value of our assets from time to time. The 50% passive asset test described above is generally based on the fair market value of each asset, with the value of goodwill and going concern value determined in large part by reference to the market value of our ordinary shares, which may be volatile. If we are characterized as a “controlled foreign corporation,” or a “CFC”, under Section 957(a) of the Code and not considered publicly traded throughout the relevant taxable year, however, the passive asset test may be applied based on the adjusted tax bases of our assets instead of the fair market value of each asset (as described above). However, if we are treated as publicly traded for at least 20 trading days during the relevant taxable year, our assets would generally be required to be measured at their fair market value, even if we are a CFC.

Based on our gross income and assets, the market price of our ordinary shares, and the nature of our business, we believe that we may have been a PFIC for the taxable year ended December 31, 2021. However, this determination is subject to uncertainty. In addition, there is a significant risk that we may be a PFIC for future taxable years, unless the market price of our ordinary shares increases, or we reduce the amount of cash and other passive assets we hold relative to the amount of non-passive assets we hold. Accordingly, no assurances can be made regarding our PFIC status in one or more subsequent years, and our U.S. counsel expresses no opinion with respect to our PFIC status in the taxable year ended December 31, 2021, or the current year 2021, and also expresses no opinion with respect to our predictions or past determinations regarding our PFIC status in the past or in the future.

If we are characterized as a PFIC, U.S. holders of our ordinary shares may suffer adverse tax consequences, including having gains realized on the sale of our ordinary shares treated as ordinary income, rather than capital gain, the loss of the preferential tax rate applicable to dividends received on our ordinary shares by individuals who are U.S. holders and having interest charges apply to distributions by us and to the proceeds of sales of our ordinary shares. In addition, special information reporting may be required. 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 or being able to make a qualified electing fund election). 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.

Additionally, if we are characterized as a PFIC, for any taxable year during which a U.S. holder holds ordinary shares, we generally will continue to be treated as a PFIC with respect to such U.S. holder for all succeeding years during which such U.S. holder holds ordinary shares unless we cease to be a PFIC and such U.S. holder makes a “deemed sale” election with respect to such ordinary shares. If such election is made, such U.S. holder will be deemed to have sold such ordinary shares held by such U.S. holder at their fair market value on the last day of the last taxable year in which we qualified as a PFIC, and any gain from such deemed sale would be treated as described above.

Each U.S. holder of our ordinary shares is strongly urged to consult his, her or its tax advisor regarding the application of these rules and the availability of any potential elections.

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

Our ordinary shares were first publicly offered in our initial public offering in September 2014, at a price of \$300.00 per share, and our ordinary shares have subsequently traded as high as \$1,092.75 per share and as low as \$0.41 per share through February 24, 2022. All prices have been adjusted to reflect our 25-to-1 reverse stock split, which we effected in 2019. The market price of our ordinary shares could be highly volatile and may fluctuate substantially as a result of many factors. Moreover, while there is no established public trading market for the warrants offered in our follow-on public offerings, and we do not expect one to develop, our ordinary shares will be issuable pursuant to exercise of these warrants. Because the warrants are exercisable into our ordinary shares, volatility, or a reduction in the market price of our ordinary shares could have an adverse effect on the trading price of the warrants. Factors which may cause fluctuations in the price of our ordinary shares include, but are not limited to:

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

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. Technical factors in the public trading market for our ordinary shares may produce price movements that may or may not comport with macro, industry or Company-specific fundamentals, including, without limitation, the sentiment of retail investors (including as may be expressed on financial trading and other social media sites), the amount and status of short interest in our securities, access to margin debt, trading in options and other derivatives on our ordinary shares and any related hedging or other technical trading factors. 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, as was the case for ReWalk in a securities class action dismissed in full in November 2020. If we become involved in any similar litigation, we could incur substantial costs and our management's attention and resources could be diverted.

## **Risks Related 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, and quality and regulatory personnel, as well as the facility of our contract manufacturer, Sanmina, are located in Israel. Many of our employees, directors and officers are residents of Israel. Accordingly, political, economic, and military conditions in Israel and the surrounding region may directly affect our business. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its Arab neighbors, Hamas (an Islamist militia and political group in the Gaza Strip), Hezbollah (an Islamist militia and political group in Lebanon) and other armed groups. Any hostilities involving Israel or the interruption or curtailment of trade within Israel or between Israel and its trading partners could materially and adversely affect our business, financial condition and results of operations and could make it more difficult for us to raise capital. In particular, an interruption of operations at the Tel Aviv airport related to the conflict in the Gaza Strip or otherwise could prevent or delay shipments of our components or products. Although we maintain inventory in the United States and Germany, an extended interruption could materially and adversely affect our business, financial condition, and results of operations.

Recent political uprisings, social unrest, and violence in various countries in the Middle East and North Africa, including Israel's neighbors Lebanon, 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. It is possible that there will be additional military reserve duty call-ups in the future in connection with this conflict or otherwise. Some of our executive officers and employees, as well as those of Sanmina, the manufacturer of all of our products, are required to perform annual military reserve duty in Israel and may be called to active duty at any time under emergency circumstances. Although these call-ups have not had a material impact on our operations or on Sanmina's ability to manufacture our products, our operations and the operations of Sanmina could be disrupted by such call-ups.

***Our sales may be adversely affected by boycotts of Israel.***

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

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

Some of our operations in Israel, referred to as “Beneficiary Enterprises,” carry certain tax benefits under the Israeli Law for the Encouragement of Capital Investments, 5719-1959, or the Investment Law. Substantially all of our future income before taxes can be attributed to these programs. If we do not meet the requirements for maintaining these benefits or if our assumptions regarding the key elements affecting our tax rates are rejected by the tax authorities, they may be reduced or cancelled, and the relevant operations would be subject to Israeli corporate tax at the standard rate. In addition to being subject to the standard corporate tax rate, we could be required to refund any tax benefits that we may receive in the future, plus interest and penalties thereon. Even if we continue to meet the relevant requirements, the tax benefits that our current “Beneficiary Enterprises” receive may not be continued in the future at their current levels or at all. If these tax benefits were reduced or eliminated, the amount of taxes that we pay would likely increase, as all of our Israeli operations would consequently be subject to corporate tax at the standard rate, which could adversely affect our results of operations. Additionally, if we increase our activities outside of Israel, for example, by way of acquisitions, our increased activities may not be eligible for inclusion in Israeli tax benefit programs. For a discussion of our current tax obligations, see “Part II. Item 7, Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

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

From our inception through December 31, 2021, we received a total of \$1.97 million from the Israel Innovation Authority, or the IIA. We may in the future apply to receive additional grants from the IIA to support our research and development activities. With respect to such grants, we are committed to paying royalties at a rate of 3.0% 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, Development and Technological Innovation Law, 1984, or the R&D Law, and related regulations, with respect to those past grants. When a company develops know-how, technology or products using IIA grants, the terms of these grants and the R&D Law restrict the transfer outside of Israel of such know-how, and of the manufacturing or manufacturing rights of such products, technologies, or know-how, without the prior approval of the IIA. Therefore, if aspects of our technologies are deemed to have been developed with IIA funding, the discretionary approval of an IIA committee would be required for any transfer to third parties outside of Israel of know-how or manufacturing or manufacturing rights related to those aspects of such technologies. Furthermore, the IIA may impose certain conditions on any arrangement under which it permits us to transfer technology or development out of Israel or may not grant such approvals at all.

Furthermore, the consideration available to our shareholders in a future transaction involving the transfer outside of Israel of technology or know-how developed with IIA funding (such as a merger or similar transaction) may be reduced by any amounts that we are required to pay to the IIA.

In addition to the above, any non-Israeli citizen, resident or entity that, among other things, (i) becomes a holder of 5% or more of our share capital or voting rights, (ii) is entitled to appoint one or more of our directors or our chief executive officer or (iii) serves as one of our directors or as our chief executive officer (including holders of 25% or more of the voting power, equity or the right to nominate directors in such direct holder, if applicable) is required to notify the IIA and undertake to comply with the rules and regulations applicable to the grant programs of the IIA, including the restrictions on transfer described above. Such notification will be required in connection with the investment being made by an investor which may discourage or limit investments from foreign investors in our company

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

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

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

Israeli corporate law regulates mergers, requires tender offers for acquisitions of shares above specified thresholds, requires special approvals for transactions involving directors, officers or significant shareholders and regulates other matters that may be relevant to such types of transactions. For example, a tender offer for all of a company's issued and outstanding shares can only be completed if the acquirer receives positive responses from the holders of at least 95% of the issued share capital. Completion of the tender offer also requires approval of a majority of the offerees that do not have a personal interest in the tender offer, unless at least 98% of the company's outstanding shares are tendered. Furthermore, the shareholders, including those who indicated their acceptance of the tender offer (unless the acquirer stipulated in its tender offer that a shareholder that accepts the offer may not seek appraisal rights), may, at any time within six months following the completion of the tender offer, petition an Israeli court to alter the consideration for the acquisition. Israeli law also requires a "special tender offer" in certain cases where a shareholder crosses the 25% or 45% holding threshold, and it imposes procedural and special voting requirements for the approval of a merger in certain cases.

Our Articles of Association provide that our directors (other than external directors, a requirement of Israeli corporate law from which we have opted out in accordance with an exemption for which we are currently eligible) 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.

***We recently amended our articles of association to increase our authorized share capital. There are certain risks associated with this increase.***

In April 2021, following the receipt of shareholder approval, we amended our articles of association to increase the Company's authorized share capital. As a result of this increase, the Company is now authorized to issue 120,000,000 ordinary shares, of which 62,507,717 ordinary shares were outstanding as of February 24, 2022. The objective of the increase in authorized share capital was to maintain our flexibility to raise money in the capital markets, including in the event of a reduction in the value of our shares.

Although the purpose of the increase in authorized share capital was to preserve our capital-raising position, these additional shares may also be issued in the future for other purposes, such as compensation, or equity based mergers, acquisition or licensing deals, giving rise to further opportunities for dilution. Future issuances of ordinary shares will dilute the voting power and ownership of our existing shareholders, and, depending on the amount of consideration received in connection with the issuance, could also reduce shareholders' equity on a per-share basis. Due to the increase in authorized capital, the dilution to the ownership interest of our existing shareholders may be greater than would occur had the increase not been effected.

The newly available authorized shares resulting from the increase in authorized share capital may have the potential to limit the opportunity for our shareholders to dispose of their ordinary shares at a premium. We currently do not have any acquisitions or other major transactions planned that would require us to increase our authorized share capital, and our board does not intend to use the increase of the newly authorized reserve as an anti-takeover device. However, the authorized shares could, in theory, also be used to resist or frustrate a third-party transaction that is favored by a majority of the independent shareholders (for example, by permitting issuances that would dilute the share ownership of a person seeking to effect a change in the composition of the board or management of the Company or contemplating a tender offer or other transaction for the combination of the Company with another company).

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

We are incorporated in Israel. Although the majority of our directors and executive officers reside within the United States and most of the assets of these persons are also likely located within the United States, some of our directors and executive officers reside and may have the majority of their assets outside the United States. Additionally, most of our assets are located outside of the United States. Therefore, a judgment obtained against us, or those of our directors and executive officers residing outside of the United States, including a judgment based on the civil liability provisions of the U.S. federal securities laws, may not be collectible in the United States and may not be enforced by an Israeli court. It also may be difficult for you to effect service of process in the United States on those directors and executive officers residing outside of the United States or to assert U.S. securities law claims in original actions instituted in Israel. Israeli courts may refuse to hear a claim based on an alleged violation of U.S. securities laws reasoning that Israel is not the most appropriate forum in which to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proven as a fact by expert witnesses, which can be a time-consuming and costly process. Certain matters of procedure will also be governed by Israeli law. There is little binding case law in Israel that addresses the matters described above. As a result of the difficulty associated with enforcing a judgment against us in Israel, you may be able to collect only limited, or may be unable to collect any, damages awarded by either a U.S. or foreign court.

In April 2021, we amended our articles of association such that, unless we consent in writing to the selection of an alternative forum, (i) the federal courts of the United States will be the exclusive forum for the resolution of any claim arising under the Securities Act, and (ii) the Tel-Aviv District Court will be the exclusive forum for (a) a derivative action or derivative proceeding that is filed in the name of the Company; (b) any action grounded in a breach of fiduciary duty of a director, officer or other employee towards us or our shareholders; or (c) any action the cause of which results from any provision of the Companies Law or the Israel Securities Law, 5728-1968. We have retained the ability to consent to an alternative forum in circumstances if we determine shareholder interests are best served by permitting a particular dispute to proceed in a forum other than the federal district courts or State of Israel, as applicable. However, there is uncertainty as to whether a court would enforce these provisions.

***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.

***Our business could be negatively affected as a result of actions of activist shareholders, and such activism could impact the trading value of our securities.***

In recent years, certain Israeli issuers listed on United States exchanges have been faced with governance-related demands from activist shareholders, unsolicited tender offers and proxy contests. Given our relatively low market cap and cash balance we might be an attractive target for such activists. Responding to these types of actions by activist shareholders could be costly and time-consuming, disrupting our operations and diverting the attention of management and our employees. Such activities could interfere with our ability to execute our strategic plan. In addition, a proxy contest for the election of directors at our annual meeting would require us to incur significant legal fees and proxy solicitation expenses and require significant time and attention by management and our board of directors. The perceived uncertainties as to our future direction also could affect the market price and volatility of our securities.

## **General Risks**

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

The U.S. dollar is our functional and reporting currency. Since 2015, most of our expenses were denominated in U.S. dollars and the remaining expenses were denominated in NIS and euros. Until 2018, most of our revenues were denominated in U.S. dollars and the remainder of our revenues was denominated in euros and British pound, whereas in the last two years our euro revenues are higher than our U.S. dollar revenues. Accordingly, any appreciation of the NIS or Euro relative to the U.S. dollar would adversely impact our net loss or net income, if any. For example, we are exposed to the risks that the shekel may appreciate relative to the dollar, or, if the shekel instead devalues relative to the dollar, that the inflation rate in Israel may exceed such rate of devaluation of the shekel, or that the timing of such devaluation may lag behind inflation in Israel. In any such event, the dollar cost of our operations in Israel would increase and our dollar-denominated results of operations would be adversely affected.

We cannot predict any future trends in the rate of inflation in Israel or the rate of devaluation (if any) of the shekel against the dollar. For example, while the shekel appreciated against the dollar at a rate of approximately 3% during the fiscal year 2021 and 7% during the fiscal year of 2020, during the year 2017 the shekel devalued against the dollar at a rate of approximately 7%. The appreciation of the shekel against the dollar had the effect of increasing the dollar cost of our operations in Israel. If the dollar declines in value in relation to the shekel and the dollar cost of our operations in Israel increases once again, our dollar-measured results of operations will be adversely affected. Our operations also could be adversely affected if we are unable to effectively hedge against currency fluctuations in the future.

We have in the past engaged in limited hedging activities, and we may enter into other hedging arrangements with financial institutions from time to time. Any hedging strategies that we may implement in the future to mitigate currency risks, such as forward contracts, options and foreign exchange swaps related to transaction exposures may not eliminate our exposure to foreign exchange fluctuations. For further information, see “Part I, Item 1A. Risk Factors—The economic effects of ‘Brexit’ may affect relationships with existing and future customers and could have an adverse impact on our business and operating results.”

***We are subject to certain regulatory regimes that may affect the way that we conduct business internationally, and our failure to comply with applicable laws and regulations could materially adversely affect our reputation and result in penalties and increased costs.***

We are subject to a complex system of laws and regulations related to international trade, including economic sanctions and export control laws and regulations. We also depend on our distributors and agents for compliance and adherence to local laws and regulations in the markets in which they operate. Significant political or regulatory developments in the jurisdictions in which we sell our products, such as those stemming from the presidential administration in the United States or the U.K.'s exit from the E.U. (known as "Brexit"), are difficult to predict and may have a material adverse effect on us. For example, in the United States, the Trump administration imposed tariffs on imports from China, Mexico, Canada, and other countries, and expressed support for greater restrictions on free trade and increase tariffs on goods imported into the United States. Changes in U.S. political, regulatory, and economic conditions or in its policies governing international trade and foreign manufacturing and investment in the United States could adversely affect our sales in the United States.

We are also subject to the U.S. Foreign Corrupt Practices Act and may be subject to similar worldwide anti-bribery laws that generally prohibit companies and their intermediaries from making improper payments to government officials for the purpose of obtaining or retaining business. Despite our compliance and training programs, we cannot be certain that our procedures will be sufficient to ensure consistent compliance with all applicable international trade and anti-corruption laws, or that our employees or channel partners will strictly follow all policies and requirements to which we subject them. Any alleged or actual violations of these laws may subject us to government scrutiny, investigation, debarment, and civil and criminal penalties, which may have an adverse effect on our results of operations, financial condition and reputation.

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

The U.S. Tax Cuts and Jobs Act of 2017 (the "TCJA") made significant changes to the U.S. Internal Revenue Code of 1986, as amended (the "Code"). Such changes include a reduction in the corporate tax rate from a top marginal rate of 35% to a flat rate of 21% and limitations on certain corporate deductions and credits, among other changes. In addition, the TCJA requires complex computations to be performed that were not previously required in U.S. tax law, significant judgments to be made in interpretation of the provisions of the TCJA and significant estimates in calculations, and the preparation and analysis of information not previously relevant or regularly produced.

While to date we believe the effect of the TCJA in our Consolidated Financial Statements the application of accounting guidance for various items, and the ultimate impact of the TCJA on our business are not material, the final impacts of the TCJA could be materially different from our analysis. For example, adverse changes in the underlying profitability and financial outlook of our operations or changes in tax law could lead to changes in our valuation allowances against deferred tax assets on our consolidated balance sheets, which could materially affect our results of operations. The U.S. Treasury Department, the Internal Revenue Service (the "IRS"), and other standard-setting bodies could interpret or issue guidance on how provisions of the TCJA will be applied or otherwise administered that is different from our interpretation which may materially affect our results of operations. In addition, the Biden presidential administration may implement further changes to U.S. tax policy, including a corporate alternative minimum tax on adjusted financial statement income. If any or all of these (or similar) proposals are ultimately enacted into law, in whole or in part, they could have a negative impact to the Company's effective tax rate.

Finally, foreign governments may enact tax laws in response to the TCJA or otherwise that could result in further changes to global taxation and materially affect our financial position and results of operations. The uncertainty surrounding the effect of the reforms on our financial results and business could also weaken confidence among investors in our financial condition. This could, in turn, have a materially adverse effect on the price of our ordinary shares.

***Certain U.S. holders of our ordinary shares may suffer adverse U.S. tax consequences if we are characterized as a controlled foreign corporation, or a CFC, under Section 957 of the Code.***

Each "Ten Percent Shareholder" (as defined below) in a non-U.S. corporation that is classified as a "controlled foreign corporation," or a CFC, for U.S. federal income tax purposes generally is required to include in income for U.S. federal tax purposes such Ten Percent Shareholder's pro rata share of the CFC's "Subpart F income," global intangible low-taxed income, and investment of earnings in U.S. property, even if the CFC has made no distributions to its shareholders. Subpart F income generally includes dividends, interest, rents and royalties, gains from the sale of securities and income from certain transactions with related parties. In addition, a Ten Percent Shareholder that realizes gain from the sale or exchange of shares in a CFC may be required to classify a portion of such gain as dividend income rather than capital gain. A non-U.S. corporation generally will be classified as a CFC for U.S. federal income tax purposes if Ten Percent Shareholders own, directly or indirectly, more than 50% of either the total combined voting power of all classes of stock of such corporation entitled to vote or of the total value of the stock of such corporation. A "Ten Percent Shareholder" is a United States person (as defined by the Code), who owns or is considered to own 10% or more of (1) the total combined voting power of all classes of stock entitled to vote or (2) the value of all classes of stock of such corporation. The determination of CFC status is complex and includes attribution rules, the application of which is not entirely certain.



During our 2021 taxable year we do not believe that we had certain shareholders that were Ten Percent Shareholders for U.S. federal income tax purposes. However, our CFC status for the taxable year ending on December 31, 2021 and our current taxable year is unknown and we may be a CFC for the taxable year ending on December 31, 2021, our current taxable year or a following year. In addition, recent changes to the attribution rules relation to the determination of CFC status may make it difficult to determine our CFC status for any taxable year or the CFC status of any of our subsidiaries. U.S. holders should consult their own tax advisors with respect to the potential adverse U.S. tax consequences of becoming a Ten Percent Shareholder in a CFC. If we are classified as both a CFC and a passive foreign investment company, or PFIC, we generally will not be treated as a PFIC with respect to those U.S. holders that meet the definition of a Ten Percent Shareholder during the period in which we are a CFC.

***We may seek to grow our business through acquisitions of businesses, 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 or license 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;
- problems integrating employees from an acquired organization into our company and integrating each company's accounting, management information, human resources and other administrative systems;
- unanticipated costs associated with acquisitions;
- diversion of management's attention from our existing business operations;
- potential incurrence of debt, contingent liabilities or amortization expenses, or write-offs of goodwill;
- 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 or licensing. We do not know if we will be able to identify such acquisitions or licensing we deem suitable, whether we will be able to successfully complete any such transactions 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 our products' 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 our products' software to perform as we anticipate or our failure to effectively implement new information technology systems could disrupt our entire operation or adversely affect our software products and could result in decreased sales, increased overhead costs, and product shortages, all of which could have a material adverse effect on our reputation, business, financial condition, and operating results.

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

Our growth and product expansion 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 are highly dependent on the knowledge and skills of our senior management, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.***

Our ability to compete in the highly competitive medical devices industry depends upon our ability to attract and retain highly qualified managerial, scientific, sales and medical personnel. We are highly dependent on our senior management team and 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. The loss of the services of any of our executive officers and other key employees, and our inability to find suitable replacements could result in delays in product development and harm our business. Competition for senior management in our industry is intense and we cannot guarantee that we will be able to retain our personnel. Additionally, we do not carry key man insurance on any of our current executive officers. The loss of the services of certain members of our senior management could prevent or delay the implementation and completion of our strategic objectives or divert management's attention to seeking qualified replacements.

