

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, 2022

or

TRANSITION REPORT PURSUANT OR 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 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.

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).

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

Yes No

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, 2022 (the last business day of the Registrant's most recently completed second fiscal quarter) was \$58,466,801.

As of February 23, 2023, the Registrant had outstanding 59,480,132 Ordinary Shares, par value NIS 0.25 per share.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of our proxy statement for our 2023 Annual Meeting of Shareholders, which is to be filed within 120 days after the end of our 2022 fiscal year, are incorporated by reference into Part III of this annual report on Form 10-K.

REWALK ROBOTICS LTD.
FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2022
TABLE OF CONTENTS

	Page No
PART I	
<u>ITEM 1. BUSINESS</u>	1
<u>ITEM 1A. RISK FACTORS</u>	21
<u>ITEM 1B. UNRESOLVED STAFF COMMENTS</u>	52
<u>ITEM 2. PROPERTIES</u>	52
<u>ITEM 3. LEGAL PROCEEDINGS</u>	52
<u>ITEM 4. MINE SAFETY DISCLOSURES</u>	52
PART II	
<u>ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES</u>	53
<u>ITEM 6. SELECTED FINANCIAL DATA</u>	55
<u>ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	55
<u>ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	68
<u>ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA</u>	69
<u>ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u>	69
<u>ITEM 9A. CONTROLS AND PROCEDURES</u>	69
<u>ITEM 9B. OTHER INFORMATION</u>	70
PART III	
<u>ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE</u>	71
<u>ITEM 11. EXECUTIVE COMPENSATION</u>	71
<u>ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</u>	72
<u>ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE</u>	72
<u>ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES</u>	72
PART IV	
<u>ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES</u>	73
<u>ITEM 16. FORM 10-K SUMMARY</u>	76
<u>SIGNATURES</u>	77
<u>POWER OF ATTORNEY</u>	78
<u>INDEX TO CONSOLIDATED FINANCIAL STATEMENTS</u>	F-1

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 regain and maintain compliance with the continued requirements of the Nasdaq Capital Market and the risk that our ordinary shares will be delisted if we fail to regain compliance with such requirements;
- the adverse impact that the COVID-19 pandemic has had, and other pandemics may in the future 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, including the extent to which inflation or global instability may disrupt our business operations or our financial condition or the financial condition of our customers and suppliers; 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. 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 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.

ITEM 1. BUSINESS

Overview

We are a medical device company that is designing, developing, and commercializing innovative technologies that enable mobility and wellness in rehabilitation and daily life for individuals with neurological conditions. Our initial product offerings were the ReWalk Personal and ReWalk Rehabilitation Exoskeleton devices for individuals with spinal cord injury (“SCI Products”). These devices are robotic exoskeletons that are designed for individuals with paraplegia that use our patented tilt-sensor technology and an onboard computer and motion sensors to drive motorized legs that power movement. These SCI Products allow individuals with spinal cord injury the ability to stand and walk again during everyday activities at home or in the community.

We have sought to expand our product offerings beyond the SCI Products through internal development and distribution agreements. We have developed our ReStore Exo-Suit device, which we began commercializing in June 2019. The ReStore is a powered, lightweight soft exo-suit intended for use during the rehabilitation of individuals with lower limb disabilities 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 MYOLYN MyoCycle FES Pro cycles to U.S. rehabilitation clinics and for the MyoCycle Home cycles available to US veterans through the U.S. Department of Veterans Affairs (“VA”) hospitals. In the second quarter of 2020, we also became the exclusive distributor of the MediTouch Tutor movement biofeedback systems in the United States; however, due to unsatisfactory sales performance of the MediTouch product lines, we terminated this agreement as of January 31, 2023. We refer to the MediTouch and MyoCycle devices as our “Distributed Products.” We will continue to evaluate other products for distribution or acquisition that can broaden our product offerings further to help individuals with neurological injury and disability.

We are in the research stage of ReBoot, a personal soft exo-suit for home and community use by individuals post-stroke, and we are currently evaluating the reimbursement landscape and the potential clinical impact of this device. This product would be a complementary product to ReStore as it provides active assistance to the ankle during plantar flexion and dorsiflexion for gait and mobility improvement in the home environment, and it received Breakthrough Device Designation from the U.S. Food and Drug Administration (“FDA”) in November 2021. Further investment in the development path of the ReBoot has been temporarily paused in 2023 pending further determination about the clinical and commercial opportunity of this device.

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 revenue 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 exoskeleton technologies such as the ReWalk Personal Exoskeleton, 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 updates with the Centers for Medicare and Medicaid Services (“CMS”), to clarify the Medicare coverage category (i.e., benefit category) applicable for personal exoskeletons. In 2021, the National Spinal Cord Injury Statistical Center (“NSCISC”) reported the Medicare and Medicaid are the primary payors for approximately 56% 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 Exoskeleton (effective October 1, 2020), which may be used for purposes of claim submission to Medicare, Medicaid, and other payors. We are currently seeking a nationwide Medicare benefit category determination from CMS to designate the relevant Medicare benefit category. CMS has stated that, until a nationwide benefit category determination is issued, coverage and payment can be adjudicated on a case-by-case basis by the Medicare Administrative contractors (“MACs”).

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 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 Exoskeleton 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.

COVID-19 Pandemic Impact

The impact of the COVID-19 pandemic resulted in significant disruptions to the global economy and the capital markets, as well as our business. A significant number of our global suppliers, vendors, distributors, and manufacturing facilities are located in regions that were affected by the pandemic. Those operations were materially adversely affected by restrictive government and private enterprise measures implemented in response to the pandemic, which in turn, negatively impacted our operations.

Shut-downs and other limitations imposed in response to the COVID-19 pandemic adversely affected our ability to identify potential new customers through trade shows and events, engage with our existing customers, conduct product trials with prospective users, deliver ordered units or repair existing systems and provide training for our products to new patients, who largely remained at home during local movement restrictions, and to rehabilitation centers, which temporarily shifted priorities and responses to pandemic-related medical equipment. In addition, staffing shortages within the healthcare system itself resulted in a diminished demand for our SCI Products as the attention of healthcare workers and potential patients turned elsewhere. Some clinics, such as VA clinics, and many other healthcare facilities, enforced in-clinic restrictions, which affected our ability to demonstrate our devices to patients or start training for qualified potential customers.

Although these restrictions have now mostly been lifted, allowing us to restart market development and access programs, we have not seen a full return to pre-pandemic levels, and we believe that our business will continue to be adversely impacted by the effects of the pandemic-related restrictions and shut-downs.

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 6.0 Exoskeleton is a novel product that seeks to fundamentally change the health and life experiences of users. Designed for daily 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 user controls the device movement using a combination of user inputs on the wrist-worn controller, as well as through subtle weight shifts of the upper body. Because the exoskeleton supports its own weight and facilitates the user's gait, users do not expend unnecessary energy while walking. The ReWalk Personal Exoskeleton also allows users to sit, stand and depending on local regulatory approvals, climb and descend stairs and curbs. This stair ascend/descend function is currently under review by the FDA in the United States.

- *ReWalk Personal 6.0:* intended for everyday use at home, at work or in the community with a trained companion. We began marketing ReWalk Personal Exoskeleton 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 6th generation device.
- *ReWalk Rehabilitation:* the current offering for clinics who wish to implement exoskeleton training is composed of our Personal 6.0 unit along with multiple sizing of different parts, enabling multiple patient use. ReWalk Rehabilitation provides a valuable means of exercise and therapy. It also enables individuals to evaluate their capacity for using ReWalk Personal in the future. We began marketing a unique design for use in hospitals, rehabilitation centers and stand-alone training centers in the United States and Europe in 2011 and, as of December 2020, we have eliminated the need for a unique design for the rehabilitation units and instead shifted to offering a sizing and accessory kit that adapts the Personal 6.0 base unit to enable fitting across multiple users in a clinic setting.

ReWalk Personal 6.0



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."

Spinal Cord Injury

The spine is the central core of the human skeleton and provides structural support, alignment, and flexibility to the body. The spinal cord, housed inside the bones of the spinal column, is a complex bundle of nerves serving as the main pathway for information connecting the brain, and nervous system. Spinal cord injury is a serious medical condition that occurs as a result of physical damage to the nerves of the spinal cord, resulting 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.

Market Opportunity

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 the 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 who are veterans and are eligible for medical care and other benefits from the VA, out of which the VA states that 27,000 veterans are receiving SCI treatment annually. With 25 VA spinal cord injury centers designated SCI/D Hub locations, 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 2021 report by the NSCISC, 40% 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 Exoskeleton 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 exo-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 also include marketing of our ReWalk Personal Exoskeleton with patients, physicians, and physical therapists as a medically necessary intervention that can be used to enable a home-based functional ambulation regimen that elevates the health and wellness of individuals living with SCI.

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

As of December 31, 2022, we had placed 128 ReWalk Rehabilitation units in use at rehabilitation centers and 572 ReWalk Personal units in a home or community use, compared to 121 ReWalk Rehabilitation units and 533 ReWalk Personal units as of December 31, 2021. 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.

United States

In the U.S., individuals typically obtain a ReWalk Personal Exoskeleton for home use through third-party medical coverage. For an individual who suffered an SCI through a work-related incident, workers' compensation insurance can be a source of funding to purchase the device. Similarly, for U.S. veterans, an individual may be covered by the VA for the purchase of the device regardless of whether the SCI occurred during active military service.

In December 2014, the VA issued a national policy or standard operating procedure (SOP) for the evaluation, training, and procurement of ReWalk Personal exoskeleton systems for all qualifying veterans across the United States and U.S. Territories. The VA SOP is the first national coverage policy in the United States for qualifying individuals who have suffered spinal cord injury. In June 2018, the VA updated the SOP, in part, to expand training options for individuals who could not complete the mandatory training due to excessive distance/drive times from a VA-designated site. As of December 31, 2022, we had placed 34 units as part of the VA policy. The VA accounted for 14% of our total revenue for the year ended December 31, 2022.

We continue to work with the VA to both accelerate the pace of implementation of the current VA policy nationally, and to again expand opportunities for veterans to gain access to assessments, training, and devices in facilities outside VA's traditional spinal cord injury "hub and spoke" infrastructure. Community-based, non-VA clinics are also being leveraged to allow veterans to be trained in communities closer to their homes, while still being reimbursed by the VA as part of the VA's Community Care Network program.

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, 2022, we had 13 cases pending in the United States for insurance coverage decisions.