***Shutdowns of the U.S. federal government could materially impair our business and financial condition.***

Development of our product candidates and/or regulatory approval may be delayed for reasons beyond our control. For example, in 2018 and 2019 the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC, and other government employees and stop critical activities. If a prolonged government shutdown or budget sequestration occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets, such as through the declaration of effectiveness of registration statements and obtain necessary capital in order to properly capitalize and continue our operations.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

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

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

	Square feet (approximate)
Marlborough, Massachusetts	11,850
Yokneam, Israel	11,500
Berlin, Germany	753
Total	24,103

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

### ITEM 3. LEGAL PROCEEDINGS

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

Where we determine an unfavorable outcome is not probable or reasonably estimable, we do not accrue for any potential litigation loss. These subjective determinations are based on the status of such legal or regulatory proceedings, the merits of our defenses and consultation with legal counsel. Actual outcomes of these legal and regulatory proceedings may materially differ from our current estimates. It is possible that resolution of one or more of the legal matters currently pending or threatened could result in losses material to our consolidated results of operations, liquidity, or financial condition.

For information regarding legal proceedings, see Note 7 “Commitments and Contingent Liabilities” in the notes to our audited consolidated financial statements included in this annual report, which discussion we incorporate by reference into this Item.

### ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

## PART II

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

#### Market Information

Our ordinary shares began trading publicly on The Nasdaq Global Market on September 12, 2014 under the symbol “RWLK” and were transferred for listing on The Nasdaq Capital Market effective May 25, 2017.

#### Dividend Policy

We have never declared or paid any cash dividends on our ordinary shares. We do not anticipate paying any cash dividends in the foreseeable future. We currently intend to retain future earnings, if any, to finance operations and expand our business. Any future determination relating to our dividend policy will be made at the discretion of our board of directors and will depend on a number of factors, including future earnings, capital requirements, financial condition and future prospects and other factors our board of directors may deem relevant. The distribution of dividends may also be limited by Israeli law, which permits the distribution of dividends only out of retained earnings or otherwise upon the permission of an Israeli court.

#### Israeli Taxes Applicable to U.S. Holders

A non-Israeli resident who derives capital gains from the sale of shares in an Israeli resident company that were purchased after the company was listed for trading on a stock exchange outside of Israel will be exempt from Israeli tax so long as the shares were not held through a permanent establishment that the non-resident maintains in Israel. A partial exemption may be available for non-Israeli resident shareholders who acquired their shares prior to the issuer’s initial public offering.

However, non-Israeli corporations will not be entitled to the foregoing exemption if Israeli residents (i) have a controlling interest of more than 25% in such non-Israeli corporation or (ii) are the beneficiaries of, or are entitled to, 25% or more of the revenues or profits of such non-Israeli corporation, whether directly or indirectly. Such exemption is not applicable to a person whose gains from selling or otherwise disposing of the shares are deemed to be a business income. Additionally, under the United States-Israel Tax Treaty, or the treaty, the disposition of shares by a shareholder who (i) is a U.S. resident (for purposes of the treaty), (ii) holds the shares as a capital asset, and (iii) is entitled to claim the benefits afforded to such person by the treaty, is generally exempt from Israeli capital gains tax. Such exemption will not apply if: (i) the capital gain arising from the disposition can be attributed to a permanent establishment in Israel; (ii) the shareholder holds, directly or indirectly, shares representing 10% or more of the voting capital during any part of the 12-month period preceding the disposition, subject to certain conditions; or (iii) such U.S. resident is an individual and was present in Israel for 183 days or more during the relevant taxable year. In such case, the sale, exchange, or disposition of our ordinary shares should be subject to Israeli tax, to the extent applicable; however, under the treaty, the taxpayer would be permitted to claim a credit for such taxes against the U.S. federal income tax imposed with respect to such sale, exchange, or disposition, subject to the limitations under U.S. law applicable to foreign tax credits. If the above exemptions from capital gains tax are not available, corporations will be subject to the corporate tax rate (23%) on capital gains derived from the sale of shares. The treaty does not relate to U.S. state or local taxes.

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

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

Individuals who are subject to tax in Israel are also subject to an additional tax at the rate of 3% on annual income exceeding a certain threshold (NIS 663,240 for 2022, linked to the annual change in the Israeli Consumer Price Index), including, but not limited to, income derived from dividends, interest, and capital gains.

## Stock Performance Graph

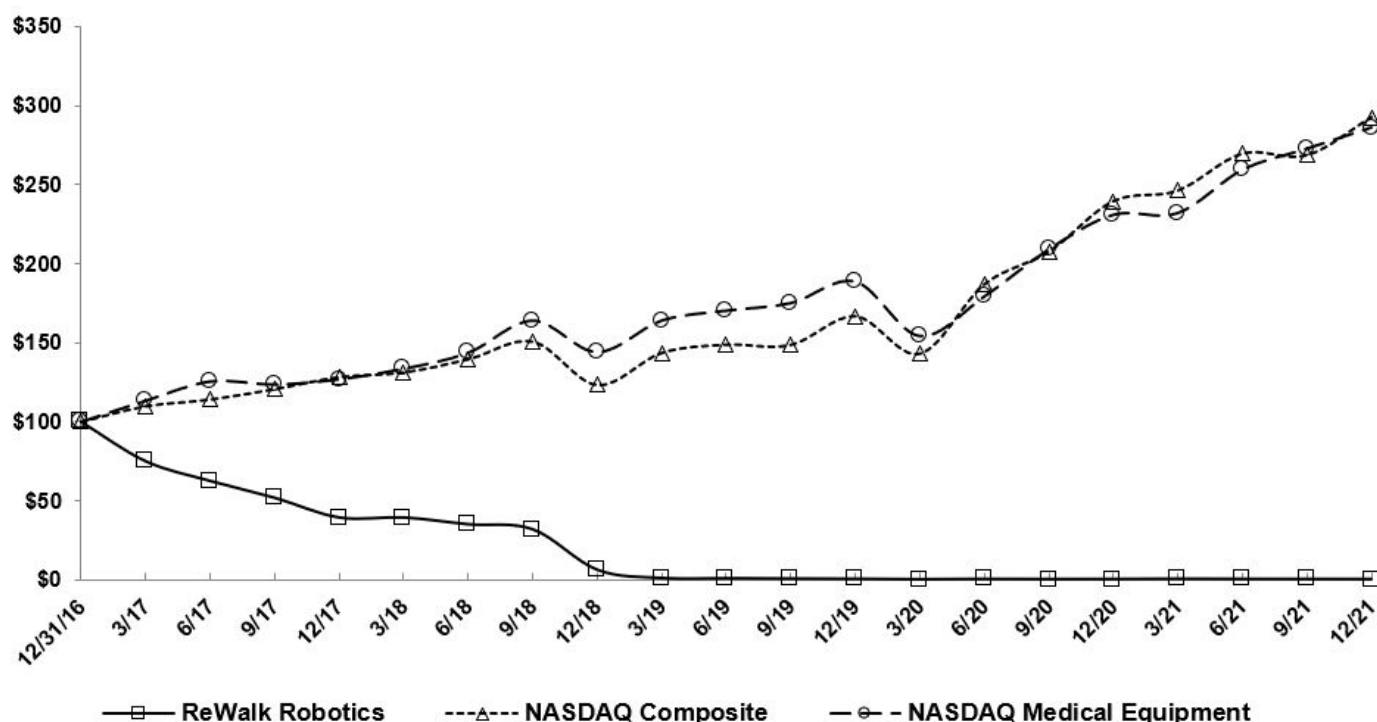
The following stock performance graph represents the cumulative total shareholder return for the period September 12, 2016, through December 31, 2021 for our ordinary shares, compared to the Nasdaq Composite Index and the Nasdaq Medical Equipment Index. The returns shown in the graph below may not be indicative of future performance.

### COMPARISON OF 60 MONTH CUMULATIVE TOTAL RETURN\*

Among ReWalk Robotics, the NASDAQ Composite Index  
and the NASDAQ Medical Equipment Index

### COMPARISON OF 60 MONTH CUMULATIVE TOTAL RETURN\*

Among ReWalk Robotics, the NASDAQ Composite Index  
and the NASDAQ Medical Equipment Index



\*\$100 invested on 31/12/16 in stock or 12/31/2016 in index, including reinvestment of dividends.  
Fiscal year ending December 31

\*\$100 invested on 12/31/16 in our ordinary shares or in either of the two indexes, including reinvestment of dividends.

Fiscal year ending December 31.

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

## Recent Sales of Unregistered Equity Securities

All sales of unregistered equity securities during the covered period were disclosed on a Current Report on Form 8-K or a Quarterly Report on Form 10-Q.

## Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

## ITEM 6. [RESERVED]

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

*The following discussion and analysis should be read in conjunction with our audited consolidated financial statements and the related notes included elsewhere in this annual report. This discussion contains forward-looking statements that are based on our management's current expectations, estimates and projections for our business, which are subject to a number of risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those set forth under "Special Note Regarding Forward-Looking Statements and "Part I. Item 1A. Risk Factors."*

### Overview

We are an innovative medical device company that is designing, developing, and commercializing robotic exoskeletons that allow individuals with mobility impairments or other medical conditions the ability to stand and walk once again. We have developed and are continuing to commercialize our ReWalk Personal and ReWalk Rehabilitation devices for individuals with spinal cord injury ("SCI Products"), which are exoskeletons designed for individuals with paraplegia that use our patented tilt-sensor technology and an on-board computer and motion sensors to drive motorized legs that power movement.

We have also developed and began commercializing our ReStore device in June 2019. ReStore is a powered, lightweight soft exo-suit intended for use in the rehabilitation of individuals with lower limb disability due to stroke. During the second quarter of 2020 we have finalized and moved to implement two separate agreements to distribute additional product lines in the U.S. market. The Company will be the exclusive distributor of the MediTouch Tutor movement biofeedback systems in the United States and will also have distribution rights for the MYOLYN MyoCycle FES cycles to U.S. rehabilitation clinics and personal sales through the U.S. Department of Veterans Affairs ("VA") hospitals and other personal sales. These new products will improve our product offering to clinics as well as patients within the VA as they both have similar clinician and patient profile.

Our principal markets are the United States and Europe. In Europe, we have a direct sales operation in Germany and the United Kingdom and work with distribution partners in certain other major countries. We have offices in Marlborough, Massachusetts, Berlin, Germany and Yokneam, Israel, where we operate our business from.

We have in the past generated and expect to generate in the future revenues from a combination of third-party payors, self-payors, including private and government employers, and institutions. While a broad uniform policy of coverage and reimbursement by third-party commercial payors currently does not exist in the United States for electronic exoskeleton technologies such as the ReWalk Personal, we are pursuing various paths of reimbursement and support fundraising efforts by institutions and clinics. In December 2015, the U.S. Department of Veterans Affairs, or the VA, issued a national policy for the evaluation, training and procurement of ReWalk Personal exoskeleton systems for all qualifying veterans across the United States. The VA policy is the first national coverage policy in the United States for qualifying individuals who have suffered spinal cord injury. As of December 31, 2021, we had placed 25 units as part of the VA policy.

According to a 2017 report published by the Centers for Medicare and Medicaid Services, or CMS, approximately 55% of the spinal cord injury population which are at least five years post their injury date are covered by CMS. In July 2020, a code was issued for ReWalk Personal 6.0 (effective October 1, 2020), which might later be followed by coverage policy of CMS.

Additionally, to date, several private insurers in the United States and Europe have provided reimbursement for ReWalk in certain cases. In Germany, we continue to make progress toward achieving ReWalk coverage from the various government, private and worker's compensation payors. In September 2017, each of German insurer BARMER GEK ("Barmer") and national social accident insurance provider Deutsche Gesetzliche Unfallversicherung ("DGUV"), indicated that they will provide coverage to users who meet certain inclusion and exclusion criteria. In February 2018, the head office of German statutory health insurance, or SHI, Spitzenverband ("GKV") confirmed their decision to list the ReWalk Personal 6.0 exoskeleton system in the German Medical Device Directory. This decision means that ReWalk will be listed among all medical devices for compensation, which SHI providers can procure for any approved beneficiary on a case-by-case basis. During the year 2020 we announced several new agreements with German SHIs such as TK and DAK Gesundheit and others as well as the first German Private Health Insurer ("PHI") that have chosen to enter into an agreement that outlines the process of obtaining a device for eligible insured patient. We are currently working with several additional SHIs and PHIs on securing a formal operating contract that will establish the process of obtaining a ReWalk Personal 6.0 device for their beneficiaries within their system.

During the second quarter of 2020 we finalized and moved to implement two separate agreements to distribute additional product lines in the U.S. market. The Company will be the exclusive distributor of the MediTouch Tutor movement biofeedback systems in the United States and will also have distribution rights for the MYOLYN MyoCycle FES cycles to U.S. rehabilitation clinics and personal sales through the VA hospitals. These new products will improve our product offering to clinics as well as patients within the VA as they both have similar clinician and patient profile. We have incurred net losses and negative cash flow from operations since inception and anticipate this to continue in the near term. We will continue to evaluate spending while continuing to focus resources on activities to commercialize the Restore device for stroke patients, achieving additional commercial reimbursement coverage decisions for our ReWalk Personal device, continued research and development activities related mainly to our product line maintenance as well as our soft exo-suit design and activities related to our FDA 522 postmarket study.

For information on the effects to our Company from the ongoing COVID-19 pandemic, see "Part I, Item 1. Business—Evolving COVID-19 Pandemic."



## Components of Our Statements of Operations

### *Revenues*

We currently rely, and in the future will rely, on sales and rentals of our ReWalk Personal 6.0 device, our ReStore device, additional devices such as MyoCycle and MediTouch which we are distributing (“Distributed Products”) and related service contracts and extended warranties for our revenue. Our revenue is generated from a combination of third-party payors, institutions, and self-payors, including private and government employers. Payments for our products by third party payors have been made primarily through case-by-case determinations. Third-party payors include, without limitation, private insurance plans and managed care programs, government programs including the VA, and worker’s compensation payments. We expect that third-party payors will be an increasingly important source of revenue in the future as well as clinics that will be interested in the ReStore device. In December 2015, the VA issued a national policy for the evaluation, training and procurement of ReWalk Personal exoskeleton systems for all qualifying veterans across the United States. The VA policy is the first national coverage policy in the United States for qualifying individuals who have suffered spinal cord injury.

All of our ReWalk Personal and ReWalk Rehabilitation systems are covered by a five-year warranty from the date of purchase, which is included in the purchase price. We offer customers the ability to purchase, any time during the initial warranty period, an extended warranty for up to three additional years. Both warranties cover all elements of the systems, including the batteries, other than normal wear and tear. Our ReStore device is sold with a two-year warranty. Warranties for our Distributed Products warranty ranges between one year to ten years depending on the specific product and part.

### *Cost of Revenues and Gross Profit*

Cost of revenue consists primarily of systems purchased from our outsourced manufacturer, Sanmina, salaries, personnel costs including non-cash share-based compensation, associated with manufacturing and inventory management, training and inspection, warranty and service costs, shipping and handling and inventory write off expenses. Cost of revenues also includes royalties and expenses related to royalty-bearing research and development grants.

Our gross profit and gross margin as a percentage of sales is influenced by a number of factors, including primarily the volume and price of our products sold and fluctuations in our cost of revenues. We expect gross profit and gross margin as a percentage of sales will improve in the future as we increase our sales volumes and decrease the product manufacturing costs.

### *Operating Expenses*

#### *Research and Development Expenses, Net*

Research and development expenses, net consist primarily of salaries, related personnel costs including share-based compensation, supplies, materials and consulting expenses related to product design and development, clinical studies, regulatory submissions, patent costs, sponsored research costs and other expenses related to our product development and research programs. We expense all research and development expenses as they are incurred.

Research and development expenses are presented net of the amount of any grants we receive for research and development in the period in which we receive the grant. We previously received grants and other funding from the Israel Innovation Authority, (formerly known as the Office of the Chief Scientist) (“IIA”). Certain of those grants require us to pay royalties on sales of certain systems, which are recorded as cost of revenues. We may receive additional funding from these entities or others in the future. See “Grants and Other Funding” below.

### *Sales and Marketing Expenses*

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

### *General and Administrative Expenses*

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

### *Financial Expenses (Income), Net*

Financial income and expenses consist of bank commissions, foreign exchange gains and losses, interest earned on investments in short term deposits, interest expenses related to the Loan Agreement (as defined below) with Kreos (as defined below).

Interest income consists of interest earned on our cash and cash equivalent balances. Interest expense consists of interest accrued on, and certain other costs with respect to any indebtedness. Foreign currency exchange changes reflect gains or losses related to transactions denominated in currencies other than the U.S. dollar.

On December 30, 2015, we entered into a Loan Agreement (the “Loan Agreement”) with Kreos Capital V (Expert Fund) Limited (“Kreos”) pursuant to which Kreos extended a line of credit to us in the amount of \$20.0 million. In connection with the Loan Agreement, we issued to Kreos a warrant to purchase up to 4,771 of our ordinary shares at an exercise price of \$241.00 as we drew down \$12.0 million under the Loan Agreement, which amount was increased to 6,679 ordinary shares upon an additional drawdown of \$8.0 million. On June 9, 2017, \$3.0 million of the outstanding principal amount was extended by an additional three years with the same interest rate and became subject to repayment in accordance with, and subject to the terms of a secured convertible promissory note (the “Kreos Convertible Note”). On November 20, 2018, we agreed to repay \$3.6 million to Kreos in satisfaction of all outstanding indebtedness under the Kreos Convertible Note and other related payments, including prepayment costs and end of loan payments and Kreos agreed to terminate the Kreos Convertible Note. We repaid Kreos the \$3.6 million by issuing to Kreos 192,000 units (each unit consisting of one ordinary share and one warrant to purchase one ordinary share) and 288,000 pre-funded units (each pre-funded unit consisting of one pre-funded warrant to purchase one ordinary share and one warrant to purchase one ordinary share) at the a public offering price of \$0.30 and \$0.29, respectively, for an aggregate price of \$3.6 million (including the aggregate exercise price for the ordinary shares to be received upon exercise of the pre-funded warrants, assuming Kreos exercises all of the pre-funded warrants it purchased as part of our public offering. We and Kreos also agreed to revise the principal and the repayment schedule under the Kreos Loan Agreement. Additionally, we entered into the Kreos Warrant Amendment with Kreos, which amended the exercise price of the warrant to purchase 6,679 ordinary shares currently held by Kreos from \$241.00 to \$7.50. On December 29, 2020, we repaid in full the remaining loan principal amount to Kreos including the end of loan payments, and by that discharged all of our obligations to Kreos.

For further discussion of the Loan Agreement with Kreos, see “-Liquidity and Capital Resources” below and also Note 6 to our audited consolidated financial statements below.

### *Taxes on Income*

As of December 31, 2021, we had not yet generated taxable income in Israel. As of that date, our net operating loss carry forwards for Israeli tax purposes amounted to approximately \$205.8 million and our net operating loss carry forwards for U.S. tax purposes amounted to approximately \$74 thousand. After we utilize our net operating loss carry forwards, we are eligible for certain tax benefits in Israel under the Law for the Encouragement of Capital Investments, 1959. Our benefit period currently ends ten years after the year in which we first have taxable income in Israel provided that the benefit period will not extend beyond 2024.

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

## Grants and Other Funding

### *Israel Innovation Authority (formerly known as the Office of the Chief Scientist)*

From our inception through December 31, 2021, we have received a total of \$1.97 million in funding from the IIA, \$1.57 million of which are royalty-bearing grants, while \$400 thousand were received in consideration for an investment in our preferred shares. Out of the royalty-bearing grants received, we have paid royalties to the IIA in the total amount of \$99 thousand. The agreements with IIA require us to pay royalties at a rate of 3% on sales of certain systems and related services up to the total amount of funding received for the development of these systems, linked to the dollar, and bearing interest at an annual rate of LIBOR applicable to dollar deposits. If we transfer IIA-supported technology or know-how outside of Israel, we will be liable for additional payments to IIA depending upon the value of the transferred technology or know-how, the amount of IIA support, the time of completion of the IIA-supported research project and other factors. As of December 31, 2021, the aggregate contingent liability to the IIA was \$1.5 million. For more information, see “Part I, Item 1A. Risk Factors-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.”

## Results of Operations

### *Year Ended December 31, 2021 Compared to Year Ended December 31, 2020*

#### *Revenues*

Our revenues for 2021 and 2020 were as follows (dollars in thousands, except unit amounts)

	Years Ended December 31,	
	2021	2020
Personal unit revenues	\$ 4,820	\$ 4,220
Rehabilitation unit revenues	\$ 1,146	\$ 173
Revenues	<u>\$ 5,966</u>	<u>\$ 4,393</u>

Personal unit revenues consist of ReWalk Personal 6.0 and Distributed Products sale, rental, service and warranty revenue for individual use.

Rehabilitation unit revenues consist of ReStore, Distributed Products and SCI Products sale, rental, service and warranty revenue to clinics and hospitals for treating patients with relevant medical conditions or for usage by medical academic centers.

Revenues increased by \$1.6 million, or 36%, during 2021 compared to 2020. The increase was driven primarily by higher number of rehabilitation units sold in the United States including a multiple unit order to a medical academic center as well as an increase in personal unit revenues in Germany as we have seen reduced COVID-19 restrictions.

In the future we expect our growth to be driven by sales of our ReWalk Personal device to third-party payors as we continue to focus our resources on broader commercial coverage policies with third-party payors as well as sales of the ReStore and other products to rehabilitation clinics and personal users.

### **Gross Profit**

Our gross profit for 2021 and 2020 were as follows (in thousands):

	Years Ended December 31,	
	2021	2020
Gross profit	\$ 2,903	\$ 2,189

Gross profit was 49% of revenue for 2021, compared to a gross profit of 50% of revenue for 2020. Our gross profit declined because of a higher inventory write-off of ReStore parts due to lower than expected sales during the pandemic and increased service expenses, partially offset by a higher number of Personal 6.0 units sold and an increase in our average selling price due to a change in sales mix.

We expect our gross profit to improve, assuming we increase our sales volumes, which could also decrease the product manufacturing costs. Improvements may be partially offset by the lower margins we currently expect from ReStore and our Distributed Products as well as due to an increase in the cost of product parts, especially as long as COVID-19 pandemic is affecting the market.

### **Research and Development Expenses, Net**

Our research and development expenses, net for 2021 and 2020 were as follows (in thousands):

	Years Ended December 31,	
	2021	2020
Research and development expenses, net	\$ 2,939	\$ 3,459

Research and development expenses, decreased by \$520 thousand, or 15%, during 2021 compared to 2020. The decrease is attributable to decreased personnel and personnel related expenses partially offset with higher subcontractors' expenses.