According to the NSCISC report, approximately 56% of the spinal cord injury population received primary coverage from Medicare and Medicaid within five years after their injury date, with Medicare representing the larger primary payor.

In order to be covered and reimbursed by Medicare, the ReWalk Personal Exoskeleton 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 nationwide 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 Exoskeleton and, in July 2020, a unique code was issued for ReWalk Personal Exoskeleton (effective October 1, 2020). With the issuance of a unique code, we are currently seeking clarity from CMS as to the applicable Medicare benefit category. The Medicare benefit category determination by CMS is a significant factor affecting the coverage and payment level for a product. If CMS determines that no Medicare benefit category is available, this results in the product not being covered by Medicare. While we believe that a determination from CMS as to the applicable Medicare benefit category for the ReWalk Personal Exoskeleton may result in greater access to our exoskeletons by SCI patients, 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 reimbursements 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.

In June 2022, ReWalk Robotics presented our request for CMS to issue a nationwide Medicare benefit category determination for the ReWalk Personal exoskeleton system as part of CMS's Bi-Annual Healthcare Common Procedural Coding System ("HCPCS") Public Meeting. In September 2022, CMS issued a statement that it intends to provide more information on the topic of the benefit category for personal exoskeletons in the near future and re-affirmed that, in the meantime, coverage and payment decisions can be adjudicated by the MACs on a case-by-case basis. ReWalk is continuing to work with CMS and the Durable Medical Equipment Prosthetics/Orthotics & Supplies ("DMEPOS") MACs to pursue both a nationwide benefit category determination from CMS and prompt and appropriated case-by-case adjudication of coverage while a nationwide benefit determination is pending.

For more information about coverage and reimbursement risk factors, see "Part I, Item 1A. Risk Factors—Risks Related to our Business and our Industry."

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 Exoskeleton.

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 workers' compensation payors. Specifically:

- In September 2017, the German insurer BARMER confirmed it will provide ReWalk systems to all qualifying beneficiaries. BARMER provides 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 payors, 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 Exoskeleton 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 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 chose 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 Exoskeleton to eligible persons in Germany.
- In June 2020, BARMER 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. BARMER initially appealed this ruling with the Federal Social Court (*Bundessozialgericht*), but later, in November 2022, withdrew its pending case and accepted the prior ruling from the state court that exoskeletons are considered as a direct disability compensation. This outcome means that an eligible insured person with spinal cord injury (SCI) in Germany has a legal basis for the supply of an exoskeleton as an orthopedic aid for direct disability compensation. Patients in Germany 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 Exoskeleton for their beneficiaries within their system.

As of December 31, 2022, there were 47 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 revenue that is 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 and 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, provides 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.

Other Funding Sources

In addition to being funded by third-party payors, including private insurance plans, government programs such as the VA, and workers' compensation plans, 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 that 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 provides targeted mechanical assistance to the patient's 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 enabling the therapist to specifically target and train for improved propulsion symmetry, which is a key contributor to improved walking speed and efficiency for patients recovering from stroke.

Published clinical trials using the soft exo-suit design on stroke patients have shown varying levels of improvements, with the main ones being improved walking speed, improved propulsion symmetry, reductions in compensatory behaviors including paretic hip hiking and circumduction as well as reduction in metabolic burden associated with post stroke walking. There are additional studies ongoing with the ReStore device that examine the improvement in walking speed following training with the soft exo-suit as well as comparing the results of traditional training with soft exo-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 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 to accelerate product penetration after receiving FDA and CE clearance. These efforts were adversely impacted by the COVID-19 pandemic, as clinics and hospitals shifted resources and attention during the pandemic. While we have seen some recovery as the COVID-19 pandemic has abated, we are still experiencing adverse impacts from these resource shifts. Geographically, we see our commercial priorities for the ReStore device as being 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 approximately 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 exosuit has an opportunity to be adopted by clinics for use in therapy of their stroke patients. 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 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, 2022, and December 31, 2021, we had placed 33 and 30 ReStore units, respectively.

ReBoot

We are also in the research stage of ReBoot, a soft exoskeleton for stroke home and community use, and are currently evaluating the reimbursement landscape and the potential clinical impact of this device. This product would be a complementary product to ReStore, and it received Breakthrough Device Designation from the FDA in November 2021. The ReBoot is a lightweight, battery-powered exosuit 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 approximately 400,000 annual stroke patients who require walking assistance after being discharged home. Further investment in the development path of the ReBoot has been temporarily paused in 2023 pending further determination about the clinical and commercial opportunity of this device.

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 several 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: EKSO), Rex Bionics Pty, Cyberdyne (Tokyo Stock Exchange: 7779), FREE Bionics, DIH (formerly known as Hocoma), AlterG, Wandercraft, and Bioness (acquired by Bioventus (NASDAQ: BVS). Parker Hannifin (NYSE: PH) was a prior competitor but exited the exoskeleton market in December 2022 with its divestiture of its Human Motion and Control business unit, which includes the Indego lower limb exoskeleton line of products, to Ekso Bionics. The competitors' products may also compete with the ReStore soft 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, Aretch 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 neurorehabilitation conferences and professional organizations 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 are working on product design improvements and expanded labeling for the ReWalk Personal 6.0 product which we plan to launch following regulatory approvals. In the longer term we are conducting research for our next generation device with design improvements and advanced robotic technologies as part of the Human Robot Interaction Consortium research program. 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, 2022, we received funding totaling \$2.3 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 April 1, 2022, we entered a research and development cooperation agreement with several companies and universities in the Human Robot Interaction (HRI) Consortium, part of the Israel Innovation Authority's MAGNET incentive program. This incentive program provides grants for R&D collaboration as part of a consortium comprised of private businesses and leading academic centers. The goals of the HRI consortium are to "develop advanced technologies aimed at providing robots with social capabilities, enabling them to carry out various tasks and effective interactions with different users in diverse operational environments." The total program has a budget of NIS 57 million, which includes funding for research and development grants to help drive technological innovation. The Consortium is a 3-year program which has allocated NIS 1.745 million to fund ReWalk-specific projects over the first 18-month period of the program. As a member of the HRI Consortium, we collaborate with several universities to develop advanced technologies aimed at improving the human-exoskeleton interaction. This research collaboration with top researchers in the fields of robotics, behavioral sciences and human-computer interaction will seek to make the use of exoskeletons easier and more natural to promote wider adoption of the technology.

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 paid Harvard quarterly installment payments to help fund the research. Subject to the terms of the Collaboration Agreement, we and Harvard were required to report our respective research results and findings to each other on a regular basis. The Collaboration Agreement governed ownership of the research results and inventions generated in performance of the research collaboration and provided 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 concluded on March 31, 2022.

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 Harvard License Agreement contains, 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, 2022.

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, 2022, we have 12 issued patents in the United States and 19 issued patents outside of the United States, as well as 11 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 will expire in April of 2023 due to patent term adjustment (PTA) of 689 days for delays in examination by the United States Patent and Trademark Office.

We currently hold a registered trademark in the United States, Europe, Israel, and 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 classification 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 in order to market or commercially distribute those devices. To obtain 510(k) clearance, a substantial equivalence determination for their devices, manufacturers must submit to the FDA a premarket notification 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, (iii) a device that was found substantially equivalent through the 510(k) process or (iv) a device that was granted marketing authorization through the de novo classification process under section 513(f)(2) of the FDCA. 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" classification 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 FDCA to complete its review of a PMA, although in practice, the FDA's review often takes significantly longer, and can take one year or even longer.

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 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, and classified ReWalk as a Class II powered exoskeleton device 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 classification order for all powered exoskeleton devices include the following: clinical testing to demonstrate safe and effective use considering the level of supervision necessary and the use environment; non-clinical safety and 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 powered exoskeleton 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 for powered exoskeletons as described above. In order for us to market ReStore and ReWalk, we must comply with both these special controls as well as general controls, including controls related to quality, facility registration, reporting of adverse events and labeling. Failure to comply with the general and special controls could lead to removal of ReStore or ReWalk from the market, which would have a material adverse effect on our business.

In June 2022, ReWalk submitted a 510(k) premarket notification for ReWalk Personal 6.0 seeking to enable the stairs functionality and add uses on stairs and curbs to the indication for use for the device in the US. FDA issued a request for additional information, to which ReWalk responded and is pending FDA review.

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.”

Post-market Regulatory Requirements

After a device is cleared for 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 submitted a 510(k) amendment to our original submission to reflect the findings of the study. FDA acknowledged and closed the amendment in May 2022.

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 June 2024), 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. A person or entity may be found to violate the anti-kickback statute even absent actual knowledge of this statute or specific intent to violate it. In addition, 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 federal False Claims Act ("FCA").

The civil 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, FCA lawsuits against biopharmaceutical and device 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 statute under which medical device companies may potentially be subject to enforcement. Among other things, the civil monetary penalties statute imposes fines against any person who offers to provide remuneration to any individual eligible for benefits under Medicare or Medicaid that the offerer knows or should know is likely to influence the individual to order or receive from a particular provider or supplier of any item or service reimbursable under those programs.

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 Physician Payments Sunshine Act (“Sunshine Act”) requires annual reporting, by applicable device and drug manufacturers, of covered products, payments and other transfers of value to certain health care providers, and ownership and investment interests held by physicians and their immediate family members.

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, 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 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 revenue 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 ACA, substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The ACA 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 ACA has been subject to challenges in the courts. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA 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, but did not invalidate the entire law, and remanded the case to the Texas District Court to reconsider its earlier invalidation of the entire ACA. An appeal was taken to the U.S. Supreme Court, which ruled on June 17, 2021, 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 ACA. 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 ACA remain possible, although President Biden indicated that he intends to use executive orders to undo changes to the ACA made by the Trump administration and would advocate for legislation to build on the ACA. 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 ACA or 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 materials 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 increases. 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, 2022, we had 56 employees (including full-time and hourly employees), of whom 24 were located in the United States, 17 were located in Israel and 15 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 revenue for each of the years ended December 31, 2022, and 2021 (in thousands):

	Year Ended December 31,	
	2022	2021
Revenue based on customer's location:		
Israel	\$ 32	\$ —
United States	2,303	2,519
Europe	3,057	3,381
Asia-Pacific	115	60
Africa	4	6
Total revenue	<u>\$ 5,511</u>	<u>\$ 5,966</u>

Additional discussion of financial information by reportable segment and geographic area and sales in excess of 10% of total revenue 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

- Revenue for the fourth quarter of 2022 was \$2.2 million, compared to \$1.2 million in the fourth quarter of 2021, an increase of 75%;
- ReWalk submitted first case for Medicare coverage through the Medicare Administrative Contractors (“MACs”) in Q4’22;
- ReWalk advanced its commercial readiness and finalized plans for expanded Medicare patient access following the satisfactory resolution of the first submitted claim;
- Since the initiation of share repurchase program in Q3’22, ReWalk has repurchased \$3.3 million of ordinary shares; and
- The cash position remained strong with \$67.9 million as of December 31, 2022, with no debt.