We intend to focus our research and development expenses mainly on our current products maintenance and improvement as well as developing our "soft suit" exoskeleton for additional indications affecting the ability to walk or a home use design such as the ReBoot design.

### **Sales and Marketing Expenses**

Our sales and marketing expenses for 2021 and 2020 were as follows (in thousands):

	Years Ended December 31,	
	2021	2020
Sales and marketing expenses	\$ 6,993	\$ 5,754

Sales and marketing expenses increased by \$1.24 million, or 22%, during 2021 compared to 2020. The increase was driven by higher employee and employee related expenses including sales related compensation, travel and tradeshow activity as well as our Payment Protection Program ("PPP") grant forgiveness which reduced the expenses last year and higher professional expense during 2021.

In the near term our sales and marketing expenses are expected to be driven by our efforts expand our reimbursement coverage of our ReWalk Personal device and to expand our current product commercialization.

### **General and Administrative Expenses**

Our general and administrative expenses for 2021 and 2020 were as follows (in thousands):

	Years Ended December 31,	
	2021	2020
General and administrative	\$ 5,626	\$ 4,980

General and administrative expenses increased by \$646 thousand, or 13%, during 2021 compared to 2020. The increase was driven by increased personnel and personnel related expenses, higher share-based compensation expenses as well as professional services expenses.

### **Financial Expenses (income), Net**

Our financial expenses, net for 2021 and 2020 were as follows (in thousands):

	Years Ended December 31,	
	2021	2020
Financial expenses (income), net	\$ (13)	\$ 921

Financial expenses (income), net, decreased by \$934 thousand, or 101% during 2021 compared to 2020. The decrease is mainly due to lower interest expenses related to the Loan Agreement with Kreos, which was fully repaid in December 2020. For further discussion of the Loan Agreement with Kreos, see “-Liquidity and Capital Resources” section below and Note 6 to our audited consolidated financial statements.

### **Income Tax**

Our income tax for 2021 and 2020 was as follows (in thousands):

	Years Ended December 31,	
	2021	2020
Taxes on income	\$ 94	\$ 51

Income taxes increased by \$43 thousand or 84% during 2021 compared to 2020 mainly due to our subsidiary’s activity in Germany.

### **Year Ended December 31, 2020 Compared to Year Ended December 31, 2019**

A discussion of changes in our results of operations in 2020 compared to 2019 has been omitted from this annual report on Form 10-K but may be found in “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” of our Form 10-K for the fiscal year ended December 31, 2020, filed with the SEC on February 18, 2021, which is available free of charge on the SECs website at [www.sec.gov](http://www.sec.gov) and at [www.rewalk.com](http://www.rewalk.com), and is incorporated by reference herein.

## Critical Accounting Policies

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

### ***Revenue Recognition***

On January 1, 2018, we adopted Topic 606 using the modified retrospective method for contracts that were not completed as of January 1, 2018. Under the modified retrospective method, we recognized the cumulative effect of initially applying the new revenue standard as an adjustment to the opening balance of retained earnings. This adjustment did not have a material impact on our consolidated financial statements. Results for reporting periods beginning after January 1, 2018 are presented under Topic 606, while prior period amounts are not adjusted and continue to be reported in accordance with our historic accounting under Revenue Recognition ("Topic 605").

The adoption of Topic 606 represents a change in accounting principle that will provide financial statement readers with enhanced revenue recognition disclosures. In accordance with Topic 606, revenue is recognized when obligations under the terms of a contract with our customer are satisfied; generally, this occurs with the transfer of control of our products or services. Revenue is measured as the amount of consideration to which we expect to be entitled in exchange for transferring products or providing services. To achieve this core principle, the Company applies the following five steps:

1. Identify the contract with a customer
2. Identify the performance obligations in the contract
3. Determine the transaction price
4. Allocate the transaction price to performance obligations in the contract
5. Recognize revenue when or as the Company satisfies a performance obligation

Provisions are made at the time of revenue recognition for any applicable warranty cost expected to be incurred. The timing for revenue recognition among the various products and customers is dependent upon satisfaction of such criteria and generally varies from either shipment or delivery to the customer depending on the specific shipping terms of a given transaction, as stipulated in the agreement with each customer. Other than pricing terms which may differ due to the different volumes of purchases between distributors and end-users, there are no material differences in the terms and arrangements involving direct and indirect customers. Our products sold through agreements with distributors are non-exchangeable, non-refundable, non-returnable and without any rights of price protection or stock rotation. Accordingly, we consider all the distributors as end-users. We generally do not grant a right of return for our products. There have been a few occasions in which we experienced a return of our products. Therefore, we recorded reductions to revenue for expected future product returns based on our historical experience.

For the majority of sales of Rehabilitation systems, we include training and consider the elements in the arrangement to be a single unit of accounting. In accordance with ASC 606, we have concluded that the training is essential to the functionality of our systems. Therefore, we recognize revenue for the system and training only after delivery, in accordance with the agreement delivery terms, to the customer and after the training has been completed, once all other revenue recognition criteria have been met. For sales of Personal systems to end users, and for sales of Personal or Rehabilitation systems to third party distributors, we do not provide training to the end user as this training is completed by the rehabilitation centers or by the distributor that have previously completed the ReWalk Training program.

Warranties are classified as either assurance type or service type warranty. A warranty is considered an assurance type warranty if it provides the consumer with assurance that the product will function as intended for a limited period of time.

In the beginning of 2018, we updated our service policy to include a five-year warranty compared to a period of two years that were included in the past for parts and services. The first two years are considered as assurance type warranty and the additional period is considered an extended service arrangement, which is a service type warranty. An assurance type warranty is not accounted for as separate performance obligations under the revenue model. A service type warranty is either sold with a unit or separately for units for which the warranty has expired. Revenue is then recognized ratably over the life of the warranty.

The Company also offers a rent-to-purchase option for its ReWalk Personal device. Those transactions provide potential customers the option to use the device for a short term, after which they can choose whether to purchase it. In such cases we recognize revenue ratably according to the agreed rental monthly fee. For units placed, we transfer control and recognize a sale when title has passed to our customer and rental revenue ratably according to the agreed rental monthly fee. Each unit placed is considered an independent, unbundled performance obligation.

#### ***Share-Based Compensation – Option and Restricted Stock Units (“RSUs”) Valuations***

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

We selected the Black-Scholes-Merton option pricing model as the most appropriate method for determining the estimated fair value of options. The resulting cost of an equity incentive award is recognized as an expense over the requisite service period of the award, which is usually the vesting period. We recognize compensation expense over the vesting period using the straight-line method and classify these amounts in the consolidated financial statements based on the department to which the related employee reports.

The determination of the grant date fair value of options using the Black-Scholes-Merton option pricing model is affected by estimates and assumptions regarding a number of complex and subjective variables. These variables include the expected volatility of our share price over the expected term of the options, share option exercise and cancellation behaviors, risk-free interest rates and expected dividends, which are estimated as follows:

*Risk-free Interest Rate.* The risk-free interest rate is based on the yield from U.S. Treasury zero-coupon bonds with a term equivalent to the contractual life of the options.

*Dividend Yield.* We have never declared or paid any cash dividends and do not presently plan to pay cash dividends in the foreseeable future. Consequently, we used an expected dividend yield of zero.

*Expected Volatility.* We estimated the expected share price volatility for our ordinary shares by considering the historic price volatility for industry peers based on price observations over a period equivalent to the expected term of the share option grants. Industry peers consist of public companies in the medical device and healthcare industries. We intend to continue to consistently apply this process using the same or similar industry peers until a sufficient amount of historical information regarding the volatility of our ordinary share price becomes available, or unless circumstances change such that the identified companies are no longer similar to us, in which case, more suitable companies whose share prices are publicly available would be utilized in the calculation.

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

The fair value of RSUs granted is determined based on the price of the Company's ordinary shares on the date of grant.

#### ***Income Taxes***

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

ASU 2015-17, "Balance Sheet Classification of Deferred Taxes" provides presentation requirements to classify deferred tax assets and liabilities, along with any related valuation allowance, are classified as non-current on the balance sheet. We account for uncertain tax positions in accordance with ASC 740 and recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position should be measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. Accordingly, we report a liability for unrecognized tax benefits resulting from uncertain tax positions taken or expected to be taken in a tax return. We recognize interest and penalties, if any, related to unrecognized tax benefits in tax expense.

#### **Recently Issued and Adopted Accounting Pronouncements**

A discussion of recent accounting pronouncements is included in Note 2w, New Accounting Pronouncements to our consolidated financial statements in this annual report.



## Liquidity and Capital Resources

### *Sources of Liquidity and Outlook*

Since inception, we have funded our operations primarily through the sale of our equity securities and convertible notes to investors in private placements, the sale of our equity securities in public offerings, cash exercises of outstanding warrants and the incurrence of bank debt.

For the full year ended December 31, 2021, the Company incurred a consolidated net loss of \$12.7 million and has an accumulated deficit in the total amount of \$194.2 million. Our cash and cash equivalent on December 31, 2021, totaled \$88.3 million. The Company's negative operating cash flow for the full year ended December 31, 2021, was \$11.5 million. The Company has sufficient funds to support its operation for more than 12 months following the approval of our consolidated financial statements for the fiscal year ended December 31, 2021.

We expect to incur future net losses and our transition to profitability is dependent upon, among other things, the successful development and commercialization of our products and product candidates, the achievement of a level of revenues adequate to support our cost structure. Until we achieve profitability or generate positive cash flows, we will continue to need to raise additional cash. We intend to fund future operations through cash on hand, additional private and/or public offerings of debt or equity securities, cash exercises of outstanding warrants or a combination of the foregoing. In addition, we may seek additional capital through arrangements with strategic partners or from other sources and we will continue to address our cost structure. Notwithstanding, there can be no assurance that we will be able to raise additional funds or achieve or sustain profitability or positive cash flows from operations.

We previously considered the Investment Agreement (as defined below) with Timwell (as defined below) as a potential source of ongoing liquidity. However, in March 2020, Timwell notified us that it would not invest the second and third tranches under the Investment Agreement. For more information, see "Timwell Private Placement" below.

Our anticipated primary uses of cash are (i) sales, marketing and reimbursement expenses related to market development activities of our ReStore and Personal 6.0 devices, broadening third-party payor and CMS coverage for our ReWalk Personal device and commercializing our new product lines added through distribution agreements; (ii) research and development of our lightweight exo-suit technology for potential home personal health utilization for multiple indications and future generation designs for our spinal cord injury device; (iii) routine product updates; (iv) general corporate purposes, including working capital needs; and (v) potential acquisitions of business. Our future cash requirements will depend on many factors, including our rate of revenue growth, the expansion of our sales and marketing activities, the timing and extent of our spending on research and development efforts and international expansion. If our current estimates of revenue, expenses or capital or liquidity requirements change or are inaccurate, we may seek to sell additional equity or debt securities, arrange for additional bank debt financing, or refinance our indebtedness. There can be no assurance that we will be able to raise such funds on acceptable terms.

### *Loan Agreement with Kreos and Related Warrant to Purchase Ordinary Shares*

#### *Loan Agreement*

On December 30, 2015, we entered into the Loan Agreement with Kreos pursuant to which Kreos extended a line of credit to us in the amount of \$20.0 million, which was subsequently amended on June 9, 2017 whereby \$3.0 million of the outstanding principal under the Loan Agreement became subject to repayment pursuant to the senior secured Kreos Convertible Note issued on that date. On November 20, 2018 we and Kreos entered into the Second Amendment to the Loan Agreement, in which we repaid Kreos the \$3.6 million other related payments, including prepayment costs and end of loan payments, terminating the Kreos Note, by issuing to Kreos 192,000 units and 288,000 pre-funded units as part of an underwritten public offering at the public offering prices, and the parties agreed to revise the principal and the repayment schedule under the Kreos Loan. On December 29, 2020, we repaid in full the remaining loan principal amount to Kreos including end of loan payments and by that discharged all of its obligation to Kreos. Accordingly, as of December 31, 2020 the outstanding principal amount under the Kreos Loan Agreement was zero.

### *Warrant to Purchase Ordinary Shares*

Pursuant to the terms of the Loan Agreement, on January 4, 2016, we issued to Kreos a warrant to purchase up to 4,771 of our ordinary shares at an exercise price of \$241.0 per share, increased to 6,679 ordinary shares on December 28, 2016. Subject to the terms of the warrant, the warrant is exercisable, in whole or in part, at any time prior to the earlier of (i) December 30, 2025, or (ii) immediately prior to the consummation of a merger, consolidation, or reorganization of us with or into, or the sale or license of all or substantially all our assets or shares to, any other entity or person, other than a wholly-owned subsidiary of us, excluding any transaction in which our shareholders prior to the transaction will hold more than 50% of the voting and economic rights of the surviving entity after the transaction. On June 5, 2019 and June 6, 2019, we entered into warrant exercise agreements with certain institutional investors of warrants to purchase our ordinary shares, pursuant to which, Kreos agreed to exercise in cash their November 2018 warrants at the then-effective exercise price of \$7.50 per share. Under the exercise agreements, we also agreed to issue to Kreos new warrants to purchase up to 480,000 ordinary shares at an exercise price of \$7.50 per share with an exercise period of five years. Additionally, Kreos and we entered into the Kreos Warrant Amendment, which amended the exercise price of the warrant to purchase 6,679 ordinary shares currently held by Kreos from \$241 to \$7.5.

### *Paycheck Protection Program Loan Agreement*

On April 21, 2020, ReWalk Robotics Inc (“RRI”) entered into a Note agreement evidencing an unsecured loan in the amount of \$392 thousand under the PPP as part of the CARES Act enacted on March 27, 2020. The Note provides for an interest rate of 1.00% per year and matures two years after the date of initial disbursement. Beginning on the seventh month following the date of initial disbursement, RRI is required to make 18 monthly payments of principal and interest. The Note may be used for payroll costs, costs related to certain group health care benefits and insurance premiums, rent payments, utility payments, mortgage interest payments and interest payments on any other debt obligation that were incurred before February 15, 2020. Under the terms of the CARES Act, PPP loan recipients can apply for and be granted forgiveness for all or a portion of loan granted under the PPP, with such forgiveness to be determined, subject to limitations, based on the use of the loan proceeds for payment of payroll costs and any payments of mortgage interest, rent, and utilities. The terms of any forgiveness may also be subject to further requirements in any regulations and guidelines the Small Business Administration may adopt.

On September 29, 2020, the Company submitted an application for loan forgiveness and on November 6, 2020 the Company received confirmation of its PPP Note forgiveness. For more information see Note 10 to our consolidated financial statements set forth in “Part II. Item 8. Financial Statements and Supplementary Data” of this annual report.

### *Equity Raises*

#### *Use of Form S-3*

Beginning with the filing of our Form 10-K on February 17, 2017, we were subject to limitations under the applicable rules of Form S-3, which constrained our ability to secure capital pursuant to our ATM Offering Program or other public offerings pursuant to our effective Form S-3. These rules limit the size of primary securities offerings conducted by issuers with a public float of less than \$75 million to no more than one-third of their public float in any 12-month period. At the time of filing our annual report for the year ended December 31, 2020, we were no longer subject to these limitations, because our public float had reached at least \$75 million in the 60 days preceding the filing of that annual report. Likewise, because our public float was at least \$75 million within the 60 days preceding the date of this annual report, we are not currently subject to these limitations. Our currently effective registration statement on Form S-3 expires on May 23, 2022. If we file a new registration statement on Form S-3 to replace our expiring registration statement, we will be required to re-test our compliance with these rules at that time. Assuming we are not subject to these limitations at the time the new registration statement is filed, if we choose to do so, then we will not be subject to these limitations for the remainder of the 2022 fiscal year and until such time as we file our next annual report for the year ended December 31, 2022, at which time we will be required to re-test our status under these rules. If our public float subsequently drops below \$75 million as of the filing of our next annual report on Form 10-K, or at the time we file a new Form S-3, we will become subject to these limitations again, until the date that our public float again reaches \$75 million. These limitations do not apply to secondary offerings for the resale of our ordinary shares or other securities by selling shareholders or to the issuance of ordinary shares upon conversion by holders of convertible securities, such as warrants. We have registered up to \$100 million of ordinary shares warrants and/or debt securities and certain other outstanding securities with registration rights on our current registration statement on Form S-3.

On February 10, 2020, the Company closed a “best efforts” public offering whereby the Company issued an aggregate of 5,600,000 of common units and pre-funded units at a public offering price of \$1.25 per common unit and \$1.249 per pre-funded unit. As part of the public offering, the Company entered into a securities purchase agreement with certain institutional purchasers. Each common unit consisted of one ordinary share, par value NIS 0.25 per share, and one common warrant to purchase one ordinary share. Each pre-funded unit consisted of one pre-funded warrant to purchase one ordinary share and one common warrant. Additionally, the Company issued warrants to purchase up to 336,000 ordinary shares, with an exercise price of \$1.5625 per share, to representatives of H.C. Wainwright as compensation for its role as the placement agent in the Company’s February 2020 offering. As of December 31, 2020, all pre-funded warrants to purchase ordinary shares had been exercised and 1,831,500 common warrants to purchase ordinary shares had been exercised.

On July 6, 2020, the Company entered into a purchase agreement with certain institutional investors for the issuance and sale of 4,938,278 ordinary shares, par value NIS 0.25 per share, at \$1.8225 per ordinary share and warrants to purchase up to 2,469,139 ordinary shares with an exercise price of \$1.76 per share, exercisable from July 6, 2020, until January 6, 2026. Additionally, the Company issued warrants to purchase up to 296,297 ordinary shares, with an exercise price of \$2.2781 per share, exercisable from July 6, 2020, until July 2, 2025, to certain representatives of H.C. Wainwright as compensation for its role as the placement agent in our July 2020 registered direct offering.

On December 8, 2020, the Company entered into a private placement with certain institutional investors for the issuance and sale of 5,579,776 ordinary shares, par value NIS 0.25 per share, at \$1.43375 per ordinary and warrants to purchase up to 4,184,832 ordinary shares with exercise price of \$1.34 per share, exercisable from December 8, 2020 until June 8, 2026. Additionally, the Company issued warrants to purchase up to 334,787 ordinary shares, with an exercise price of \$1.7922 per share, exercisable from December 8, 2020, until June 8, 2026, to certain representatives of H.C. Wainwright as compensation for its role as the placement agent in our December 2020 private placement.

On February 19, 2021, the Company entered into a purchase agreement with certain institutional and other accredited investors for the issuance and sale of 10,921,502 ordinary shares, par value NIS 0.25 per share at \$3.6625 per ordinary share and warrants to purchase up to an aggregate of 5,460,751 ordinary shares with an exercise price of \$3.6 per share, exercisable from February 19, 2021, until August 26, 2026. Additionally, the Company issued warrants to purchase up to 655,290 ordinary shares, with an exercise price of \$4.578125 per share, exercisable from February 19, 2021, until August 26, 2026, to certain representatives of H.C. Wainwright as compensation for its role as the placement agent in our February 2021 private placement offering.

On September 27, 2021, we signed a purchase agreement with certain institutional investors for the issuance and sale of 15,403,014 ordinary shares, pre-funded warrants to purchase up to an aggregate of 610,504 ordinary shares and ordinary warrants to purchase up to an aggregate of 8,006,759 ordinary shares at an exercise price of \$2.00 per share. The pre-funded warrants have an exercise price of \$0.001 per ordinary share and are immediately exercisable and can be exercised at any time after their original issuance until such pre-funded warrants are exercised in full. Each ordinary share was sold at an offering price of \$2.035 and each pre-funded warrant was sold at an offering price of \$2.034 (equal to the purchase price per ordinary share minus the exercise price of the pre-funded warrant). The offering of the ordinary shares, the pre-funded warrants and the ordinary shares that are issuable from time to time upon exercise of the pre-funded warrants was made pursuant to our shelf registration statement on Form S-3 initially filed with the SEC on May 9, 2019, and declared effective by the SEC on May 23, 2019, and the ordinary warrants were issued in a concurrent private placement. The ordinary warrants are exercisable at any time and from time to time, in whole or in part, following the date of issuance and ending five and one-half years from the date of issuance. All of the pre-funded warrants were exercised in full on September 27, 2021, and the offering closed on September 29, 2021. Additionally, we issued warrants to purchase up to 960,811 ordinary shares, with an exercise price of \$2.5438 per share, exercisable from September 27, 2021, until September 27, 2026, to certain representatives of H.C. Wainwright as compensation for its role as the placement agent in our September 2021 private placement offering.

During the twelve months ended December 31, 2021, we received a total of 9,814,754 outstanding warrants exercises with exercise prices ranging from \$1.25 to \$1.79 were exercised, for total gross proceeds of approximately \$13.8 million.

#### *ATM Offering Program*

On May 10, 2016, we entered into our Equity Distribution Agreement with Piper Jaffray, as amended on May 9, 2019, pursuant to which we may offer and sell, from time to time, ordinary shares having an aggregate offering price of up to \$25.0 million through Piper Jaffray acting as our agent. Subject to the terms and conditions of the Equity Distribution Agreement, Piper Jaffray will use its commercially reasonable efforts to sell on our behalf all of the ordinary shares requested to be sold by us, consistent with its normal trading and sales practices. Piper Jaffray may also act as principal in the sale of ordinary shares under the Equity Distribution Agreement. Such sales may be made under our Form S-3 in what may be deemed “at-the-market” equity offerings as defined in Rule 415 promulgated under the Securities Act, directly on or through the Nasdaq Capital Market, to or through a market maker other than on an exchange or otherwise, in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices, and/or any other method permitted by law, including in privately negotiated transactions.

Piper Jaffray is entitled to compensation at a fixed commission rate of 3% of the gross sales price per share sold through it as agent under the Equity Distribution Agreement. Where Piper Jaffray acts as principal in the sale of ordinary shares under the Equity Distribution Agreement, such rate of compensation will not apply, but in no event will the total compensation of Piper Jaffray, when combined with the reimbursement of Piper Jaffray for the out-of-pocket fees and disbursements of its legal counsel, exceed 8.0% of the gross proceeds received from the sale of the ordinary shares.

We may instruct Piper Jaffray not to sell ordinary shares if the sales cannot be effected at or above the price designated by us in any instruction. We or Piper Jaffray may suspend an offering of ordinary shares under the ATM Offering Program upon proper notice and subject to other conditions, as further described in the Equity Distribution Agreement. Additionally, the ATM Offering Program will terminate on the earlier of (i) the sale of all ordinary shares subject to the Equity Distribution Agreement, (ii) the date that is three years after a new registration statement on Form S-3 goes effective, (iii) our becoming ineligible to use Form S-3 and (iv) termination of the Equity Distribution Agreement by the parties. The Equity Distribution Agreement may be terminated by Piper Jaffray or us at any time on the close of business on the date of receipt of written notice, and by Piper Jaffray at any time in certain circumstances, including any suspension or limitation on the trading of our ordinary shares on the Nasdaq Capital Market, as further described in the Equity Distribution Agreement. We temporarily suspended use of the ATM Offering Program on February 20, 2019 to facilitate our February 2019 “best efforts” public offering. As of September 30, 2020, we had sold 302,092 ordinary shares under the ATM Offering Program for net proceeds to us of \$14.5 million (after commissions, fees, and expenses). Additionally, as of that date, we had paid Piper Jaffray compensation of \$471 thousand and had incurred total expenses (including such commissions) of approximately \$1.2 million in connection with the ATM Offering Program.

We intend to continue using the at-the-market offering or similar continuous offering programs opportunistically to raise additional funds, although we are currently subject to restrictions on using the ATM Offering Program with Piper Jaffray. Under our September 2021 purchase agreement with certain investors, equity or debt securities convertible into, or exercisable or exchangeable for, ordinary shares at a conversion price, exercise price or exchange price which floats with the trading price of the ordinary shares or which may be adjusted after issuance upon the occurrence of certain events or (ii) enter into any agreement, including an equity line of credit, whereby the Company may issue securities at a future-determined price, other than an at-the-market facility with the placement agent, H.C. Wainwright & Co, LLC, beginning on March 29, 2022. Such limitations may inhibit our ability to access capital efficiently.

On March 6, 2018, we entered into an investment agreement with Timwell Corporation Limited, a Hong Kong corporation (“Timwell”), as amended on May 15, 2018 (the “Investment Agreement”), pursuant to which we agreed, in return for aggregate gross proceeds to us of \$20 million, to issue to Timwell an aggregate of 640,000 of our ordinary shares, at a price per share of \$1.25. The Investment Agreement contemplates issuances in three tranches, including \$5 million for 160,000 shares in the first tranche, \$10 million for 320,000 shares in the second tranche and \$5 million for 160,000 shares in the third tranche.

The first tranche, consisting of \$5 million for 160,000 shares, closed on May 15, 2018. The net aggregate proceeds after deducting commissions, fees and offering expenses in the amount of approximately \$705 thousand were approximately \$4.3 million.

The closings of the Second Tranche and Third Tranche were subject to specified closing conditions, including the formation of a joint venture, the signing of a license agreement and a supply agreement, and the successful production of certain ReWalk products. The Third Tranche Closing was to have occurred by December 31, 2018 and no later than April 1, 2019. We believe that Timwell committed various material breaches of the Investment Agreement, including failure to consummate its second and third investment tranches in the Company for a total of \$15 million, failure to enter into a detailed joint venture with the Company, and failure to make payments for product-related commitments. Nevertheless, until March 2020 we continued to engage in a dialogue with Timwell (and its affiliate RealCan) on alternative pathways to allow us to commercialize our products in China through RealCan and its affiliates, and also provide for RealCan or an affiliate to invest in us.

In late March 2020, Timwell notified us that it would not invest the second and third tranches under the Investment Agreement. In response, in early April 2020, our Board of Directors also removed Timwell’s designee, who was appointed pursuant to the Investment Agreement, from the Board of Directors, due to this breach pursuant to the terms of the Investment Agreement. We continue to view China as a market with key opportunities for products designed for stroke patients, and therefore we continue to evaluate potential relationships with other groups to penetrate the Chinese market.

#### Cash Flows

	Years Ended December 31,		
	2021	2020	2019
Net cash used in operating activities	\$ (11,469)	\$ (12,589)	\$ (14,815)
Net cash provided by used in investing activities	(47)	(73)	(22)
Net cash provided by financing activities	79,512	16,724	21,482
Net cash flow	<u>\$ 67,996</u>	<u>\$ 4,062</u>	<u>\$ 6,645</u>

#### Year Ended December 31, 2021 to Year Ended December 31, 2020

##### Net Cash Used in Operating Activities

Net cash used in operating activities decreased by \$1.1 million in 2021 compared to 2020 mainly due to due to improvement in working capital as well as no interest payments to Kreos as we repaid our debt under the Loan Agreement in full in December 2020.

### Net Cash Used in Investing Activities

Net cash used in investing activities decreased from \$73 thousand in 2020 to \$47 thousand in 2021, primarily as a result of decreased use of cash for the purchase of property and equipment.

### Net Cash Provided by Financing Activities

We generated \$79.5 million from financing activities in 2021 compared to \$16.7 million in 2020. The increase is primarily due to the higher proceeds received through our first and third quarter equity raise and warrants exercises, as well as the fact that we did not have any principal payments pursuant to the Loan Agreement with Kreos after repaying our debt in full in December 2020.

### Year Ended December 31, 2020 Compared to Year Ended December 31, 2019

A discussion of changes in our cash flows in 2020 compared to 2019 has been omitted from this annual report on Form 10-K but may be found in “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” of our Form 10-K for the fiscal year ended December 31, 2020, filed with the SEC on February 18, 2021, which is available free of charge on the SEC’s website at [www.sec.gov](http://www.sec.gov) and at [www.rewalk.com](http://www.rewalk.com), and is incorporated by reference herein.

### Obligations and Commercial Commitments

Set forth below is a summary of our contractual obligations as of December 31, 2021:

Contractual obligations	Payments due by period (in dollars, in thousands)		
	Total	Less than 1 year	1-3 years
Purchase obligations (1)	\$ 1,457	\$ 1,457	\$ —
Collaboration Agreement and License Agreement obligations (2)	145	145	—
Operating lease obligations (3)	1,189	689	500
<b>Total</b>	<b>\$ 2,791</b>	<b>\$ 2,291</b>	<b>\$ 500</b>

- (1) The Company depends on one contract manufacturer, Sanmina Corporation, for both the ReStore products and the SCI Products. We place our manufacturing orders with Sanmina pursuant to purchase orders or by providing forecasts for future requirements
- (2) Our Collaboration Agreement was originally signed for a period of six years and as of December 31, 2021 has a remaining term of 0.25 years, it requires us to pay in quarterly installments for the funding of our joint research collaboration with Harvard, subject to a minimum funding commitment under applicable circumstances. Our License Agreement consists of patent reimbursement expenses payments and of a license upfront fee payment. There are also several milestone payments contingent upon the achievement of certain product development and commercialization milestones and royalty payments on net sales from certain patents licensed to Harvard. These product development milestones have been met as of December 31, 2021. There are commercialization milestones which depend on us reaching certain sales amounts some or all of which may not occur.
- (3) Our operating leases consist of leases for our facilities and motor vehicles.

We calculated the payments due under our operating lease obligation for our Israeli office that are to be paid in NIS at a rate of exchange of NIS 3.11:\$1.00, and the payments due under our operating lease obligation for our German subsidiary that are to be paid in euros at a rate of exchange of €1.00:\$1.13, both of which were the applicable exchange rates as of December 31, 2021.

## Off-Balance Sheet Arrangements

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

## Trend Information

For information on significant known trends, please see “Part I-Item 1. “Business – Overview” in this annual report.

## ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

### Currency Exchange Risk

Our results of operations and cash flows are affected by fluctuations in foreign currency exchange rates. Since 2015, most of our expenses were denominated in U.S. dollars and the remaining expenses were denominated in NIS and euros, until 2018 most of our revenues were denominated in U.S. dollars and the remainder of our revenues was denominated in euros and British pound whereas in the last three years our euro revenues are higher than our U.S dollar revenues. Accordingly, changes in the value of the NIS and euro relative to the U.S. dollar in each of the years 2021, 2020, and 2019 impacted amounts recorded on our consolidated statements of operations for those periods. We expect that the denominations of our revenue and expenses in 2022 will be consistent with what we experienced in 2021.

The following table presents information about the changes in the exchange rates of the NIS and euro against the U.S. dollar in 2021, 2020 and 2019:

Period	Change in Average Exchange Rate	
	NIS against the U.S. Dollar (%)	Euro against the U.S. Dollar (%)
2021	(6.38)	3.46
2020	3.76	2.07
2019	0.87	(5.16)

The figures above represent the change in the average exchange rate in the given period compared to the average exchange rate in the immediately preceding period. Negative figures represent depreciation of the U.S. dollar compared to the NIS or the euro. A 10% increase or decrease in the value of the NIS against the U.S. dollar would have decreased or increased our net loss by approximately \$587 thousand in 2021. A 10% increase or decrease in the value of the euro against the U.S. dollar would have decreased or increased our net loss by approximately \$82 thousand in 2021.

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

### Other Market Risks

We do not believe that we have material exposure to interest rate risks or to inflationary risks.

## ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required hereunder is set forth under Report of Independent Registered Public Accounting Firm, Consolidated Balance Sheets, Consolidated Statements of Operations, Statements of Changes in Shareholders' Equity, Consolidated Statements of Cash Flows and Notes to Consolidated Financial Statements included in the Consolidated Financial Statements that are a part of this annual report. Other financial information is included in the Consolidated Financial Statements that are a part of this annual report.

## ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

## ITEM 9A. CONTROLS AND PROCEDURES

### Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required financial disclosure.

As of the end of the period covered by this annual report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Exchange Act). Based upon, and as of the date of, this evaluation, the Chief Executive Officer and the Chief Financial Officer concluded that our disclosure controls and procedures were effective such that the information required to be disclosed by us in our SEC reports is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

### Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP.



Our internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on our financial statements.

Management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2021. In making its assessment, management used the criteria described in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Based on management's assessment, management has concluded that our internal control over financial reporting was effective as of December 31, 2021 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external reporting purposes in accordance with U.S. GAAP.

This annual report does not include an attestation report of our independent registered public accounting firm regarding internal controls over financial reporting because we are exempt from this requirement as a smaller reporting company and non-accelerated filer.

#### **Changes in Internal Control over Financial Reporting**

During the fourth quarter of the fiscal year ended December 31, 2021, there were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

#### **ITEM 9B. OTHER INFORMATION**

Not applicable

### PART III

#### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

##### Information About Our Executive Officers

The following table sets forth the name, age and position of each of our executive officers as of February 18, 2021:

Name	Age	Position
Larry Jasinski	64	Chief Executive Officer and Director
Ori Gon	40	Chief Financial Officer

*Larry Jasinski* has served as our Chief Executive Officer and as a member of our board since February 2012. From 2005 until 2012, Mr. Jasinski served as the President and Chief Executive Officer of Soteira, Inc., a company engaged in development and commercialization of products used to treat individuals with vertebral compression fractures, which was acquired by Globus Medical in 2012. From 2001 to 2005, Mr. Jasinski was President and Chief Executive Officer of Cortek, Inc., a company that developed next-generation treatments for degenerative disc disease, which was acquired by Alphatec in 2005. From 1985 until 2001, Mr. Jasinski served in multiple sales, research and development, and general management roles at Boston Scientific Corporation. Mr. Jasinski has served on the board of directors of Massachusetts Bay Lines since 2015 and of LeMaitre Vascular, Inc. since 2003. Mr. Jasinski holds a B.Sc. in marketing from Providence College and an MBA from the University of Bridgeport.

*Ori Gon* became our Chief Financial Officer effective February 22, 2018. From 2015 to 2018, Mr. Gon served as our Corporate Controller. Prior to ReWalk Robotics Mr. Gon served as Corporate Controller at Oti Ltd from 2012 to 2015. Mr. Gon is a Certified Public Accountant in Israel and holds a B.A. in Economics from Hebrew University of Jerusalem. Mr. Gon has informed the Company that he intends to resign from the Company, effective March 12, 2022. Mr. Gon will continue to serve as the Company's Chief Financial Officer, Principal Financial Officer and Principal Accounting Officer until March 12, 2022.

The remaining information required by this Item will be included in, and is incorporated herein by reference from, our definitive proxy statement for our 2021 Annual Meeting of Shareholders to be filed with the SEC pursuant to Regulation 14A within 120 days after the end of our fiscal year ended December 31, 2021 (the "Proxy Statement").

#### ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item 11 will be included in, and is incorporated herein by reference from, our Proxy Statement.

#### ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item 12 will be included in and is incorporated herein by reference from, our Proxy Statement.

#### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item 13 will be included in and is incorporated herein by reference, from our Proxy Statement.

#### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item 14 will be included in and is incorporated herein by reference, from our Proxy Statement.

## ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

## (a)(1) Financial Statements.

The Consolidated Financial Statements filed as part of this annual report are identified in the Index to Consolidated Financial Statements on page F-1 hereto.

## (a)(2) Financial Statement Schedules.

Financial Statement Schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

## (a)(3) Exhibits.

See accompanying Exhibit Index included after the signature page of this report for a list of the exhibits filed or furnished with or incorporated by reference in this report.

## EXHIBIT INDEX

<a href="#"><u>3.1</u></a>	<a href="#"><u>Fourth Amended and Restated Articles of Association of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on May 21, 2021).</u></a>
<a href="#"><u>4.1</u></a>	<a href="#"><u>Specimen share certificate (incorporated by reference to Exhibit 4.1 to the Company's registration statement on Form F-1/A (File No. 333-197344), filed with the SEC on August 20, 2014).</u></a>
<a href="#"><u>4.2</u></a>	<a href="#"><u>Description of the registrant's securities registered pursuant to Section 12 of the Securities Exchange Act of 1934.</u></a>
<a href="#"><u>4.3</u></a>	<a href="#"><u>Warrant, dated December 30, 2015, between the Company and Kreos Capital V (Expert Fund) Limited (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on January 4, 2016).</u></a>
<a href="#"><u>4.4</u></a>	<a href="#"><u>Form of warrant issued in connection with the Company's follow-on offering in November 2016 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on October 31, 2016).</u></a>
<a href="#"><u>4.5</u></a>	<a href="#"><u>Form of common warrant to purchase ordinary shares in November 2018 follow-on offering (incorporated by reference to Exhibit 4.7 to the Company's registration statement on Form S-1/A (File No. 333-227852), filed with the SEC on November 14, 2018).</u></a>
<a href="#"><u>4.6</u></a>	<a href="#"><u>Form of underwriter warrant from November 2018 follow-on offering (incorporated by reference to Exhibit 4.8 to the Company's registration statement on Form S-1/A (File No. 333-227852), filed with the SEC on November 14, 2018).</u></a>
<a href="#"><u>4.7</u></a>	<a href="#"><u>First Amendment to Warrant to Purchase Shares between the Company and Kreos Capital V (Expert Fund) Limited, dated November 20, 2018 (incorporated by reference to Exhibit 4.1 to the Company's current report on Form 8-K filed with the SEC on November 21, 2018).</u></a>
<a href="#"><u>4.8</u></a>	<a href="#"><u>Form of placement agent warrant from February 2019 "best efforts" public offering (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on February 25, 2019).</u></a>
<a href="#"><u>4.9</u></a>	<a href="#"><u>Form of purchaser warrant from April 2019 registered direct offering and concurrent private placement of warrants (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on April 5, 2019).</u></a>

<a href="#">4.10</a>	<a href="#">Form of placement agent warrant from April 2019 registered direct offering and concurrent private placement of warrants (incorporated by reference to Exhibit 4.2 of the Company's Current Report on Form 8-K filed with the SEC on April 5, 2019).</a>
<a href="#">4.11</a>	<a href="#">Registration Rights Agreement, dated May 15, 2018, between the Company and Timwell Corporation Limited (incorporated by reference to Exhibit 99.4 to the Schedule 13D filed by Timwell Corporation Limited with the SEC on May 29, 2018).</a>
<a href="#">4.12</a>	<a href="#">Form of private placement warrant from June 2019 private placement of warrants (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on June 11, 2019).</a>
<a href="#">4.13</a>	<a href="#">Form of placement agent warrant from June 2019 private placement of warrants (incorporated by reference to Exhibit 4.2 of the Company's Current Report on Form 8-K filed with the SEC on June 11, 2019).</a>
<a href="#">4.14</a>	<a href="#">Form of purchaser warrant from June 2019 registered direct offering and concurrent private placement of warrants (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on June 12, 2019).</a>
<a href="#">4.15</a>	<a href="#">Form of placement agent warrant from June 2019 registered direct offering and concurrent private placement of warrants (incorporated by reference to Exhibit 4.2 of the Company's Current Report on Form 8-K filed with the SEC on June 12, 2019).</a>
<a href="#">4.16</a>	<a href="#">Form of common warrant from February 2020 best efforts offering (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on February 10, 2020).</a>
<a href="#">4.17</a>	<a href="#">Form of placement agent warrant from February 2020 best efforts offering (incorporated by reference to Exhibit 4.3 of the Company's Current Report on Form 8-K filed with the SEC on February 10, 2020).</a>
<a href="#">4.18</a>	<a href="#">Form of purchaser warrant from July 2020 registered direct offering (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed on July 6, 2020).</a>
<a href="#">4.19</a>	<a href="#">Form of placement agent agreement from July 2020 registered direct offering (incorporated by reference to Exhibit 4.2 of the Company's Current Report on Form 8-K filed on July 6, 2020).</a>
<a href="#">4.20</a>	<a href="#">Form of purchaser warrant from December 2020 private placement (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on December 8, 2020).</a>
<a href="#">4.21</a>	<a href="#">Form of placement agent warrant from December 2020 private placement (incorporated by reference to Exhibit 4.2 of the Company's Current Report on Form 8-K filed with the SEC on December 8, 2020).</a>
<a href="#">4.22</a>	<a href="#">Form of registration rights agreement from December 2020 private placement (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on December 8, 2020).</a>
<a href="#">4.23</a>	<a href="#">Form of ordinary warrant from September 2021 private placement (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on September 29, 2021).</a>
<a href="#">4.24</a>	<a href="#">Form of placement agent warrant from September 2021 private placement (incorporated by reference to Exhibit 4.2 of the Company's Current Report on Form 8-K filed with the SEC on September 29, 2021).</a>
<a href="#">4.25</a>	<a href="#">Form of pre-funded warrant from September 2021 private placement (incorporated by reference to Exhibit 4.3 of the Company's Current Report on Form 8-K filed with the SEC on September 29, 2021).</a>

10.1	Letter of Agreement, dated July 11, 2013, between the Company and Sanmina Corporation.*
10.2	Research Collaboration Agreement, dated May 16, 2016, between the Company and the President and Fellows of Harvard College.*
10.3	License Agreement, dated May 16, 2016, between the Company and the President and Fellows of Harvard College.*
10.4	<a href="#"><u>Form of indemnification agreement between the Company and each of its directors and executive officers (incorporated by reference to Exhibit 10.11 to the Company's registration statement on Form F-1/A (File No. 333-197344), filed with the SEC on August 20, 2014).**</u></a>
10.5	<a href="#"><u>2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.12 to the Company's registration statement on Form F-1 (File No. 333-197344), filed with the SEC on July 10, 2014).**</u></a>
10.6	<a href="#"><u>2012 Israeli Equity Incentive Sub Plan (incorporated by reference to Exhibit 10.13 to the Company's registration statement on Form F-1 (File No. 333-197344), filed with the SEC on July 10, 2014).**</u></a>
10.7	<a href="#"><u>2012 U.S. Equity Incentive Sub Plan (incorporated by reference to Exhibit 10.14 to the Company's registration statement on Form F-1 (File No. 333-197344), filed with the SEC on July 10, 2014).**</u></a>
10.8	<a href="#"><u>2006 Stock Option Plan (incorporated by reference to Exhibit 10.15 to the Company's registration statement on Form F-1 (File No. 333-197344), filed with the SEC on July 10, 2014).**</u></a>
10.9	<a href="#"><u>2014 Incentive Compensation Plan, as amended (incorporated by reference to Exhibit 99.1 to the Company's registration statement on Form S-8 (File No. 333-239258), filed with the SEC on June 18, 2020).**</u></a>
10.10	<a href="#"><u>Executive Employment Agreement, dated as of January 17, 2011, between the Company and Larry Jasinski (incorporated by reference to Exhibit 10.16 to the Company's Annual Report on Form 10-K filed with the SEC on February 29, 2016, as amended on May 6, 2016).**</u></a>
10.11	<a href="#"><u>2014 Incentive Compensation Plan Form of Option Award Agreement for employees and executives (incorporated by reference to Exhibit 10.18 to the Company's Annual Report on Form 10-K filed with the SEC on February 29, 2016, as amended on May 6, 2016).**</u></a>
10.12	<a href="#"><u>2014 Incentive Compensation Plan Form of Restricted Share Unit Award Agreement for non-Israeli employees and executives (incorporated by reference to Exhibit 10.19 to the Company's Annual Report on Form 10-K filed with the SEC on February 29, 2016, as amended on May 6, 2016).**</u></a>
10.13	<a href="#"><u>2014 Incentive Compensation Plan Form of Restricted Share Unit Award Agreement for Israeli non-employee directors, employees and executives (incorporated by reference to Exhibit 10.20.1 to the Company's registration statement on Form S-1 (File No. 333-227852), filed with the SEC on October 15, 2018).**</u></a>
10.14	<a href="#"><u>2014 Incentive Compensation Plan Form of Restricted Share Unit Award Agreement between the Company and Jeffrey Dykan, as director (incorporated by reference to Exhibit 10.20.2 to the Company's registration statement on Form S-1 (File No. 333-227852), filed with the SEC on October 15, 2018).**</u></a>
10.15	<a href="#"><u>2014 Incentive Compensation Plan Prior Form of Restricted Share Unit Award Agreement for non-Israeli non-employee directors (incorporated by reference to Exhibit 10.20 to the Company's Annual Report on Form 10-K filed with the SEC on February 29, 2016, as amended on May 6, 2016).**</u></a>
10.16	<a href="#"><u>2014 Incentive Compensation Plan New Form of Restricted Share Unit Award Agreement for non-Israeli non-employee directors (incorporated by reference to Exhibit 10.22 to the Company's registration statement on Form S-1 (File No. 333-227852), filed with the SEC on October 15, 2018).**</u></a>
10.17	<a href="#"><u>2014 Incentive Compensation Plan Prior Form of Option Award Agreement for Israeli non-employee directors (incorporated by reference to Exhibit 10.21 to the Company's Annual Report on Form 10-K filed with the SEC on February 17, 2017, as amended on April 27, 2017).**</u></a>