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

Global, regional, and local economic weakness and uncertainty could adversely affect our demand for our products and services and our business and financial performance.

Our business and financial performance depends on worldwide economic conditions and the demand for our products and services in the markets in which we compete. Ongoing economic weakness, including an economic slowdown or recession, uncertainty in markets throughout the world and other adverse economic conditions, including inflation, changes in monetary policy and increased interest rates, have resulted, and may result in the future, in decreased demand for our products and services and increased expenses and difficulty in managing inventory levels and accurately forecasting revenue, gross margin, cash flows and expenses. Ongoing U.S. federal government spending limits may continue to reduce demand for our products and services from organizations that receive funding from the U.S. government and could negatively affect macroeconomic conditions in the United States, which could further reduce demand for our products and services.

Prolonged or more severe economic weakness and uncertainty could also cause our expenses to vary materially from our expectations. Any financial turmoil affecting the banking system and financial markets or any significant financial services institution failures could negatively impact our treasury operations, as the financial condition of such parties may deteriorate rapidly and without notice. Poor financial performance of asset markets and the adverse effects of fluctuating currency exchange rates could lead to higher pension and post-retirement benefit expenses. Interest and other expenses could vary materially from expectations depending on changes in interest rates, borrowing costs, currency exchange rates, costs of hedging activities and the fair value of derivative instruments. Economic downturns also may lead to future restructuring actions and associated expenses.

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 resulted in significant disruptions to the global economy and the capital markets, as well as our business. A significant number of our global suppliers, vendors, distributors, and manufacturing facilities are located in regions that were affected by the pandemic. Those operations were materially adversely affected by restrictive government and private enterprise measures implemented in response to the pandemic, which in turn, negatively impacted our operations.

Shut-downs and other limitations imposed in response to the COVID-19 pandemic adversely affected our ability to identify potential new customers through trade shows and events, engage with our existing customers, conduct product trials with prospective users, deliver ordered units or repair existing systems and provide training for our products to new patients, who largely remained at home during local movement restrictions, and to rehabilitation centers, which temporarily shifted priorities and responses to pandemic-related medical equipment. In addition, staffing shortages within the healthcare system itself resulted in a diminished demand for our SCI Products as the attention of healthcare workers and potential patients turned elsewhere. Some clinics, such as VA clinics, and many other healthcare facilities, enforced in-clinic restrictions, which affected our ability to demonstrate our devices to patients or start training for qualified potential customers.

Although these restrictions have now mostly been lifted, allowing us to restart market development and access programs, we have not seen a full return to pre-pandemic levels, and we believe that our business will continue to be adversely impacted by the effects of the pandemic-related restrictions and shut-downs.

We may not have sufficient funds to meet certain future operating needs or 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 which may also further dilute our shareholders or place us under restrictive covenants limiting our ability to operate freely.

We intend to finance our business by close management of our operating expenses until we reach profitable operation using existing cash on hand, issuances of equity and/or debt securities, and other future public or private issuances of securities, cash exercised of outstanding warrants, 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 alternatives are not available to us or unavailable on reasonable terms. Although we had a cash and cash equivalent of \$67.9 million as of December 31, 2022, which we believe will be sufficient to fund our planned operations through at least the next twelve 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 are 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 unless our public float rises above \$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, due to these limitations on our use of Form S-3, 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 The Nasdaq Stock Market LLC (“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.

We do not satisfy all listing requirements for the Nasdaq Capital Market. We can provide no assurance that we will be able to comply with the continued listing requirements over time and that our common stock will continue to be listed on the Nasdaq Capital Market.

As previously disclosed, on October 10, 2022, we received a notification letter (the “Bid Price Letter”) from Nasdaq indicating that we did not satisfy the requirement for continued listing on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(a) (“Rule 5550(a)”) to maintain a minimum bid price of \$1.00 per share. We became deficient with Rule 5550(a) as of October 10, 2022 as our closing bid price was less than \$1.00 per share for 30 consecutive business days. As in the past, the Bid Price Letter is a notice of deficiency, not delisting, and does not currently affect the listing or trading of ReWalk ordinary shares on The Nasdaq Capital Market.

We have 180 calendar days, or until April 10, 2023, to regain compliance with Rule 5550(a). If at any time before April 10, 2023, the bid price of our ordinary shares closes at \$1.00 per share or more for a minimum of 10 consecutive business days, Nasdaq will provide written confirmation that we have regained compliance. Additionally, we may be eligible for a second 180-day period to satisfy the minimum bid price requirement of Rule 5550(a), if, as of April 10, 2023, we continue to have a market value of publicly held shares of at least \$1 million, meet all other initial listing standards of the Nasdaq Capital Market (with the exception of the bid price requirement) and provide written notice of our intention to cure the deficiency during such second compliance period. We intend to monitor closely the closing bid price of our ordinary shares and to consider plans for regaining compliance with Rule 5550(a). While we plan to review all available options, there can be no assurance that we will be able to regain compliance with the applicable rules during the 180-day compliance period, any subsequent extension period, or at all.