<a href="#"><u>10.18</u></a>	<a href="#"><u>2014 Incentive Compensation Plan Prior Form of Option Award Agreement for non-Israeli non-employee directors (incorporated by reference to Exhibit 10.22 to the Company's Annual Report on Form 10-K filed with the SEC on February 17, 2017, as amended on April 27, 2017). **</u></a>
<a href="#"><u>10.19</u></a>	<a href="#"><u>ReWalk Robotics Ltd. Compensation Policy for Executive Officers and Non-Executive Directors, as amended (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on May 21, 2021). **</u></a>
<a href="#"><u>10.20</u></a>	<a href="#"><u>Equity Distribution Agreement, dated May 10, 2016, between the Company and Piper Jaffray &amp; Co., as Agent (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed with the SEC on May 10, 2016).</u></a>
<a href="#"><u>10.21</u></a>	<a href="#"><u>Amendment No. 1 to Equity Distribution Agreement, dated May 9, 2019, between the Company and Piper Jaffray &amp; Co., as Agent (incorporated by reference to Exhibit 10.1 to the Company's current report on Form 8-K filed with the SEC on May 9, 2019).</u></a>
<a href="#"><u>10.22</u></a>	<a href="#"><u>Employment Agreement, dated as of January 15, 2013, between the Company and Ofir Koren (incorporated by reference to Exhibit 10.26 to the Company's annual report on Form 10-K filed with the SEC on March 8, 2018). **</u></a>
<a href="#"><u>10.23</u></a>	<a href="#"><u>Amendment to Employment Agreement, dated March 1, 2018, between the Company and Ori Gon (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on March 7, 2018). **</u></a>
<a href="#"><u>10.24</u></a>	<a href="#"><u>Employment Agreement, dated May 25, 2015, between the Company and Ori Gon (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on March 7, 2018). **</u></a>
<a href="#"><u>10.25</u></a>	<a href="#"><u>Framework Agreement Regarding a Potential Joint Venture, dated March 6, 2018, between the Company and RealCan Ambrum Healthcare Industry Investment (Shenzhen) Partnership Enterprise (Limited Partnership) (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on March 23, 2018). *</u></a>
<a href="#"><u>10.26</u></a>	<a href="#"><u>Amendment No. 1 to the Research Collaboration Agreement, dated May 1, 2017, between the Company and the President and Fellows of Harvard College (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on June 29, 2018). *</u></a>
<a href="#"><u>10.27</u></a>	<a href="#"><u>Amendment No. 1 to the Exclusive License Agreement and Amendment No. 2 to the Research Collaboration Agreement, dated April 1, 2018, between the Company and the President and Fellows of Harvard College (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on June 29, 2018). *</u></a>
<a href="#"><u>10.28</u></a>	<a href="#"><u>Form of warrant exercise agreement from June 2019 private placement of warrants (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on June 11, 2019).</u></a>
<a href="#"><u>10.29</u></a>	<a href="#"><u>Form of securities purchase agreement from February 2020 best efforts offering (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on February 10, 2020) for the units offered hereby.*</u></a>

<a href="#"><u>10.30</u></a>	<a href="#"><u>Amendment No. 1 to the Securities Purchase Agreement, dated February 7, 2020, by and among the Company and the purchasers party thereto (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on February 10, 2020).*</u></a>
<a href="#"><u>10.31</u></a>	<a href="#"><u>Form of securities purchase agreement from July 2020 registered direct offering (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on July 6, 2020).</u></a>
<a href="#"><u>10.32</u></a>	<a href="#"><u>Engagement Letter, dated June 2, 2020, between the Company and H.C. Wainwright &amp; Co., LLC from July 2020 registered direct offering (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed on July 6, 2020).</u></a>
<a href="#"><u>10.33</u></a>	<a href="#"><u>Form of securities purchase agreement from December 2020 private placement, by and among the Company and the purchasers party thereto (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on December 8, 2020).*</u></a>
<a href="#"><u>10.34</u></a>	<a href="#"><u>Form of securities purchase agreement from September 2021 private placement, by and among the Company and the purchasers party thereto (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on September 29, 2021).*</u></a>
<a href="#"><u>10.35</u></a>	<a href="#"><u>Engagement Letter, dated June 2, 2020, between the Company and H.C. Wainwright &amp; Co., LLC from July 2020 registered direct offering (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on September 29, 2021).</u></a>
<a href="#"><u>10.36</u></a>	<a href="#"><u>Engagement Letter, dated December 2, 2020, by and among the Company and H.C. Wainwright &amp; Co., LLC (incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K filed with the SEC on December 8, 2020).*</u></a>
<a href="#"><u>10.37</u></a>	<a href="#"><u>Amendment No. 3 to the Research Collaboration Agreement, dated April 30, 2020, between the Company and the President and Fellows of Harvard College (incorporated by reference to Exhibit 10.34 to the Company's Registration Statement on Form S-1 (File No. 333-239733) filed with the SEC on July 7, 2020).*</u></a>
<a href="#"><u>10.38</u></a>	<a href="#"><u>Amendment No. 4 to Research Collaboration Agreement, dated October 14, 2021, between ReWalk Robotics Ltd. and the President and Fellows of Harvard College (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on October 18, 2021).*</u></a>
<a href="#"><u>10.39</u></a>	<a href="#"><u>Employment Agreement, dated July 9, 2021, by and between the Company and Jeannine Lynch (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 10, 2021**.</u></a>
<a href="#"><u>21.1</u></a>	<a href="#"><u>List of subsidiaries of the Company (incorporated by reference to Exhibit 21.1 to the Company's registration statement on Form S-1/A (File No. 333-227852), filed with the SEC on November 7, 2018).</u></a>
<a href="#"><u>23.1</u></a>	<a href="#"><u>Consent of Kost Forer Gabbay &amp; Kasierer, a member of Ernst &amp; Young Global Limited.</u></a>
<a href="#"><u>31.1</u></a>	<a href="#"><u>Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act 2002.</u></a>
<a href="#"><u>31.2</u></a>	<a href="#"><u>Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act 2002.</u></a>
<a href="#"><u>32.1</u></a>	<a href="#"><u>Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.***</u></a>
<a href="#"><u>32.2</u></a>	<a href="#"><u>Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.***</u></a>
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.PRE	XBRL Taxonomy Presentation Linkbase Document.
101.CAL	XBRL Taxonomy Calculation Linkbase Document.
101.LAB	XBRL Taxonomy Label Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.

\* Certain identified information in the exhibit has been omitted because it is the type of information that (i) the Company customarily and actually treats as private and confidential, and (ii) is not material.

\*\* Management contract or compensatory plan, contract or arrangement.

\*\*\* Furnished herewith.

## ITEM 16. FORM 10-K SUMMARY

Not applicable.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**ReWalk Robotics Ltd.**

By: /s/ Larry Jasinski

Name: Larry Jasinski

Title: Chief Executive Officer

Date: February 24, 2022



## POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENT: That the undersigned officers and directors of ReWalk Robotics Ltd. do hereby constitute and appoint Larry Jasinski and Ori Gon the lawful attorney and agent with power and authority to do any and all acts and things and to execute any and all instruments which said attorney and agent determines may be necessary or advisable or required to enable ReWalk Robotics Ltd. to comply with the Securities and Exchange Act of 1934, as amended, and any rules or regulations or requirements of the Securities and Exchange Commission in connection with this report. Without limiting the generality of the foregoing power and authority, the powers granted include the power and authority to sign the names of the undersigned officers and directors in the capacities indicated below to this report or amendments or supplements thereto, and each of the undersigned hereby ratifies and confirms all that said attorneys and agents, or either of them, shall do or cause to be done by virtue hereof. This Power of Attorney may be signed in several counterparts.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
<u>/s/ Larry Jasinski</u> Larry Jasinski	Director and Chief Executive Officer (Principal Executive Officer)	February 24, 2022
<u>/s/ Ori Gon</u> Ori Gon	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 24, 2022
<u>/s/ Jeff Dykan</u> Jeff Dykan	Chairman of the Board	February 24, 2022
<u>/s/ Yohanan R Engelhardt</u> Yohanan R Engelhardt	Director	February 24, 2022
<u>/s/ Dr. John William Poduska</u> Dr. John William Poduska	Director	February 24, 2022
<u>/s/ Wayne B. Weisman</u> Wayne B. Weisman	Director	February 24, 2022
<u>/s/ Yasushi Ichiki</u> Yasushi Ichiki	Director	February 24, 2022
<u>/s/ Aryeh Dan</u> Aryeh Dan	Director	February 24, 2022
<u>/s/ Randel Richner</u> Randel Richner	Director	February 24, 2022

PART IV  
REWALK ROBOTICS LTD  
CONSOLIDATED FINANCIAL STATEMENTS  
U.S. DOLLARS IN THOUSANDS  
INDEX

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

**To the Shareholders and Board of Directors of**

**REWALK ROBOTICS LTD.**

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Rewalk Robotics Ltd. and subsidiaries (the Company) as of December 31, 2021 and 2020, the related consolidated statements of operations, changes in shareholders' equity and cash flows for each of the three years in the period ended December 31, 2021, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with U.S. generally accepted accounting principles.

**Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

**Critical Audit Matter**

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the account or disclosure to which it relates.

## Revenue recognition

### *Description of the Matter*

As described in Note 2 to the consolidated financial statements, the Company generates revenues from sales of products. Revenue is recognized when obligations under the terms of a contract with the Company's customers are satisfied. Revenue is measured as the amount of consideration to which the Company expects to be entitled in exchange for transferring products or providing services. In addition, the Company provides a service type warranty which is accounted for as a separate performance obligation. Revenue is then recognized ratably over the life of the warranty.

Auditing the Company's revenue recognition involves subjective assumptions used in determining the standalone selling price of distinct performance obligations.

### *How We Addressed the Matter in Our Audit*

Our audit procedures included, among others, reading the executed contract and purchase order to understand the contract, identify the performance obligations and evaluate management's identification of the distinct performance obligations for a sample of contracts. To test the management's determination of standalone selling prices for each performance obligation, our audit procedures included, among others, evaluating the methodology applied and testing the calculations as well as the completeness and accuracy of the underlying data and assumptions used by the Company in its estimates. We also evaluated the Company's disclosures included in notes to the consolidated financial statements.

KOST FORER GABBAY & KASIERER  
A Member of Ernst & Young Global

We have served as the Company's auditor since 2014.

Tel-Aviv, Israel  
February 24, 2022

**REWALK ROBOTICS LTD. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS**  
**U.S. dollars in thousands**

	<b>December 31,</b>	
	<b>2021</b>	<b>2020</b>
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 88,337	\$ 20,350
Trade receivable, net	585	684
Prepaid expenses and other current assets	610	672
Inventories	2,989	3,542
Total current assets	<u>92,521</u>	<u>25,248</u>
<b>LONG-TERM ASSETS</b>		
Restricted cash and other long term assets	1,064	1,033
Operating lease right-of-use assets	881	1,349
Property and equipment, net	284	437
Total long-term assets	<u>2,229</u>	<u>2,819</u>
Total assets	<u>\$ 94,750</u>	<u>\$ 28,067</u>

The accompanying notes are an integral part of these consolidated financial statements.

**REWALK ROBOTICS LTD. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS**  
U.S. dollars in thousands (except share and per share data)

	December 31,	
	2021	2020
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Current maturities of operating leases liability	\$ 641	\$ 660
Trade payables	1,384	2,268
Employees and payroll accruals	1,142	867
Deferred revenues	316	441
Other current liabilities	555	432
Total current liabilities	<u>4,038</u>	<u>4,668</u>
<b>LONG-TERM LIABILITIES</b>		
Deferred revenues	866	667
Non-current operating leases liability	418	923
Other long-term liabilities	45	35
Total long-term liabilities	<u>1,329</u>	<u>1,625</u>
Total liabilities	<u>5,367</u>	<u>6,293</u>
<b>COMMITMENTS AND CONTINGENT LIABILITIES</b>		
Shareholders' equity:		
Share capital		
Ordinary share of NIS 0.25 par value-Authorized: 120,000,000 and 60,000,000 shares at December 31, 2021 and 2020; Issued and outstanding: 62,480,163 and 25,332,225 shares at December 31, 2021 and December 31, 2020, respectively	4,661	1,827
Additional paid-in capital	278,903	201,392
Accumulated deficit	<u>(194,181)</u>	<u>(181,445)</u>
Total shareholders' equity	<u>89,383</u>	<u>21,774</u>
Total liabilities and shareholders' equity	<u>\$ 94,750</u>	<u>\$ 28,067</u>

The accompanying notes are an integral part of these consolidated financial statements.

**REWALK ROBOTICS LTD. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
U.S. dollars in thousands (except share and per share data)

	Year ended December 31,		
	2021	2020	2019
Revenues	\$ 5,966	\$ 4,393	\$ 4,873
Cost of revenues	3,063	2,204	2,147
Gross profit	2,903	2,189	2,726
Operating expenses:			
Research and development	2,939	3,459	5,348
Sales and marketing	6,993	5,754	6,167
General and administrative	5,626	4,980	5,259
Total operating expenses	15,558	14,193	16,774
Operating loss	(12,655)	(12,004)	(14,048)
Financial expenses (income), net	(13)	921	1,496
Loss before income taxes	(12,642)	(12,925)	(15,544)
Taxes on income	94	51	7
Net loss	\$ (12,736)	\$ (12,976)	\$ (15,551)
Net loss per ordinary share, basic and diluted	\$ (0.27)	\$ (0.82)	\$ (2.70)
Weighted average number of shares used in computing net loss per ordinary share, basic and diluted	47,935,652	15,764,980	5,763,317

The accompanying notes are an integral part of these consolidated financial statements.

**REWALK ROBOTICS LTD. AND SUBSIDIARIES**  
**STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY**  
**U.S. dollars in thousands (except share data)**

	Ordinary Share		Additional paid-in capital	Accumulated deficit	Total shareholders' equity
	Number	Amount			
Balance as of December 31, 2018	2,813,087	193	154,670	(152,918)	1,945
Share-based compensation to employees and non-employees	—	—	1,108	—	1,108
Issuance of ordinary shares upon exercise of options to purchase ordinary shares and RSUs by employees and non-employees	47,473	2	—	—	2
Issuance of ordinary shares in a "best effort" offering, net of issuance expenses in the amount of \$686 (1)	760,000	52	3,632	—	3,684
Exercise of pre-funded warrants and warrants (1)	584,087	40	1,461	—	1,501
Issuance of ordinary shares in a "Registered Direct" offering, net of issuance expenses in the amount of \$1,125 (1)	1,650,248	115	8,010	—	8,125
Issuance of ordinary shares in a "Warrant exercise" agreement, net of issuance expenses in the amount of \$1,019 (1)	1,464,665	102	9,864	—	9,966
Net loss	—	—	—	(15,551)	(15,551)
Balance as of December 31, 2019	7,319,560	504	178,745	(168,469)	10,780
Share-based compensation to employees and non-employees	—	—	749	—	749
Issuance of ordinary shares upon exercise of options to purchase ordinary shares and RSUs by employees and non-employees	63,111	3	(3)	—	—
Issuance of ordinary shares in a "Best Efforts" offering, net of issuance expenses in the amount of \$1,056 (1)	4,053,172	290	3,720	—	4,010
Exercise of pre-funded warrants and warrants (1)(2)	3,378,328	244	3,979	—	4,223
Issuance of ordinary shares in a "registered direct" offering, net of issuance expenses in the amount of \$1,019 (1)	4,938,278	357	7,624	—	7,981
Issuance of ordinary shares in a private placement, net of issuance expenses in the amount of \$993 (1)	5,579,776	429	6,578	—	7,007
Net loss	—	—	—	(12,976)	(12,976)
Balance as of December 31, 2020	25,332,225	1,827	201,392	(181,445)	21,774
Share-based compensation to employees and non-employees	—	—	833	—	833
Issuance of ordinary shares upon vesting of RSUs by employees and non-employees	398,164	31	(31)	—	—
Issuance of ordinary shares in a "Best Efforts" offering, net of issuance expenses in the amount of \$3,679 (1)	10,921,502	832	35,489	—	36,321
Exercise of pre-funded warrants and warrants (1)(2)	10,425,258	772	14,288	—	15,060
Issuance of ordinary shares in a "registered direct" offering, net of issuance expenses in the amount of \$3,215 (1)	15,403,014	1,199	26,932	—	28,131
Net loss	—	—	—	(12,736)	(12,736)
Balance as of December 31, 2021	62,480,163	4,661	278,903	(194,181)	89,383

\*) Represents an amount lower than \$1.

(1) See Note 8b.

(2) See Note 8f.

The accompanying notes are an integral part of these consolidated financial statements.



**REWALK ROBOTICS LTD. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
U.S. dollars in thousands

	Year ended December 31,		
	2021	2020	2019
<b>Cash flows used in operating activities:</b>			
Net loss	\$ (12,736)	\$ (12,976)	\$ (15,551)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	266	285	321
Share-based compensation to employees and non-employees	833	749	1,108
Deferred taxes	(29)	(44)	(57)
Gain on PPP forgiveness	—	(392)	—
Changes in assets and liabilities:			
Trade receivables, net	99	110	(36)
Prepaid expenses, operating lease right-of-use assets and other assets	592	166	64
Inventories	432	(469)	(1,221)
Trade payables	(884)	(506)	370
Employees and payroll accruals	275	197	20
Deferred revenues	74	264	176
Operating lease liabilities and other liabilities	(391)	27	(9)
Net cash used in operating activities	(11,469)	(12,589)	(14,815)
<b>Cash flows used in investing activities:</b>			
Purchase of property and equipment	(47)	(73)	(22)
Net cash used in investing activities	(47)	(73)	(22)
<b>Cash flows from financing activities:</b>			
Repayment of long-term loan	—	(6,965)	(1,722)
Proceeds from PPP loan (3)	—	392	—
Issuance of ordinary shares in a “best effort” offering, net of issuance expenses in the amount of \$686 (1)	—	—	3,684
Issuance of ordinary shares in a “registered direct” offering, net of issuance expenses in the amount of \$1,035 (1)	—	—	8,125
Issuance of ordinary shares in a “warrant exercise” agreement, net of issuance expenses in the amount of \$1,019 (1)	—	—	9,966
Issuance of ordinary shares in a “best effort” offering, net of issuance expenses in the amount of \$1,056 (1)	—	4,010	—
Issuance of ordinary shares in a “registered direct” offering, net of issuance expenses in the amount of \$977 (1)	—	8,023	—
Issuance of ordinary shares in a private placement, net of issuance expenses in the amount of \$959 (1)	—	7,041	—
Issuance of ordinary shares in a private placement, net of issuance expenses paid in the amount of \$3,679 (1)	36,321	—	—
Issuance of ordinary shares in a “registered direct” offering, net of issuance expenses in the amount of \$3,215 (1)	28,131	—	—
Exercise of pre-funded warrants and warrants (1)(2)	15,060	4,223	1,429
Net cash provided by financing activities	79,512	16,724	21,482
Increase in cash, cash equivalents, and restricted cash	67,996	4,062	6,645
Cash, cash equivalents, and restricted cash at beginning of period	21,054	16,992	10,347
Cash, cash equivalents, and restricted cash at end of period	\$ 89,050	\$ 21,054	\$ 16,992

The accompanying notes are an integral part of these consolidated financial statements.

REWALK ROBOTICS LTD. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF CASH FLOWS  
U.S. dollars in thousands

	Year ended December 31,		
	2021	2020	2019
<b>Supplemental disclosures of non-cash flow information</b>			
Expenses related to offerings not yet paid (1)	\$ —	\$ 76	\$ 90
Classification of other current assets to property and equipment, net	\$ 34	\$ 98	\$ —
Classification of inventory to other current assets	\$ 89	\$ —	\$ 164
Classification of inventory to property and equipment	\$ 32	\$ 50	\$ 174
Cashless exercise of pre-funded warrants	\$ —	\$ —	\$ 72
Initial recognition of operating lease right-of-use assets	\$ —	\$ —	\$ 2,099
Initial recognition of operating lease liabilities	\$ —	\$ —	\$ (2,249)
<b>Supplemental disclosures of cash flow information:</b>			
Cash and cash equivalents	\$ 88,337	\$ 20,350	\$ 16,253
Restricted cash included in other long-term assets	\$ 713	\$ 704	\$ 739
Total Cash, cash equivalents, and restricted cash	\$ 89,050	\$ 21,054	\$ 16,992
<b>Supplemental disclosures of cash flow information:</b>			
Cash paid for income taxes	\$ 40	\$ 13	\$ 21
Cash paid for interest	\$ —	\$ 862	\$ 1,499

(1) See Note 8b.

(2) See Note 8f.

(3) See Note 10.

The accompanying notes are an integral part of these consolidated financial statements.

**NOTE 1:- GENERAL**

- a. ReWalk Robotics Ltd. ("RRL", and together with its subsidiaries, the "Company") was incorporated under the laws of the State of Israel on June 20, 2001 and commenced operations on the same date.
- b. RRL has two wholly owned subsidiaries: (i) ReWalk Robotics Inc. ("RRI") incorporated under the laws of Delaware on February 15, 2012 and (ii) ReWalk Robotics GMBH. ("RRG") incorporated under the laws of Germany on January 14, 2013.
- c. The Company is designing, developing, and commercializing robotic exoskeletons that allow individuals with mobility impairments or other medical conditions the ability to stand and walk once again. The Company has developed and is continuing to commercialize the ReWalk, an exoskeleton designed for individuals with paraplegia that uses its patented tilt-sensor technology and an on-board computer and motion sensors to drive motorized legs that power movement. The ReWalk system consists of a light wearable brace support suit which integrates motors at the joints, rechargeable batteries, an array of sensors and a computer-based control system to power knee and hip movement. Additionally, the Company developed and, in June 2019, started to commercialize the ReStore following receipt of European Union CE mark and United States Food and Drug Administration ("FDA"). The ReStore is a powered, lightweight soft exo-suit intended for use in the rehabilitation of individuals with lower limb disability due to stroke. The Company markets and sells its products directly to institutions and individuals and through third-party distributors. The Company sells its products directly primarily in Germany and the United States, and primarily through distributors in other markets. In its direct markets, the Company has established relationships with rehabilitation centers and the spinal cord injury community, and in its indirect markets, the Company's distributors maintain these relationships. RRI markets and sells products mainly in the United States. RRG markets and sells the Company's products mainly in Germany and Europe.

During the second quarter of 2020, we have finalized two separate agreements to distribute additional product lines in the U.S. market. The Company will be the exclusive distributor of the MediTouch Tutor movement biofeedback systems in the United States and will also have distribution rights for the MYOLYN MyoCycle FES cycles to U.S. rehabilitation clinics and personal sales through the U.S. Department of Veterans Affairs ("VA") hospitals. These new products will improve our product offering to clinics as well as patients within the VA as they both have similar clinician and patient profiles.

- d. The Company depends on one contract manufacturer, Sanmina. Reliance on this vendor makes the Company vulnerable to possible capacity constraints and reduced control over component availability, delivery schedules, manufacturing yields and costs.
- e. The worldwide spread of COVID-19 has resulted in a global economic slowdown and is expected to continue to disrupt general business operations until the disease is contained. This has had a negative impact on the Company's sales and results of operations since the start of the pandemic, and the Company expects that it will continue to negatively affect its sales and results of operations, but the Company is currently unable to predict the scale and duration of that impact. As of the date of issuance of these financial statements, the Company is not aware of any specific event or circumstance that would require an update of its accounting estimates or judgments or revision of the carrying value of its assets or liabilities. This determination may change as new events occur and additional information is obtained. Actual results could differ from our estimates and judgments, and any such differences may be material to our financial statements.

- f. For the full year ended December 31, 2021 the Company incurred a consolidated net loss of \$12.7 million and has an accumulated deficit in the total amount of \$194.2 million. The Company's negative operating cash flow for the full year ended December 31, 2021 was \$11.5 million. Our cash and cash equivalent on December 31, 2021 totaled \$88.3 million. The Company has sufficient funds to support its operation for more than 12 months following the approval of its consolidated financial statements for the fiscal year ended December 31, 2021.

The Company expects to incur future net losses and our transition to profitability is dependent upon, among other things, the successful development and commercialization of the Company's products and product candidates, the achievement of a level of revenues adequate to support the cost structure. Until the Company achieves profitability or generates positive cash flows, it will continue to need to raise additional cash. The Company intends to fund future operations through cash on hand, additional private and/or public offerings of debt or equity securities, cash exercises of outstanding warrants or a combination of the foregoing. In addition, the Company may seek additional capital through arrangements with strategic partners or from other sources and will continue to address its cost structure. Notwithstanding, there can be no assurance that the Company will be able to raise additional funds or achieve or sustain profitability or positive cash flows from operations.

## NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES

The consolidated financial statements are prepared according to United States generally accepted accounting principles ("U.S. GAAP"), applied on a consistent basis, as follows:

### a. Use of Estimates

The preparation of the consolidated financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates, judgments, and assumptions. The Company's management believes that the estimates, judgments, and assumptions used are reasonable based upon information available at the time they are made. These estimates, judgments and assumptions can affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. On an ongoing basis, the Company's management evaluates estimates, including those related to inventories, fair values of share-based awards and warrants, contingent liabilities, provision for warranty, allowance for doubtful account and sales return reserve. Such estimates are based on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities.

### b. Financial Statements in U.S. Dollars:

Since 2015, most of the Company's expenses were denominated in United States dollars ("dollars") and the remaining expenses were denominated in New Israeli Shekel ("NIS") and Euros. Until 2018 most of the Company's revenues were denominated in U.S. dollars and the remainder of our revenues was denominated in Euros and British pound whereas in the last three years our Euro revenues are higher than the ones in dollars. However, the selling prices are linked to the Company's price list which is determined in dollars, the budget is managed in dollars, financing activities including loans and fundraising activities, are made in U.S. dollars and the Company's management believes that the dollar is the primary currency of the economic environment in which the Company and each of its subsidiaries operate. Thus, the dollar is the Company's and its subsidiaries' functional and reporting currency.

Accordingly, transactions denominated in currencies other than the functional currency are re-measured to the functional currency in accordance with Accounting Standards Codification ("ASC") No. 830, "Foreign Currency Matters" at the exchange rate at the date of the transaction or the average exchange rate in the relevant reporting period. At the end of each reporting period, financial assets and liabilities are re-measured to the functional currency using exchange rates in effect at the balance sheet date. Non-financial assets and liabilities are re-measured at historical exchange rates. All transaction gains and losses of the re-measured monetary balance sheet items are reflected in the consolidated statements of operations.

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### c. Principles of Consolidation:

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, RRI and RRG. All intercompany transactions and balances have been eliminated upon consolidation.

### d. Cash Equivalents:

Cash equivalents are short-term highly liquid investments that are readily convertible to cash with original maturities of three months or less, at the date acquired.

### e. Inventories:

Inventories are stated at the lower of cost or market value. Inventory reserves are provided to cover risks arising from slow-moving items or technological obsolescence.

The Company periodically evaluates the quantities on hand relative to historical, current and projected sales volume. Based on this evaluation, an impairment charge is recorded when required to write-down inventory to its market value.

Cost is determined as follows:

Finished products - on the basis of raw materials and manufacturing costs on an average basis.

Raw materials - The weighted average cost method.

The Company regularly evaluates the ability to realize the value of inventory based on a combination of factors, including historical usage rates and forecasted sales according to outstanding backlogs. Purchasing requirements and alternative usage are explored within these processes to mitigate inventory exposure. When recorded, the reserves are intended to reduce the carrying value of inventory to its net realizable value. In the years ended December 31, 2021, 2020 and 2019, the Company wrote off inventory in the amount of \$252 thousand, \$215 thousand, and \$64 thousand, respectively. The write off inventory were recorded in cost of revenue. If actual demand for the Company's products deteriorates, or market conditions are less favorable than those projected, additional inventory reserves may be required.

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### f. Balances and transactions with related parties:

The Company has a related party shareholder named Yaskawa Electric Corporation ("YEC").

In September 2013, the Company entered into a share purchase agreement and a strategic alliance with YEC, pursuant to which YEC has agreed to distribute the Company's products, in addition to providing sales, marketing, service and training functions, in Japan, China (including Hong-Kong and Macau), Taiwan, South Korea, Singapore and Thailand.

As of December 31, 2021, and 2020, there have been no related party receivable with YEC. Revenues from YEC during the years ended December 31, 2021, 2020, and 2019 amounted to \$0 thousand, \$0 thousand and \$41 thousand, respectively.

### g. Property and Equipment:

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets at the following annual rates:

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%

Computer equipment	20-33 (mainly 33)
Office furniture and equipment	6 - 10 (mainly 10)
Machinery and laboratory equipment	15
Field service units	50
Leasehold improvements	Over the shorter of the lease term or estimated useful life

h. Impairment of Long-Lived Assets:

The Company's long-lived assets are reviewed for impairment in accordance with ASC No. 360, "Property, Plant and Equipment" whenever events or changes in circumstances indicate that the carrying amount of an asset (or asset group) may not be recoverable. Recoverability of assets (or asset group) to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted cash flows expected to be generated by the assets. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. During the years ended December 31, 2021, 2020 and 2019, no impairment losses have been recorded.

i. Restricted cash and Other long-term assets:

Other long-term assets include long-term prepaid expenses and restricted cash deposits for offices and cars leasing based upon the term of the remaining restrictions.

j. Revenue Recognition:

The Company generates revenues from sales of products. The Company sells its products directly to end customers and through distributors. The Company sells its products to private individuals (who finance the purchases by themselves, through fundraising or reimbursement coverage from insurance companies), rehabilitation facilities and distributors.

The Company recognized revenue in accordance with ASC Topic 606 when, or as, control of the promised goods or services is transferred to the customer, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods or services. The Company applies the following five steps:

1. Identify the contract with a customer

The Company generally considers purchase order or a signed quote, to be contracts with customers. In evaluating the contract with a customer, the Company analyzes the customer's intent and ability to pay the amount of promised consideration (credit risk) and considers the probability of collecting substantially all of the consideration.

2. Identify the performance obligations in the contract

At a contract's inception, the Company assesses the goods or services promised in a contract with a customer and identifies the performance obligations.

3. Determine the transaction price

The transaction price is determined based on the consideration to which the Company will be entitled in exchange for transferring products or services to the customer.

Shipping and handling costs charged to customers are included in net sales. Determining the transaction price requires significant judgment, which is discussed by revenue category in further detail below.

In practice, the Company does not offer extended payment terms beyond one year to customers.

4. Allocate the transaction price to performance obligations in the contract

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price to each performance obligation based on a relative standalone selling price basis unless a portion of the variable consideration related to the contract is allocated entirely to a performance obligation. The Company determines standalone selling price based on the price at which the performance obligation is sold separately.

5. Recognize revenue when or as the Company satisfies a performance obligation

The Company generally satisfies performance obligations at a point in time, once the customer has obtained the legal title to the items purchased or service provided.

For systems sold to rehabilitation facilities, the Company includes training and considers the elements in the arrangement to be a single performance obligation. Therefore, the Company recognizes revenue for the system and training only after delivery in accordance with the agreement's delivery terms to the customer and after the training has been completed.

For sales of Personal systems to end users, and for sales of Personal or Rehabilitation systems to third party distributors, the Company does not provide training to the end user as this training is completed by the Rehabilitation centers or by the distributor that have previously completed the ReWalk Training program. Therefore, the Company recognizes revenue in such sales upon delivery.

Revenue is recognized based on the transaction price at the time the related performance obligation is satisfied by transferring a promised product or service to a customer.

The Company generally does not grant a right of return for its products. In rare circumstances the Company provides a right of return of its products. In those cases, the Company records reductions to revenue for expected future product returns based on the Company's historical experience and estimates.

Disaggregation of Revenues (in thousands)

	Year Ended December 31,		
	2021	2020	2019
Units placed	\$ 5,449	\$ 3,620	\$ 4,385
Spare parts and warranties	517	773	488
Total Revenues	<u>\$ 5,966</u>	<u>\$ 4,393</u>	<u>\$ 4,873</u>

Units placed

The Company currently offer five products: (1) ReWalk Personal, (2) ReWalk Rehabilitation, (3) ReStore, (4) MyoCycle and (5) MediTouch.

ReWalk Personal and ReWalk Rehabilitation are units for spinal cord injuries ("SCI Products"). SCI Products are currently designed for everyday use by paraplegic individuals at home and in their communities, and are custom fitted for each user, as well as for use by paraplegic patients in the clinical rehabilitation environment, where they provide individuals access to valuable exercise and therapy. ReWalk Rehabilitation current design is dated and will not be produced in the future.

ReStore is a powered, lightweight soft exo-suit intended for use in the rehabilitation of individuals with lower limb disability due to stroke in the clinical rehabilitation environment.

MyoCycle which uses Functional Electrical Stimulation (“FES”) technology and MediTouch tutor movement biofeedback devices (“Distributed Products”). The Company markets the Distributed Products in the United States for use at home or in clinic.

Units placed include revenue from sales of SCI Products, ReStore, and Distributed Products.

For units placed, the Company recognizes revenues when it transfers control and title has passed to the customer. Each unit placed is considered an independent, unbundled performance obligation. The Company also offers a rent-to-purchase model in which the Company recognizes revenue ratably according to the agreed rental monthly fee.

#### Spare parts and warranties

Spare parts are sold to private individuals, rehabilitation facilities and distributors. Revenue is recognized when the Company satisfies a performance obligation by transferring control over promised goods or services to the customer. Each part sold is considered an independent, unbundled performance obligation.

Warranties are classified as either assurance type or service type warranty. A warranty is considered an assurance type warranty if it provides the consumer with assurance that the product will function as intended for a limited period of time.

In the beginning of 2018, the Company updated its service policy for SCI Products to include a five- year warranty compared to a period of two years that were included in the past for parts and services. The first two years are considered as assurance type warranty and the additional period is considered an extended service arrangement, which is a service type warranty. An assurance type warranty is not accounted for as separate performance obligations under the revenue model. A service type warranty is either sold with a unit or separately for units for which the warranty has expired. Revenue is then recognized ratably over the life of the warranty.

The ReStore device is sold with a two-year warranty which is considered as assurance type warranty.

The Distributed Products are sold with assurance type warranty ranging between one year to ten years depending on the specific product and part.

#### Contract balances (in thousands)

	December 31, 2021	December 31, 2020
Trade receivable, net (1)	\$ 585	\$ 684
Deferred revenues (1) (2)	\$ 1,182	\$ 1,108

(1) Balance presented net of unrecognized revenues that were not yet collected.

(2) \$432 thousands of December 31, 2020 deferred revenues balance were recognized as revenues during the year ended December 31, 2021.

#### Typical timing of payment

Deferred revenue is comprised mainly of unearned revenue related to service type warranty but also includes other offerings for which the Company has been paid in advance and earns revenue when the Company transfers control of the product or service.



The Company's unfilled performance obligations as of December 31, 2021 and the estimated revenue expected to be recognized in the future related to the service type warranty amounts to \$1.21 million, which is fulfilled over one to five years.

k. Accounting for Share-Based Compensation:

The Company accounts for share-based compensation in accordance with ASC No. 718, "Compensation-Stock Compensation" ("ASC No. 718"). ASC No. 718 requires companies to estimate the fair value of equity-based payment awards on the date of grant using an Option-Pricing Model ("OPM"). The value of the portion of the award that is ultimately expected to vest is recognized as an expense over the requisite service periods in the Company's consolidated statements of operations. According to Accounting Standards Update 2016-09, "Compensation-Stock Compensation (Topic 718)" ("ASU 2016-09") the Company account for forfeitures as they occur.

The Company recognizes compensation expenses for the value of its awards granted based on the straight-line method over the requisite service period of each of the awards.

The Company selected the Black-Scholes-Merton option pricing model as the most appropriate fair value method for its share-option awards. The option-pricing model requires a number of assumptions, of which the most significant are the fair market value of the underlying ordinary share, expected share price volatility and the expected option term. Expected volatility was calculated based upon certain peer companies that the Company considered to be comparable. The expected option term represents the period of time that options granted are expected to be outstanding. The expected option term is determined based on the simplified method in accordance with Staff Accounting Bulletin No. 110, as adequate historical experience is not available to provide a reasonable estimate. The simplified method will continue to apply until enough historical experience is available to provide a reasonable estimate of the expected term. The risk-free interest rate is based on the yield from U.S. treasury bonds with an equivalent term. The Company has historically not paid dividends and has no foreseeable plans to pay dividends.

Following the IPO in September 2014, the fair value of ordinary shares is observable as they are publicly traded.

The fair value of Restricted Stock Units (RSUs) granted is determined based on the price of the Company's ordinary shares on the date of grant.

The fair value for options granted in 2019 is estimated at the date of grant using a Black-Scholes-Merton option pricing model with the following assumptions:

	2019
Expected volatility	57.5%
Risk-free rate	2.22%
Dividend yield	—%
Expected term (in years)	6.11
Share price	\$ 5.37

There were no options granted during the twelve months ended December 31, 2021, and 2020.

The Company accounts for options granted to consultants and other service providers under ASC No. 718. The fair value of these options was estimated using a Black-Scholes-Merton option-pricing model.

The non-cash compensation expenses related to employees and non-employees for the years ended December 31, 2021, 2020 and 2019 amounted to \$833 thousand, \$749 thousand, and \$1.11 million, respectively.

l. Warrants to Acquire Ordinary Shares:

During the twelve-month ended December 31, 2021, and 2020, respectively, the Company issued warrants to acquire up to 15,083,611 and 11,389,555 ordinary shares. The Company assessed the warrants pursuant to ASC 480 "Distinguishing Liabilities from Equity" and ASC 815 "Derivatives and Hedging" and determine that the warrants should be accounted for as equity and not as a derivative liability. Refer to Note 8f for additional information.

m. Research and Development Costs:

Research and development costs are charged to the consolidated statement of operations as incurred and are presented net of the amount of any grants the Company received for research and development in the period in which the grant was received.

n. Income Taxes

The Company accounts for income taxes in accordance with ASC No. 740, "Income Taxes" ("ASC No. 740"), using the liability method whereby deferred tax assets and liability account balances are determined based on the differences between financial reporting and the tax basis for assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company provides a valuation allowance, if necessary, to reduce deferred tax assets to the amounts that are more likely-than-not to be realized.

ASC No. 740 contains a two-step approach to recognizing and measuring a liability for uncertain tax positions. The first step is to evaluate the tax position taken or expected to be taken in a tax return by determining if the weight of available evidence indicates that it is more likely than not that, on an evaluation of the technical merits, the tax position will be sustained on audit, including resolution of any related appeals or litigation processes. The second step is to measure the tax benefit as the largest amount that is more than 50% likely to be realized upon ultimate settlement. The Company accrues interest and penalties related to unrecognized tax benefits in its taxes on income. As of December 31, 2021, and 2020, the Company did not identify any significant uncertain tax positions.

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o. Warranty:

The Company provided a two-year standard warranty for its products. In the beginning of 2018, we updated our service policy for new devices sold to include five-year warranties. The Company determined that the first two years of warranty is an assurance-type warranty and records a provision for the estimated cost to repair or replace products under warranty at the time of sale. Factors that affect the Company's warranty reserve include the number of units sold, historical and anticipated rates of warranty repairs and the cost per repair.

	US Dollars in thousands
Balance at December 31, 2020	\$ 140
Provision	271
Usage	(299)
Balance at December 31, 2021	112

p. Concentrations of Credit Risks:

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents and trade receivables.

The Company's cash and cash equivalents are deposited in major banks in Israel, the United States and Germany. Such deposits in the United States may be in excess of insured limits and are not insured in other jurisdictions. The Company maintains cash and cash equivalents with diverse financial institutions and monitors the amount of credit exposure to each financial institution.

Concentration of credit risk with respect to trade receivable is primarily limited to a customer to which the Company makes substantial sales.

	December 31,	
	2021	2020
Customer A	20%	*)
Customer B	18%	*)
Customer C	16%	*)
Customer D	12%	12%
Customer E	10%	*)
Customer F	*)	15%
Customer G	*)	15%
Customer H	*)	15%
Customer I	*)	14%
Customer J	*)	11%

\*) Less than 10%

The Company's trade receivables are geographically diversified and derived primarily from sales to customers in various countries, mainly in the United States and Europe. Concentration of credit risk with respect to trade receivables is limited by credit limits, ongoing credit evaluation and account monitoring procedures. The Company performs ongoing credit evaluations of its distributors based upon a specific review of all significant outstanding invoices. The Company writes off receivables when they

are deemed uncollectible and having exhausted all collection efforts. As of December 31, 2021, and 2020 trade receivables are presented net of \$42 thousand and \$102 thousand allowance for doubtful accounts, respectively, and net of sales return reserve of \$43 thousand and \$0 thousand, respectively.

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q. Accrued Severance Pay:

Pursuant to Israel's Severance Pay Law, Israeli employees are entitled to severance pay equal to one month's salary for each year of employment, or a portion thereof. All of the employees of the RRL elected to be included under section 14 of the Severance Pay Law, 1963 ("section 14"). According to this section, these employees are entitled only to monthly deposits, at a rate of 8.33% of their monthly salary, made in their name with insurance companies. Payments in accordance with section 14 release the Company from any future severance payments (under the above Israeli Severance Pay Law) in respect of those employees; therefore, related assets and liabilities are not presented in the balance sheet.

Total Company's expenses related to severance pay amounted to \$104 thousand, \$125 thousand and \$156 thousand for the years ended December 31, 2021, 2020 and 2019, respectively.

r. Fair Value Measurements:

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The Company uses a three-tier fair value hierarchy to classify and disclose all assets and liabilities measured at fair value on a recurring basis, as well as assets and liabilities measured at fair value on a non-recurring basis, in periods subsequent to their initial measurement. The hierarchy requires the Company to use observable inputs when available, and to minimize the use of unobservable inputs when determining fair value. If a financial instrument uses inputs that fall in different levels of the hierarchy, the instrument will be categorized based upon the lowest level of input that is significant to the fair value calculation. The three-tiers are defined as follows:

- **Level 1.** Observable inputs based on unadjusted quoted prices in active markets for identical assets or liabilities;
- **Level 2.** Inputs, other than quoted prices in active markets, that are observable either directly or indirectly; and
- **Level 3.** Unobservable inputs for which there is little or no market data requiring the Company to develop its own assumptions.

The carrying amounts of cash and cash equivalents, short term deposits, trade receivables and trade payables approximate their fair value due to the short-term maturity of such instruments.

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s. Basic and Diluted Net Loss Per Share:

Basic net loss per share is computed by dividing the net loss by the weighted-average number of shares of ordinary shares outstanding during the period.

Diluted net loss per share is computed by giving effect to all potential shares of ordinary shares, including stock options, convertible preferred share warrants, to the extent dilutive, all in accordance with ASC No. 260, "Earning Per Share".

The following table sets forth the computation of the Company's basic and diluted net loss per ordinary share (in thousands, except share and per share data):

	Year ended December 31,		
	2021	2020	2019
Net loss	\$ (12,736)	\$ (12,976)	\$ (15,551)
Net loss attributable to ordinary shares	(12,736)	(12,976)	(15,551)
Shares used in computing net loss per ordinary shares, basic and diluted	47,935,652	15,764,980	5,763,317
Net loss per ordinary share, basic and diluted	\$ (0.27)	\$ (0.82)	\$ (2.70)

Basic and diluted net loss per share was the same for each period presented as the inclusion of all potential shares of ordinary shares and warrants outstanding would have been anti-dilutive.

t. Contingent liabilities

The Company accounts for its contingent liabilities in accordance with ASC No. 450, "Contingencies". A provision is recorded when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated.

With respect to legal matters, provisions are reviewed and adjusted to reflect the impact of negotiations, estimated settlements, legal rulings, advice of legal counsel and other information and events pertaining to a particular matter.

See Note 7e for further information.

u. Government grants

Government grants received by the Company relating to categories of operating expenditures are credited to the consolidated statements of operations during the period in which the expenditure to which they relate is charged. Royalty and non-royalty-bearing grants from the Israel Innovation Authority, or the IIA, (formerly known as the Israeli Office of the Chief Scientist), for funding certain approved research and development projects which are recognized at the time when the Company is entitled to such grants, on the basis of the related costs incurred, and are included as a deduction from research and development expenses (see Note 7c).