If we do not regain compliance with Rule 5550(a) during the applicable cure period, Nasdaq will notify us that our ordinary shares are subject to delisting. We would then 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. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement, or prevent future non-compliance with Nasdaq's listing requirements.

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. In 2019, we commercialized our first product for stroke patients, the ReStore Exo-Suit. For more information, see "Part I, Item 1. Business—ReStore Products" above. While our Collaboration Agreement with Harvard for the 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 successfully concluded on March 31, 2022, Harvard has 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 revenue will be derived, in the next few years, from the ReStore soft exo-suit product and, in later years, if we choose to advance the current designs, from other potential new products, such as ReBoot, a home use device for stroke patients, or new products 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 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. While we received governmental clearance to market our ReStore product on the anticipated timetable in 2019, obtaining clearance for any other 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 a 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.

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 and reimbursement coverage in 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 and coverage for these indications in a timely manner, or at all.

While our new products currently under development will share some aspects of the core technology platform of 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 revenue 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 revenue 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 the ReStore lightweight soft exo-suit in 2019 in the United States and the EU (following the receipt of FDA and CE mark clearance) 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 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 the device, 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 support for the device to convince them to alter the treatment methods they typically recommend, such as expanded reimbursement coverage by payors, and/or recommendations by prominent healthcare providers or other key opinion leaders in the spinal cord injury community that ReWalk is effective in providing identifiable immediate and long-term health benefits.

In the United States, many private third-party payors use coverage decisions and payment amounts determined by CMS as guidelines in setting their coverage and reimbursement policies. We have started the process of obtaining coverage and reimbursement from CMS, and in July 2020, CMS issued a Healthcare Common Procedure Coding System Level II Code for ReWalk Personal Exoskeleton (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 potential positive coverage and reimbursement response by CMS will result in a response of expanded 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, or if at all. Additionally, we cannot predict other approval terms that will be decided by CMS such as the price per unit or product labeling requirements should we achieve approval. Even with a positive coverage and reimbursement response 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.

- *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 only indicated for use 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 only indicated for use in a clinical setting 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 2021 report by the NSCISC, 40% 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% 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 revenue 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, workers’ compensation plans, 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 payors 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.

In the United States, many private third-party payors use coverage decisions and payment amounts determined by CMS as guidelines in setting their coverage and reimbursement policies. We have started the process of obtaining coverage and reimbursement from CMS, and in July 2020, CMS issued a Healthcare Common Procedure Coding System Level II Code for ReWalk Personal Exoskeleton (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 potential positive coverage and reimbursement response by CMS will result in a response of expanded 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, or if at all. Additionally, we cannot predict other approval terms that will be decided by CMS such as the price per unit or product labeling requirements should we achieve approval. Even with a positive coverage and reimbursement response 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 2021, 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 510(k) containing revised instructions for use in May 2020.

In addition, our products incorporate sophisticated computer software and hardware. 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, in 2021 ReWalk 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, and this project remains in process. 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, the need for additional regulatory filings, product recalls, increased service and warranty costs, product liability claims, and loss of revenue relating to 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 clearance and CE mark, 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 three years, which has resulted in lower sales than originally anticipated. In addition, we are actively working toward, but have not yet achieved, meaningful coverage and 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, retention, and motivation 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 revenue, 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 existing and recruit new trainers to our clinical staff, 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 of such products.

Although published research and users of our ReWalk products 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 large scale, randomized clinical trial establishing the secondary health benefits of ReWalk products due to the relatively small size of the applicable user population. There is also a lack of randomized 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 products 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 supplier 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 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 quality levels, 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. Moreover, the failure of Sanmina to comply with applicable regulatory requirements could expose us to regulatory action including warning letters, product recalls, termination of distribution, product seizures or civil penalties.

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 COVID-19 pandemic, we have seen several components, mainly electronic parts, experience 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 acceptable suppliers, which could 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 clearances or 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, Rex Bionics, Cyberdyne, FREE Bionics, Wandercraft, 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, which is a unit of Bioventus. 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 other 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 revenue.

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 revenue 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. After several years of commercial collaboration, we determined that the agreement with MediTouch would not yield commercially acceptable results for us and we terminated the agreement as of January 31, 2023. Similarly, the distribution arrangement with MYOLYN or other new future arrangements 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. The Collaboration Agreement concluded on March 31, 2022. The License Agreement will continue in full force and effect until the expiration of the last-to-expire valid claim of the licensed patents. 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.

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.

Risks Related to Government Regulation

Although the FDA granted Breakthrough Device Designation status to both our new ReBoot device and the ReWalk with stair functionality, this designation does not guarantee regulatory clearance, or a speedier clearance timeline.

In November 2021, the FDA granted Breakthrough Device Designation status to ReBoot, a personal soft exo-suit for home and community use by individuals post-stroke. In May 2021, the FDA granted Breakthrough Device Designation status to the ReWalk with stair functionality.

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 classification 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 premarket 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 a premarket submission to the FDA or any foreign regulatory agency for clearance or other marketing authorization 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 payors. 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.

Further legislative and regulatory changes under the ACA remain possible, although President Biden indicated that he intends to use executive orders to undo changes to the ACA made by the Trump administration and would advocate for legislation to build on the ACA. 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 ACA or 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.