No royalty-bearing grants were recorded for the years ended December 31, 2021, 2020, and 2019.

Total Company expenses related to royalties amounted to \$14 thousand, \$46 thousand and \$15 thousand for the years ended December 31, 2021, 2020 and 2019, respectively.

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v. Leases

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU"), No. 2016-02, Leases (Topic 842), to enhance the transparency and comparability of financial reporting related to leasing arrangements. The Company adopted the standard effective January 1, 2019.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company utilizes its incremental borrowing rate, which is the rate incurred to borrow on a collateralized

basis over a similar term an amount equal to the lease payments in a similar economic environment. Certain adjustments to the right-of-use asset may be required for items, such as initial direct costs paid or incentives received.

Lease expense is recognized over the expected lease term on a straight-line basis. Operating leases are recognized on the balance sheet as right-of-use assets, lease liabilities current and lease liabilities non-current. As a result, the Company no longer recognizes deferred rent on the balance sheet.

Leases with an initial term of 12 months or less are not recorded on the balance sheet. The Company recognizes the lease expense for such leases on a straight-line basis over the lease term.

w. New Accounting Pronouncements

*Recent Accounting Pronouncements Not Yet Adopted*

i. Accounting for Convertible Instruments and Contracts in an Entity's Own Equity

In August 2020, the Financial Accounting Standards Board ("FASB") issued ASU No. 2020-06, Accounting for Convertible Instruments and Contracts in an Entity's Own Equity ("ASU 2020-06"), which simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts in an entity's own equity. Among other changes, ASU 2020-06 removes from U.S. GAAP the liability and equity separation model for convertible instruments with a cash conversion feature and a beneficial conversion feature, and as a result, after adoption, entities will no longer separately present in equity an embedded conversion feature for such debt. Similarly, the embedded conversion feature will no longer be amortized into income as interest expense over the life of the instrument. Instead, entities will account for a convertible debt instrument wholly as debt unless (1) a convertible instrument contains features that require bifurcation as a derivative under ASC Topic 815, Derivatives and Hedging, or (2) a convertible debt instrument was issued at a substantial premium. Additionally, ASU 2020-06 requires the application of the if-converted method to calculate the impact of convertible instruments on diluted earnings per share ("EPS"). ASU 2020-06 is effective for fiscal years beginning after December 15, 2021, with early adoption permitted for fiscal years beginning after December 15, 2020 and can be adopted on either a fully retrospective or modified retrospective basis. The adoption of this standard is not expected to result in a material impact to the Company's financial statements.

ii. Financial Instruments

In June 2016, FASB issued ASU 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. ASU 2016-13 amends the impairment model to utilize an expected loss methodology in place of the currently used incurred loss methodology, which will result in the more timely recognition of losses. Topic 326 will be effective on the Company beginning on January 1, 2023. The Company is currently evaluating the impact of this new standard on its financial statements.

iii. Income Taxes

In December 2019, the FASB issued ASU 2019-12 to simplify the accounting for income taxes. The guidance eliminates certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period, and the recognition of deferred tax liabilities for outside basis differences related to changes in ownership of equity method investments and foreign subsidiaries.

The guidance also simplifies aspects of accounting for franchise taxes and enacted changes in tax laws or rates and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. The standard will be effective for the Company beginning January 1, 2022. The adoption of ASU 2019-12 is not expected to result in a material impact on the Company's consolidated financial statements.

**NOTE 3:- PREPAID EXPENSES AND OTHER CURRENT ASSETS**

The components of prepaid expenses and other current assets are as follows (in thousands):

	December 31,	
	2021	2020
Government institutions	\$ 207	\$ 87
Prepaid expenses	335	311
Advances to vendors	5	241
Other assets	63	33
	<u>\$ 610</u>	<u>\$ 672</u>

**NOTE 4:- INVENTORIES**

The components of inventories are as follows (in thousands):

	December 31,	
	2021	2020
Finished products	\$ 2,284	\$ 2,764
Raw materials	705	778
	<u>\$ 2,989</u>	<u>\$ 3,542</u>

**NOTE 5:- PROPERTY AND EQUIPMENT, NET**

The components of property and equipment, net are as follows (in thousands):

	December 31,	
	2021	2020
Cost:		
Computer equipment	\$ 741	\$ 725
Office furniture and equipment	301	298
Machinery and laboratory equipment	620	612
Field service units	1,712	1,626
Leasehold improvements	333	333
	<u>\$ 3,707</u>	<u>\$ 3,594</u>
	December 31,	
	2021	2020
Accumulated depreciation	<u>3,423</u>	<u>3,157</u>
Property and equipment, net	<u>\$ 284</u>	<u>\$ 437</u>

Depreciation expenses amounted to \$266 thousand, \$285 thousand, and \$321 thousand for the years ended December 31, 2021, 2020 and 2019, respectively.

## NOTE 6: - LOAN AGREEMENT WITH KREOS AND RELATED WARRANT TO PURCHASE ORDINARY SHARES

On December 30, 2015, the Company entered into the loan agreement (the “Loan Agreement”) with Kreos Capital V (Expert Fund) Limited (“Kreos”), pursuant to which Kreos extended a line of credit to us in the amount of \$20 million, with interest payable monthly in arrears on any amounts drawn down at a rate of 10.75% per year from the applicable drawdown date through the date on which all principal is repaid. As of June 30, 2017, the Company raised more than \$20 million in connection with the issuance of its share capital and, therefore, in accordance with the terms of the Loan Agreement, the repayment period was extended from 24 months to 36 months. The principal was also reduced in connection with the issuance of the Kreos Convertible Note on June 9, 2017. Pursuant to the Loan Agreement, we granted Kreos a first priority security interest over all of our assets, including certain intellectual property and equity interests in its subsidiaries, subject to certain permitted security interests.

Pursuant to the terms of the warrant, in connection with the \$20.0 million drawdown under the Loan Agreement on January 4, 2016, we issued to Kreos the warrant to purchase up to 4,771 of our ordinary shares at an exercise price of \$241.0 per share, increased to 6,679 ordinary shares on December 28, 2016. Subject to the terms of the warrant, the warrant is exercisable, in whole or in part, at any time prior to the earlier of (i) December 30, 2025, or (ii) immediately prior to the consummation of a merger, consolidation, or reorganization of us with or into, or the sale or license of all or substantially all our assets or shares to, any other entity or person, other than a wholly-owned subsidiary of us, excluding any transaction in which our shareholders prior to the transaction will hold more than 50% of the voting and economic rights of the surviving entity after the transaction.

On June 9, 2017, the Company and Kreos entered into the First Amendment, under which \$3.0 million of the outstanding principal under the Loan Agreement became subject to repayment pursuant to the senior secured Kreos Convertible Note issued on June 9, 2017.

On November 20, 2018, the Company and Kreos entered into the Second Amendment of the Loan Agreement, in which the Company repaid Kreos the \$3.6 million other related payments, including prepayment costs and end of loan payments, terminating the Kreos Note, by issuing to Kreos 192,000 units and 288,000 pre-funded units as part of an underwritten public offering at the public offering prices, and the parties agreed to revise the principal and the repayment schedule under the Kreos Loan. Additionally, Kreos and the Company entered into the Kreos Warrant Amendment, which amended the exercise price of the warrant to purchase 6,679 ordinary shares currently held by Kreos from \$241.0 to \$7.50.

On June 5, 2019, and June 6, 2019, the Company entered into warrant exercise agreements with certain institutional investors of warrants to purchase the Company’s ordinary shares, pursuant to which, Kreos agreed to exercise in cash their November 2018 warrants at the existing exercise price of \$7.50 per share. Under the exercise agreements, the Company also agreed to issue to Kreos new warrants to purchase up to 480,000 ordinary shares at an exercise price of \$7.50 per share and exercise period of five years.

On December 29, 2020, the Company repaid in full the remaining loan principal amount to Kreos including the end of loan payments, and by that discharged all of its obligations to Kreos and as of December 31, 2020, the outstanding principal amount under the Kreos Loan Agreement was zero.

The Company recorded interest expense in the amount of \$907 thousand during the fiscal year ended December 31, 2020.

**NOTE 7:- COMMITMENTS AND CONTINGENT LIABILITIES****a. Purchase commitment:**

The Company has contractual obligations to purchase goods from its contract manufacturer as well as raw materials from different vendors. Purchase obligations do not include contracts that may be canceled without penalty. As of December 31, 2021, non-cancelable outstanding obligations amounted to approximately \$1.5 million.

**b. Operating lease commitment:**

- (i) The Company operates from leased facilities in Israel, the United States and Germany. These leases expire between 2022 and 2023. A portion of the Company's facilities leases is generally subject to annual changes in the Consumer Price Index (CPI). The changes to the CPI are treated as variable lease payments and recognized in the period in which the obligation for those payments was incurred.
- (ii) RRL and RRG lease cars for their employees under cancelable operating lease agreements expiring at various dates in between 2022 and 2023. A subset of the Company's cars leases is considered variable. The variable lease payments for such cars leases are based on actual mileage incurred at the stated contractual rate. RRL and RRG have an option to be released from these agreements, which may result in penalties in a maximum amount of approximately \$20 thousand as of December 31, 2021.

The Company's future lease payments for its facilities and cars, which are presented as current maturities of operating leases and non-current operating leases liabilities on the Company's consolidated balance sheets as of December 31, 2021 are as follows (in thousands):

2022	\$	689
2023		500
Total lease payments		1,189
Less: imputed interest		(130)
Present value of future lease payments		1,059
Less: current maturities of operating leases		(641)
Non-current operating leases	\$	418
Weighted-average remaining lease term (in years)		1.74
Weighted-average discount rate		12.6%

Total rent expenses for the years ended December 31, 2021, 2020 and 2019 were \$730 thousand, \$764 thousand, and \$739 thousand, respectively.

c. Royalties:

The Company's research and development efforts are financed, in part, through funding from the IIA. Since the Company's inception through December 31, 2021, the Company received funding from the IIA in the total amount of \$1.97 million. Out of the \$1.97 million in funding from the IIA, a total amount of \$1.57 million were royalty-bearing grants (as of December 31, 2021, the Company paid royalties to the IIA in the total amount of \$99 thousand), while a total amount of \$400 thousand was received in consideration of 209 convertible preferred A shares, which converted after the Company's initial public offering in September 2014 into ordinary shares in a conversion ratio of 1 to 1. The Company is obligated to pay royalties to the IIA, amounting to 3% of the sales of the products and other related revenues generated from such projects, up to 100% of the grants received. The royalty payment obligations also bear interest at the LIBOR rate. The obligation to pay these royalties is contingent on actual sales of the applicable products and in the absence of such sales, no payment is required.

Additionally, the License Agreement requires the Company to pay Harvard royalties on net sales, see Note 9 below for more information about the Collaboration Agreement and the License Agreement.

Royalties expenses in cost of revenue were \$14 thousand, \$46 thousand and \$15 thousand for the years ended December 31, 2021, 2020 and 2019, respectively.

As of December 31, 2021, the contingent liability to the IIA amounted to \$1.5 million. The Israeli Research and Development Law provides that know-how developed under an approved research and development program may not be transferred to third parties without the approval of the IIA. Such approval is not required for the sale or export of any products resulting from such research or development. The IIA, under special circumstances, may approve the transfer of IIA-funded know-how outside Israel, in the following cases:

(a) the grant recipient pays to the IIA a portion of the sale price paid in consideration for such IIA-funded know-how or in consideration for the sale of the grant recipient itself, as the case may be, which portion will not exceed six times the amount of the grants received plus interest (or three times the amount of the grant received plus interest, in the event that the recipient of the know-how has committed to retain the R&D activities of the grant recipient in Israel after the transfer); (b) the grant recipient receives know-how from a third party in exchange for its IIA-funded know-how; (c) such transfer of IIA-funded know-how arises in connection with certain types of cooperation in research and development activities; or (d) If such transfer of know-how arises in connection with a liquidation by reason of insolvency or receivership of the grant recipient.

d. Liens

As part of the Company's Restricted cash and other long-term assets, as of December 31, 2021, an amount of \$713 thousand has been pledged as security in respect of a guarantee granted to a third party. Such deposit cannot be pledged to others or withdrawn without the consent of such third party.



e. Legal Claims:

Occasionally, the Company is involved in various claims such as product liability claims, lawsuits, regulatory examinations, investigations, and other legal matters arising, for the most part, in the ordinary course of business. While the outcome of any pending or threatened litigation and other legal matters is inherently uncertain, the Company does not believe the outcome of any of the matters will have a material adverse effect on the Company's consolidated results of operation, liquidity or financial condition.

## NOTE 8: - SHAREHOLDERS' EQUITY

### a. Reverse share split:

On March 27, 2019, the Company's shareholders approved (i) a reverse share split within a range of 1:8 to 1:32, to be effective at the ratio and on a date to be determined by the Board of Directors, and (ii) amendments to the Company's Articles of Association authorizing an increase in the Company's authorized share capital (and corresponding authorized number of ordinary shares, proportionally adjusting such number for the reverse share split) by up to NIS 17.5 million. Following the shareholder approval, an authorized committee of the Board of Directors of the Company approved a one-for-twenty-five reverse share split of the Company's ordinary shares, and the Company filed the Third Amended and Restated Articles of Association of the Company with the Israeli Corporations Authority to affect the reverse share split and to increase the Company's authorized share capital after the effect of the reverse share split. The reverse share split became effective on April 1, 2019. Additionally, effective at the same time, the total number of ordinary shares the Company is authorized to issue changed from 250,000,000 shares to 60,000,000 shares, the par value per share of the ordinary shares changed to NIS 0.25 and the authorized share capital of the Company changed from NIS 2,500,000 to NIS 15,000,000. All share and per share data included in these consolidated financial statements, for periods before December 31, 2019, give retroactive effect to the reverse stock split.

Upon the effectiveness of the reverse share split, every twenty-five shares were automatically combined and converted into one ordinary share. Appropriate adjustments were also made to all outstanding derivative securities of the Company, including all outstanding equity awards and warrants.

No fractional shares were issued in connection with the reverse share split. Instead, all fractional shares (including shares underlying outstanding equity awards and warrants) were rounded down to the nearest whole number.

b. Equity raise:

1. Follow-on offerings

In February 2019, the Company entered into an exclusive placement agent agreement with H.C. Wainwright, on a reasonable best-efforts basis in connection with a public offering of 760,000 ordinary shares at a price of \$5.75 per share.

The total gross proceeds received from the February 2019 follow-on public offering, before deducting commissions, discounts, and expenses, were \$4.37 million. The Company also issued to H.C. Wainwright and/or its designees warrants to purchase up to 45,600 ordinary shares, which are immediately exercisable starting on February 25, 2019, until February 21, 2024 at \$7.1875 per share.

In April 2019, the Company entered into securities purchase agreements with certain institutional purchasers whereby the Company issued 816,914 ordinary shares at \$5.2025 per ordinary share and warrants to purchase up to 408,457 ordinary shares with an exercise price of \$5.14 per share, exercisable from April 5, 2019 until October 7, 2024, in a private placement that took place concurrently with the Company's registered direct offering of ordinary shares in April 2019. Additionally, the Company issued warrants to purchase up to 49,015 ordinary shares, with an exercise price of \$6.503125 per share, exercisable from April 5, 2019 until April 3, 2024, to representatives of H.C. Wainwright as compensation for its role as the placement agent in the Company's April 2019 registered direct offering and concurrent private placement of warrants.

On June 5, 2019, and June 6, 2019, the Company entered into warrant exercise agreements with certain institutional investors whereby the Company issued warrants to purchase up to 1,464,665 ordinary shares with an exercise price of \$7.50 per share, exercisable from June 5, 2019 or June 6, 2019 until June 5, 2024 or June 6, 2024, respectively. Additionally, the Company issued warrants to purchase up to 87,880 ordinary shares, with an exercise price of \$9.375 per share, exercisable from June 5, 2019, until June 5, 2024, to certain representatives of H.C. Wainwright as compensation for its role as the placement agent in the Company's June 2019 warrant exercise agreement and concurrent private placement of warrants.

On June 12, 2019, the Company entered into a purchase agreement with certain institutional investors for the issuance and sale of 833,334 ordinary shares, par value NIS 0.25 per share at \$6.00 per ordinary share and warrants to purchase up to 416,667 ordinary shares with an exercise price of \$6.00 per share, exercisable from June 12, 2019 until December 12, 2024, in a private placement that took place concurrently with the Company's registered direct offering of ordinary shares in June 2019. Additionally, the Company issued warrants to purchase up to 50,000 ordinary shares, with an exercise price of \$7.50 per share, exercisable from June 12, 2019, until June 10, 2024, to certain representatives of H.C. Wainwright as compensation for its role as the placement agent in the Company's June 2019 registered direct offering and concurrent private placement of warrants.

On February 10, 2020, the Company closed a "best efforts" public offering whereby the Company issued an aggregate of 5,600,000 of common units and pre-funded units at a public offering price of \$1.25 per common unit and \$1.249 per pre-funded unit. As part of the public offering, the Company entered into a securities purchase agreement with certain institutional purchasers. Each common unit consisted of one ordinary share, par value NIS 0.25 per share, and one common warrant to purchase one ordinary share. Each of the 1,546,828 pre-funded unit consisted of one pre-funded warrant to purchase one ordinary share and one common warrant. Additionally, the Company issued warrants to purchase up to 336,000 ordinary shares, with an exercise price of \$1.5625 per share, to representatives of H.C. Wainwright as compensation for its role as the placement agent in the Company's February 2020 offering. During the three months ended March 31, 2020, all pre-funded warrants to purchase ordinary shares were exercised. As of December 31, 2021, a total of 5,571,600 common warrants to purchase ordinary shares were exercised, additionally 230,160 common warrants to purchase ordinary shares were exercised to representatives of H.C. Wainwright.

On July 6, 2020, the Company entered into a purchase agreement with certain institutional investors for the issuance and sale of (i) 4,938,278 ordinary shares, par value NIS 0.25 per share, at a price of \$1.8225 per ordinary share and (ii) warrants to purchase up to 2,469,139 ordinary shares with an exercise price of \$1.76 per share, exercisable from July 6, 2020, until January 6, 2026. Additionally, the Company issued warrants to purchase up to 296,297 ordinary shares, with an exercise price of \$2.2781 per share, exercisable from July 6, 2020, until July 2, 2025, to certain representatives of H.C. Wainwright as compensation for its role as the placement agent in its July 2020 registered direct offering. As of December 31, 2021, a total of 2,020,441 common warrants to purchase ordinary shares were exercised.

On December 3, 2020, the Company entered into a purchase agreement with certain institutional investors for the issuance and sale of (i) 5,579,776 ordinary shares, par value NIS 0.25 per share, at a price of \$1.4337 per ordinary share and (ii) warrants to purchase up to 4,184,832 ordinary shares with an exercise price of \$1.34 per share, exercisable from December 8, 2020, until June 8, 2026. Additionally, the Company issued warrants to purchase up to 334,787 ordinary shares, with an exercise price of \$1.7922 per share, exercisable from December 8, 2020, until June 8, 2026, to certain representatives of H.C. Wainwright as compensation for its role as the placement agent in its December 2020 registered direct offering. As of December 31, 2021, a total of 3,598,072 common warrants to purchase ordinary shares were exercised, additionally 225,981 common warrants to purchase ordinary shares were exercised to representatives of H.C. Wainwright.

On February 19, 2021, the Company entered into a purchase agreement with certain institutional and other accredited investors for the issuance and sale of 10,921,502 ordinary shares, par value NIS 0.25 per share at \$3.6625 per ordinary share and warrants to purchase up to an aggregate of 5,460,751 ordinary shares with an exercise price of \$3.6 per share, exercisable from February 19, 2021, until August 26, 2026. Additionally, the Company issued warrants to purchase up to 655,290 ordinary shares, with an exercise price of \$4.578125 per share, exercisable from February 19, 2021, until August 26, 2026, to certain representatives of H.C. Wainwright as compensation for its role as the placement agent in our February 2021 private placement offering.

On September 27, 2021, the Company signed a purchase agreement with certain institutional investors for the issuance and sale of 15,403,014 ordinary shares, par value NIS 0.25 per share, pre-funded warrants to purchase up to an aggregate of 610,504 ordinary shares and ordinary warrants to purchase up to an aggregate of 8,006,759 ordinary shares at an exercise price of \$2.00 per share. The Pre-Funded Warrants have an exercise price of \$0.001 per Ordinary Share and are immediately exercisable and can be exercised at any time after their original issuance until such pre-funded warrants are exercised in full. Each ordinary shares was sold at an offering price of \$2.035 and each pre-funded warrant was sold at an offering price of \$2.034 (equal to the purchase price per ordinary share minus the exercise price of the pre-funded warrant). The offering of the ordinary shares, the pre-funded warrants and the ordinary shares that are issuable from time to time upon exercise of the pre-funded warrants was made pursuant to the Company's shelf registration statement on Form S-3 initially filed with the Securities and Exchange Commission ("SEC") on May 9, 2019, and declared effective by the SEC on May 23, 2019, and the ordinary warrants were issued in a concurrent private placement. The ordinary warrants are exercisable at any time and from time to time, in whole or in part, following the date of issuance and ending five and one-half years from the date of issuance. All of the pre-funded warrants were exercised in full on September 27, 2021, and the offering closed on September 29, 2021. Additionally, the Company issued warrants to purchase up to 960,811 ordinary shares, with an exercise price of \$2.5438 per share, exercisable from September 27, 2021, until September 27, 2026, to certain representatives of H.C. Wainwright as compensation for its role as the placement agent in our September 2021 registered direct offering.

During the twelve months ended December 31, 2021, we received a total of 9,814,754 outstanding warrants exercises with exercise prices ranging from \$1.25 to \$1.79 were exercised, for total gross proceeds of approximately \$13.8 million.

c. Share option plans:

On March 30, 2012, the Company's board of directors adopted the ReWalk Robotics Ltd. 2012 Equity Incentive Plan.

On August 19, 2014, the Company's board of directors adopted the ReWalk Robotics Ltd. 2014 Incentive Compensation Plan or the "Plan". The Plan provides for the grant of stock options, stock appreciation rights, restricted stock awards, restricted stock units, cash-based awards, other stock-based awards and dividend equivalents to the Company's and its affiliates' respective employees, non-employee directors and consultants.

Starting in 2014, the Company grants to directors and employees also Restricted Stock Units ("RSUs") under this Plan. An RSU award is an agreement to issue shares of the company's ordinary shares at the time the award is vested.

As of December 31, 2021 and 2020, the Company had reserved 233,957 and 604,320 shares of ordinary shares, respectively, available for issuance to employees, directors, officers, and non-employees of the Company.

The options generally vest over four years, with certain options granted to non-employee directors during the fiscal year ended December 31, 2019, vesting over one year.

Any option or RSUs that are forfeited or canceled before expiration becomes available for future grants under the Plan.

A summary of employee and non-employee shares options activity during the fiscal year ended 2021 is as follows:

	Number	Average exercise price	Average remaining contractual life (years)	Aggregate intrinsic value (in thousands)
Options outstanding at the beginning of the year	69,606	\$ 37.9	5.59	\$ —
Granted	—	—	—	—
Exercised	—	—	—	—
Forfeited	(7,774)	34.68	—	—
Options outstanding at the end of the year	61,832	\$ 38.34	4.55	\$ —
Options exercisable at the end of the year	55,747	\$ 41.09	4.30	\$ —

A summary of employee and non-employee RSUs activity during the fiscal year ended 2021 is as follows:

	Number of shares underlying outstanding RSUs	Weighted-average grant date fair value
Unvested RSUs at the beginning of the year	1,251,311	1.69
Granted	721,216	1.69
Vested	(398,164)	1.74
Forfeited	(218,079)	1.50
Unvested RSUs at the end of the year	1,356,284	1.61

The weighted average grant date fair values of options granted during the fiscal year ended December 31, 2019, were \$2.98, there were no options granted during the fiscal year ended December 31, 2021, and 2020. The weighted average grant date fair values of RSUs granted during the fiscal year ended December 31, 2021, 2020 and 2019, were \$1.69, \$1.44 and \$4.67, respectively.

The aggregate intrinsic value in the table above represents the total intrinsic value that would have been received by the option holders had all option holders, which hold options with positive intrinsic value, exercised their options on the last date of the exercise period. During the years ended December 31, 2021, 2020 and 2019, no options were exercised. Total fair value of shares vested during the year ended December 31, 2021, 2020 and 2019 were \$802 thousand, \$676 thousand, and \$1.18 million, respectively. As of December 31, 2021, there were \$1.8 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the 2014 Plan. This cost is expected to be recognized over a period of approximately 2.8 years.

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The number of options and RSUs outstanding as of December 31, 2021 is set forth below, with options separated by range of exercise price:

Range of exercise price	Options and RSUs Outstanding as of December 31, 2021	Weighted average remaining contractual life (years) (1)	Options Exercisable as of December 31, 2021	Weighted average remaining contractual life (years) (1)
RSUs only	1,356,284	—	—	—
\$5.37	12,425	7.24	8,542	7.24
\$20.42- \$33.75	31,155	4.08	28,953	3.91
\$37.14-\$38.75	8,946	1.98	8,946	1.98
\$50-\$52.5	6,731	5.46	6,731	5.46
\$182.5-\$524.25	2,575	3.85	2,575	3.85
	1,418,116	4.55	55,747	4.30

(1) Calculation of weighted average remaining contractual term does not include the RSUs that were granted, which have an indefinite contractual term.

d. Equity compensation issued to consultants:

The Company granted 6,680 fully vested RSUs during the fiscal year ended December 31, 2019, to non-employee consultants. As of December 31, 2021, there are no outstanding options or RSUs held by non-employee consultants.

e. Share-based compensation expense for employees and non-employees:

The Company recognized non-cash share-based compensation expense in the consolidated statements of operations as follows (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Cost of revenues	\$ 10	\$ 8	\$ 13
Research and development, net	55	136	204
Sales and marketing, net	171	163	166
General and administrative	597	442	725
Total	\$ 833	\$ 749	\$ 1,108

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f. Warrants to purchase ordinary shares:

The following table summarizes information about warrants outstanding and exercisable as of December 31, 2021:

Issuance date	Warrants outstanding (number)	Exercise price per warrant	Warrants outstanding and exercisable (number)	Contractual term
December 31, 2015 (1)	4,771	\$ 7.500	4,771	See footnote (1)
December 28, 2016 (2)	1,908	\$ 7.500	1,908	See footnote (1)
November 20, 2018 (3)	126,839	\$ 7.500	126,839	November 20, 2023
November 20, 2018 (4)	106,680	\$ 9.375	106,680	November 15, 2023
February 25, 2019 (5)	45,600	\$ 7.187	45,600	February 21, 2024
April 5, 2019 (6)	408,457	\$ 5.140	408,457	October 7, 2024
April 5, 2019 (7)	49,015	\$ 6.503	49,015	April 3, 2024
June 5, 2019, and June 6, 2019 (8)	1,464,665	\$ 7.500	1,464,665	June 5, 2024
June 5, 2019 (9)	87,880	\$ 9.375	87,880	June 5, 2024
June 12, 2019 (10)	416,667	\$ 6.000	416,667	December 12, 2024
June 10, 2019 (11)	50,000	\$ 7.500	50,000	June 10, 2024
February 10, 2020 (12)	28,400	\$ 1.250	28,400	February 10, 2025
February 10, 2020 (13)	105,840	\$ 1.563	105,840	February 10, 2025
July 6, 2020 (14)	448,698	\$ 1.760	448,698	January 2, 2026
July 6, 2020 (15)	296,297	\$ 2.278	296,297	January 2, 2026
December 8, 2020 (16)	586,760	\$ 1.340	586,760	June 8, 2026
December 8, 2020 (17)	108,806	\$ 1.792	108,806	June 8, 2026
February 26, 2021 (18)	5,460,751	\$ 3.600	5,460,751	August 26, 2026
February 26, 2021 (19)	655,290	\$ 4.578	655,290	August 26, 2026
September 29, 2021 (20)	8,006,759	\$ 2.000	8,006,759	March 29, 2027
September 29, 2021 (21)	960,811	\$ 2.544	960,811	September 27, 2026
	<u>19,420,894</u>		<u>19,420,894</u>	

- (1) Represents warrants for ordinary shares issuable upon an exercise price of \$7.500 per share, which were granted on December 31, 2015 to Kreos Capital V (Expert) Fund Limited ("Kreos") in connection with a loan made by Kreos to the Company and are currently exercisable (in whole or in part) until the earlier of (i) December 30, 2025 or (ii) immediately prior to the consummation of a merger, consolidation, or reorganization of the Company with or into, or the sale or license of all or substantially all the assets or shares of the Company to, any other entity or person, other than a wholly owned subsidiary of the Company, excluding any transaction in which the Company's shareholders prior to the transaction will hold more than 50% of the voting and economic rights of the surviving entity after the transaction. None of these warrants had been exercised as of December 31, 2021.
- (2) Represents common warrants that were issued as part of the \$8.0 million drawdown under the Loan Agreement which occurred on December 28, 2016. See footnote 1 for exercisability terms.
- (3) Represents common warrants that were issued as part of the Company's follow-on public offering in November 2018.
- (4) Represents common warrants that were issued to the underwriters as compensation for their role in the Company's follow-on public offering in November 2018.
- (5) Represents warrants that were issued to the exclusive placement agent as compensation for its role in the Company's follow-on public offering in February 2019.

- (6) Represents warrants that were issued to certain institutional purchasers in a private placement in the Company's registered direct offering of ordinary shares in April 2019.
- (7) Represents warrants that were issued to the placement agent as compensation for its role in the Company's April 2019 registered direct offering.
- (8) Represents warrants that were issued to certain institutional investors in a warrant exercise agreement on June 5, 2019, and June 6, 2019, respectively.
- (9) Represents warrants that were issued to the placement agent as compensation for its role in the Company's June 2019 warrant exercise agreement and concurrent private placement of warrants.
- (10) Represents warrants that were issued to certain institutional investors in a warrant exercise agreement in June 2019.
- (11) Represents warrants that were issued to the placement agent as compensation for its role in the Company's June 2019 registered direct offering and concurrent private placement of warrants.
- (12) Represents warrants that were issued to certain institutional purchasers in a private placement in the Company's best efforts offering of ordinary shares in February 2020. During the year ended December 31, 2021, 3,740,100 warrants were exercised for total consideration of \$4,675,125.
- (13) Represents warrants that were issued to the placement agent as compensation for its role in the Company's February 2020 best efforts offering. During the year ended December 31, 2021, 230,160 warrants were exercised for total consideration of \$359,625.
- (14) Represents warrants that were issued to certain institutional purchasers in a private placement in our registered direct offering of ordinary shares in July 2020. During the year ended December 31, 2021, 2,020,441 warrants were exercised for total consideration of \$3,555,976.
- (15) Represents warrants that were issued to the placement agent as compensation for its role in the Company's July 2020 registered direct offering.
- (16) Represents warrants that were issued to certain institutional purchasers in a private placement in our private placement offering of ordinary shares in December 2020. During the year ended December 31, 2021, 3,598,072 warrants were exercised for total consideration of \$4,821,416.
- (17) Represents warrants that were issued to the placement agent as compensation for its role in the Company's December 2020 private placement. During the year ended December 31, 2021, 225,981 warrants were exercised for total consideration of \$405,003.
- (18) Represents warrants that were issued to certain institutional purchasers in a private placement in our private placement offering of ordinary shares in February 2021.
- (19) Represents warrants that were issued to the placement agent as compensation for its role in the Company's February 2021 private placement.
- (20) Represents warrants that were issued to certain institutional purchasers in a private placement in our registered direct offering of ordinary shares in September 2021.
- (21) Represents warrants that were issued to the placement agent as compensation for its role in the Company's September 2021 registered direct offering.



**NOTE 9:- RESEARCH COLLABORATION AGREEMENT AND LICENSE AGREEMENT**

On May 16, 2016, the Company entered into a Research Collaboration Agreement (“Collaboration Agreement”) and an Exclusive License Agreement (“License Agreement”) with Harvard. The Research Collaboration Agreement was amended on May 1, 2017, and April 1, 2018 (as amended, the “Collaboration Agreement”), and the Exclusive License Agreement was amended on April 1, 2018 (as amended, the “License Agreement”), to extend the term of the Collaboration Agreement by one year to May 16, 2022 and reallocate the Company’s quarterly installment payments to Harvard through such date, and to make certain technical changes. On April 30, 2020, the Company and Harvard amended the Collaboration Agreement, which included certain adjustments to the quarterly installments and extended the term an additional three quarters until February 2023.

On October 14, 2021, the Company and Harvard further amended the Collaboration Agreement, to make certain adjustments to the quarterly installments and technical changes and establish that the term of the Collaboration Agreement will conclude on March 31, 2022. The Company and Harvard might consider new arrangement to support our research efforts in the future.

Under the Collaboration Agreement, Harvard and the Company have agreed to collaborate on research regarding the development of lightweight “soft suit” exoskeleton system technologies for lower limb disabilities, which are intended to treat stroke, multiple sclerosis, mobility limitations for the elderly and other medical applications. The Company has committed to pay in quarterly installments for the funding of this research.

Under the License Agreement, Harvard has granted the Company an exclusive, worldwide royalty-bearing license under certain patents of Harvard relating to lightweight “soft suit” exoskeleton system technologies for lower limb disabilities, a royalty-free license under certain related know-how and the option to obtain a license under certain inventions conceived under the joint research collaboration.

The License Agreement required the Company to pay Harvard an upfront fee, reimbursements for expenses that Harvard incurred in connection with the licensed patents, royalties on net sales and several milestone payments contingent upon the achievement of certain product development and commercialization milestones. The Harvard License Agreement will continue in full force and effect until the expiration of the last-to-expire valid claim of the licensed patents. As of December 31, 2021, the Company achieved three of the milestones which represent all development milestones under the License Agreement. The Company continues to evaluate the likelihood that the other milestones will be achieved on a quarterly basis.

The Company has recorded expenses in the amount of \$293 thousand, \$762 thousand, and \$1.6 million for the years ended December 31, 2021, 2020, and 2019, respectively, as research and development expenses related to the Harvard License Agreement and to the Collaboration Agreement. No withholding tax was deducted from the Company’s payments to Harvard in respect of the Collaboration Agreement and License Agreement since this is not taxable income in Israel in accordance with Section 170 of the Israel Income Tax Ordinance 1961-5721.

**NOTE 10: - PAYCHECK PROTECTION PROGRAM LOAN**

On April 21, 2020, RRI received an unsecured loan in the principal amount of \$392 thousand under the Paycheck Protection Program (the “PPP”) administered by the U.S. Small Business Administration, or the SBA, pursuant to the Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”), or the PPP loan. The terms of the PPP Loan were subsequently revised in accordance with the provisions of the Paycheck Protection Flexibility Act of 2020, or the PPP Flexibility Act, which was enacted on June 5, 2020. The PPP loan provides for an interest rate of 1.00% per year and matures two years after the date of initial disbursement, with initial principal and interest payments coming due late in fiscal 2021. The PPP loan may be used for payroll costs, costs related to certain group health care benefits and insurance premiums, rent payments, utility payments, mortgage interest payments and interest payments on any other debt obligation that were incurred before February 15, 2020. Under the terms of the CARES Act and the PPP Flexibility Act, the Company may apply for and be granted forgiveness for all or a portion of loan granted under the PPP loan, with such forgiveness to be determined, subject to limitations (including where employees of the Company have been terminated and not re-hired by a certain date), based on the use of the loan proceeds for payment of payroll costs and any payments of mortgage interest, rent, and utilities. The terms of any forgiveness may also be subject to further requirements in regulations and guidelines adopted by the SBA.

On September 29, 2020, the Company applied for loan forgiveness and on November 6, 2020, the Company received confirmation of its PPP Note forgiveness.

Forgiveness is booked as other income within the marketing and sales expenses because it was granted and used for payroll, rent, and utility costs related to sales efforts.

**NOTE 11: - INCOME TAXES**

The Company’s subsidiaries are separately taxed under the domestic tax laws of the jurisdiction of incorporation of each entity.

## a. Corporate tax rates in Israel:

Presented hereunder are the tax rates relevant to the Company in the years 2019-2021:

The Israeli statutory corporate tax rate and real capital gains were 23% in the years 2019-2021.

## b. Income (loss) before taxes on income is comprised as follows (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Domestic	\$ (12,780)	\$ (12,992)	\$ (15,599)
Foreign	138	67	55
	<u>\$ (12,642)</u>	<u>\$ (12,925)</u>	<u>\$ (15,544)</u>

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## c. Taxes on income are comprised as follows (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Current	\$ 123	\$ 95	\$ 64
Deferred	(29)	(44)	(57)
	<u>\$ 94</u>	<u>\$ 51</u>	<u>\$ 7</u>

	Year Ended December 31,		
	2021	2020	2019
Domestic	\$ —	\$ —	\$ —
Foreign	94	51	7
	<u>\$ 94</u>	<u>\$ 51</u>	<u>\$ 7</u>

## d. Deferred income taxes (in thousands):

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The Company’s deferred tax assets as of December 31, 2021 and 2020 are derived from temporary differences.

In assessing the realization of deferred tax assets, the Company considers whether it is more likely than not that all or some portion of the deferred tax assets will not be realized. Based on the Company’s history of losses, the Company established a full valuation allowance for RRL.

Undistributed earnings of certain subsidiaries as of December 31, 2021 were immaterial. The Company intends to reinvest these earnings indefinitely in the foreign subsidiaries. As a result, the Company has not provided for any deferred income taxes.

	December 31,	
	2021	2020
Deferred tax assets:		
Carry forward tax losses	\$ 47,323	\$ 41,941
Research and development carry forward expenses-temporary differences	718	946
Accrual and reserves	373	341
Lease liabilities	261	390
Total deferred tax assets	<u>48,675</u>	<u>43,618</u>
Deferred tax liabilities:		
Right-of-use asset	(261)	(390)
Net deferred tax assets	<u>48,414</u>	<u>43,228</u>
Valuation allowance	<u>(48,098)</u>	<u>(42,941)</u>
Net deferred tax assets	<u>\$ 316</u>	<u>\$ 287</u>

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The net changes in the total valuation allowance for each of the years ended December 31, 2021, 2020 and 2019, are comprised as follows (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Balance at beginning of year	\$ (42,941)	\$ (36,392)	\$ (29,655)
Changes due to exchange rate differences	(1,488)	(2,929)	(2,055)
Adjustment previous year loss	—	—	(735)

Additions during the year	(3,669)	(3,620)	(3,947)
Balance at end of year	<u>\$ (48,098)</u>	<u>\$ (42,941)</u>	<u>\$ (36,392)</u>

e. Reconciliation of the theoretical tax expenses:

A reconciliation between the theoretical tax expense, assuming all income is taxed at the statutory tax rate applicable to income of the Company, and the actual tax expense (benefit) as reported in the consolidated statements of operations is as follows (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Loss before taxes, as reported in the consolidated statements of operations	<u>\$ (12,642)</u>	<u>\$ (12,925)</u>	<u>\$ (15,544)</u>
Statutory tax rate	<u>23.0%</u>	<u>23.0%</u>	<u>23.0%</u>
Theoretical tax benefits on the above amount at the Israeli statutory tax rate	\$ (2,908)	\$ (2,973)	\$ (3,575)
Income tax at rate other than the Israeli statutory tax rate	7	3	(1)
Non-deductible expenses including equity-based compensation expenses and other	102	185	255
Operating losses and other temporary differences for which valuation allowance was provided	3,669	3,620	3,947
Permanent differences	(784)	(706)	(651)
Other	<u>8</u>	<u>(78)</u>	<u>32</u>
Actual tax expense	<u>\$ 94</u>	<u>\$ 51</u>	<u>\$ 7</u>

f. Foreign tax rates:

Taxable income of RRI was subject to tax at the rate of 21% in 2021, 2020 and 2019.

Taxable income of RRG was subject to tax at the rate of 30% in 2021, 2020, and 2019.

g. Tax benefits under the Law for the Encouragement of Capital Investments, 1959 (the "Investment Law"):

Conditions for entitlement to the benefits:

Under the Investment Law, in 2012 the Company elected "Beneficiary Enterprise" status which provides certain benefits, including tax exemptions and reduced tax rates. Income not eligible for Beneficiary Enterprise benefits is taxed at a regular rate.

Income derived from Beneficiary Enterprise from productive activity will be exempt from tax for ten years from the year in which the Company first has taxable income, providing that 12 years have not passed from the beginning of the year of election. In the event of a dividend distribution from income that is exempt from company tax, as aforementioned, the Company will be required to pay tax of 10%-25% on that income.

In the event of distribution of dividends from the said tax-exempt income, the amount distributed will be subject to corporate tax at the rate ordinarily applicable to the Beneficiary Enterprise's income. Tax-exempt income generated under the Company's "Beneficiary Enterprise" program will be subject to taxes upon dividend distribution or complete liquidation.

The entitlement to the above benefits is conditional upon the Company's fulfilling the conditions stipulated by the Law and regulations published thereunder.

On December 29, 2010, the Knesset approved an additional amendment to the Law for the Encouragement of Capital Investments, 1959. According to the amendment, a reduced uniform corporate tax rate for exporting industrial enterprises (over 25%) was established. The reduced tax rate will not be program dependent and will apply to the industrial enterprise's entire income. The tax rates for industrial enterprises have been reduced. In August 2013, the Israeli Knesset approved an amendment to the Investment Law, pursuant to which the rates for development area A will be 9% and for the rest of the country- 16% in 2014 and thereafter. The Amendment also prescribes that any dividends distributed to individuals or foreign residents from a preferred enterprise's earnings as above will be subject to taxes at a rate of 20% (subject to tax treaty benefits)

In December 2016, the Economic Efficiency Law (Legislative Amendments for Applying the Economic Policy for the 2017 and 2018 Budget Years), 2016 which includes Amendment 73 to the Law for the Encouragement of Capital Investments ("the Amendment") was published. According to the Amendment, a preferred enterprise located in development area A will be subject to a tax rate of 7.5% instead of 9% effective from January 1, 2017 (and thereafter the tax rate applicable to preferred enterprises located in other areas remains at 16%).

The Company has examined the effect of the adoption of the Amendment on its financial statements, and as of the date of the publication of the financial statements, the Company estimates that it will not apply the Amendment. The Company's estimate may change in the future.

h. Tax assessments:

RRL has had final tax assessments up to and including the 2016 tax year.

Each RRI and RRG have not had a final tax assessment since its inception.

i. Net operating carry-forward losses for tax purposes:

As of December 31, 2021, RRL has carry-forward losses amounting to approximately \$205.8 million, which can be carried forward for an indefinite period, and RRI has carry-forward losses amounting to approximately \$74 thousands, which can be carried forward for a period of 20 years.

**NOTE 12: - FINANCIAL EXPENSES (INCOME), NET**

The components of financial expenses (income), net were as follows (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Foreign currency transactions and other	\$ (38)	\$ (9)	\$ (34)
Financial expenses related to loan agreement with Kreos	—	907	1,499
Bank commissions	25	23	31
	<u>\$ (13)</u>	<u>\$ 921</u>	<u>\$ 1,496</u>

**NOTE 13: - GEOGRAPHIC INFORMATION AND MAJOR CUSTOMER AND PRODUCT DATA**

Summary information about geographic areas:

ASC 280, "Segment Reporting" establishes standards for reporting information about operating segments. Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker in deciding how to allocate resources and in assessing performance. The Company manages its business on the basis of one reportable segment and derives revenues from selling systems and services (see Note 1 for a brief description of the Company's business). The following is a summary of revenues within geographic areas (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Revenues based on customer's location:			
Israel	\$ —	\$ —	\$ 2
United States	2,519	1,746	2,003
Europe	3,381	2,631	2,832
Asia-Pacific	60	8	36
Latin America	—	6	—
Africa	6	2	—
Total revenues	<u>\$ 5,966</u>	<u>\$ 4,393</u>	<u>\$ 4,873</u>
	December 31,		
	2021	2020	
Long-lived assets by geographic region:			
Israel	\$ 629	\$ 953	
United States	493	790	
Germany	43	43	
	<u>\$ 1,165</u>	<u>\$ 1,786</u>	

(\*) Long-lived assets are comprised of property and equipment, net, and operating lease right-of-use assets.

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Major customers data as a percentage of total revenues:

	Year Ended December 31,		
	2021	2020	2019
Customer A	11.0%	*)	*)
Customer B	*)	10.0%	15.0%

\*) Less than 10%

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