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 November 2021, CMS reversed course, and rescinded the rule due primarily to clinical evidence concerns.

Other legislative changes have been proposed and adopted since passage of the ACA. 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% per fiscal year. This 2% reduction was temporarily suspended during the pandemic, but has since been reinstated and, unless Congress and/or the Administration take additional action, will begin to increase gradually starting in April 2030, reaching 4% in April 2031, until sequestration ends in October 2031. The Bipartisan Budget Act of 2018 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.

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 and the indication for use, 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 uncleared 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 FFDCAs as implemented and enforced by the FDA. Under the FFDCAs, 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 powered exoskeleton device 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 for all powered exoskeletons include the following: clinical testing to demonstrate safe and effective use considering the level of supervision necessary and the use environment; non-clinical safety and 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 and 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 powered exoskeleton devices as described above. 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 regulations and standards regulating the design, manufacture, clinical trials, labeling and adverse event (i.e., vigilance) reporting for medical devices. The Medical Devices Regulation (EU) 2017/745 (MDR) became fully applicable on May 26, 2021, repealing and replacing the pre-existing E.U. Medical Devices Directive 93/42/EEC. Devices that comply with the requirements of the MDR, subject to certain transitional provisions that allow continued compliance of certain products to the Directive until May 2024 at the latest, are entitled to bear the CE mark, indicating that the device conforms to the essential requirements of the MDR 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. As compared with the Directive, the MDR includes additional premarket and post-market requirements, as well as potential product reclassifications and 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 inspect 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, 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 or require us to conduct post-market surveillance studies. If we fail to recall the device and/or conduct requested postmarket surveillance studies to FDA’s satisfaction, we could be subject to FDA enforcement action.

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 in the European Union. 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.

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 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;
- denials or delays of approvals for pre-market approval applications relating to new products or modified products;
- withdrawals of a PMA approvals;
- refusal to provide Certificates for Foreign Government;
- refusal to grant export approval for our products; or
- pursuit of 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 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 certain healthcare providers or funds spent on marketing and promotion of medical device products. Further, some state laws require medical device companies to report information related to payments to physicians and other health care providers or marketing expenditures. They also impose additional administrative and compliance burdens on us. In particular, these laws influence, among other things, how we structure our sales offerings and other interactions with health care providers, 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 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 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. Furthermore, it is anticipated that the California Privacy Rights Act of 2020, effective January 1, 2023, expands the CCPA's requirements, including applying to personal information of business representatives and employees and establishing a new regulatory agency to implement and enforce the law. 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.

We are also subject to the requirement of Section 1502 of the Dodd-Frank Act and SEC rules related thereto to conduct due diligence and disclose and report on whether certain minerals and metals, known as “conflict minerals,” are contained in our products and whether they originate from the Democratic Republic of Congo and certain adjoining countries. Each year our management team devotes significant time to conduct the required due diligence, and we may face reputational challenges if we determine that certain of our products contain minerals not determined to be conflict free or if we are unable to sufficiently verify the origins of all conflict minerals used in our products through the procedures we implement.

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. 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 23, 2023, 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 that 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, 2022, 5,733,730 ordinary shares remained available for issuance to our and our affiliates’ respective employees, non-employee directors, and consultants under our equity incentive plans, including 2,799,051 ordinary shares subject to outstanding awards (consisting of outstanding options to purchase 43,994 ordinary shares and 2,755,057 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 8b to our consolidated financial statements for the year ended December 31, 2022, 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, 2022, there were 19,420,894 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 2022). 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 revenue 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, 2022, we recorded revenue of approximately \$5.5 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 were not PFIC for the taxable year ended December 31, 2022. 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, 2022, or the current year 2023, 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 23, 2023. 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 covers some, but not all, 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, 2022, we received a total of \$2.3 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 some grants that were royalty-bearing 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 59,480,132 ordinary shares were outstanding as of February 23, 2023. 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 taken place.

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 of Directors 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 our Board of Directors 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. In connection with our 2022 Annual General Meeting of Shareholders, Creative Value Capital Limited Partnership ("CVC"), which claimed to hold approximately three percent of our outstanding shares, nominated two candidates for election to our Board of Directors and submitted two additional proposals (including amendments to our Articles of Association) for approval at our 2022 Annual General Meeting of Shareholders held on July 27, 2022. Although none of CVC's proposals were approved at the meeting, addressing and responding to such proposals was significantly costly and time-consuming, and diverted the attention of our management and employees.

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. However, we pay a significant portion of our expenses in NIS and in euro, and we expect this to continue. As a result, we are exposed to exchange rate risks that may materially and adversely affect our financial results. 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, if the NIS appreciates against the U.S. dollar or if the value of the NIS declines against the U.S. dollar at a time when the rate of inflation in the cost of Israeli goods and services exceeds the rate of decline in the relative value of the NIS, then the U.S. dollar cost of our operations in Israel would increase and our results of operations could be materially and adversely affected.

Our operations also could be adversely affected if we are unable to effectively hedge against currency fluctuations in the future.

We cannot predict any future trends in the rate of inflation in Israel or the rate of devaluation (if any) of the NIS against the U.S. dollar. For example, while the NIS devalued against the U.S. dollar at a rate of approximately 4% during the fiscal year 2022, during the year 2021 and 2020 the NIS appreciated against the U.S. dollar at a rate of approximately 3% and 7%, respectively. The Israeli annual rate of inflation amounted to 5.3%, 1.5%, and negative 0.6% for the years ended December 31, 2022, 2021 and 2020, respectively.

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 rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service (the “IRS”) and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our ordinary shares. In recent years, many such changes have been made, and changes are likely to continue to occur in the future. It cannot be predicted whether, when, in what form or with what effective dates tax laws, regulations and rulings may be enacted, promulgated or issued, which could result in an increase in our or our shareholders’ tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law.

In addition, foreign governments may enact tax laws in response to the changes in the rules dealing with U.S. federal, state and local income taxation 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.

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 2022 taxable year, we believe that we had one shareholder that was a Ten Percent Shareholder for U.S. federal income tax purposes. However, our CFC status for the taxable year ending on December 31, 2022, and our current taxable year is unknown, and we may be a CFC for the taxable year ending on December 31, 2022, 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.

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	947
Total	<u>24,297</u>

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.

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. As of February 23, 2023, we had approximately 278,511 shareholders of record.

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

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 income tax at the rate of 25%, or 30% if the recipient of the dividend was a substantial shareholder at the time of distribution or at any time during the prior 12-month period. Such dividends are generally subject to Israeli withholding tax at a rate of 25% if the shares are registered with a nominee company (whether the recipient is a substantial shareholder or not), 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.

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

Issuer Purchases of Equity Securities

The following table sets forth information regarding the ordinary shares repurchased under our share repurchase program during the three months ended December 31, 2022:

Period	Total Number of Shares Purchased	Average Price Paid Per Share	Total Number of Shares Purchased as Part of a Publicly Announced Plan	(In Thousands) Maximum Value of Shares That May Yet Be Purchased Under the Plan
October 1 - October 30, 2022				
Share repurchase program (1)	529,319	\$ 0.90	529,319	\$ 7,330
November 1 - November 30, 2022				
Share repurchase program (1)	1,056,776	\$ 0.94	1,056,776	\$ 6,317
December 1 - December 31, 2022				
Share repurchase program (1)	1,162,484	\$ 0.80	1,162,484	\$ 5,358
Quarter Total				
Share repurchase program (1)	2,748,579	\$ 0.87	2,748,579	\$ 5,358

(1) Ordinary Shares were repurchased by us through our publicly announced share repurchase program approved by our Board of Directors on June 2, 2022, and approved by an Israeli court on July 20, 2022. The program was scheduled to expire on the earlier of January 20, 2023, or reaching \$8.0 million of repurchases. On December 22, 2022, our Board of Directors approved an extension of the repurchase program, with such extension to be in the aggregate amount of up to \$5.8 million. The extension was approved by an Israeli court on February 9, 2023, and will expire on the earlier of August 9, 2023, or reaching the additional \$5.8 million of repurchases of our ordinary shares.

Repurchases may take place in open market transactions or in privately negotiated transactions and may be made from time to time depending on market conditions, share price, trading volume and other factors our board of directors deems appropriate. Our board of directors may also suspend and/or discontinue the repurchase program at any time, in its sole discretion. All repurchases will be made in accordance with all applicable securities laws and regulations.

Subsequent to December 31, 2022, an additional 730,350 ordinary shares for an aggregate consideration of \$628,477 were repurchased under our share repurchase program during the period from January 1, 2023 to January 20, 2023. On December 22, 2022, our Board of Directors approved an extension of the repurchase program, with such extension to be in the aggregate amount of up to \$5.8 million. The extension was approved by an Israeli court on February 9, 2023, and will expire on the earlier of August 9, 2023, or reaching the additional \$5.8 million of repurchases of our ordinary shares.

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 a medical device company that is designing, developing, and commercializing innovative technologies that enable mobility and wellness in rehabilitation and daily life for individuals with neurological conditions. Our initial product offerings were the ReWalk Personal and ReWalk Rehabilitation Exoskeleton devices for individuals with spinal cord injury ("SCI Products"). These devices are robotic exoskeletons that are designed for individuals with paraplegia that use our patented tilt-sensor technology and an onboard computer and motion sensors to drive motorized legs that power movement. These SCI Products allow individuals with spinal cord injury the ability to stand and walk again during everyday activities at home or in the community.

We have sought to expand our product offerings beyond the SCI Products through internal development and distribution agreements. We have developed our ReStore Exo-Suit device, which we began commercializing in June 2019. The ReStore is a powered, lightweight soft exo-suit intended for use during the rehabilitation of individuals with lower limb disabilities 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 MYOLYN MyoCycle FES Pro cycles to U.S. rehabilitation clinics and for the MyoCycle Home cycles available to US veterans through the U.S. Department of Veterans Affairs ("VA") hospitals. In the second quarter of 2020, we also became the exclusive distributor of the MediTouch Tutor movement biofeedback systems in the United States; however, due to unsatisfactory sales performance of the MediTouch product lines, we terminated this agreement as of January 31, 2023. We refer to the MediTouch and MyoCycle devices as our "Distributed Products." We will continue to evaluate other products for distribution or acquisition that can broaden our product offerings further to help individuals with neurological injury and disability.

We are in the research stage of ReBoot, a personal soft exo-suit for home and community use by individuals post-stroke, and we are currently evaluating the reimbursement landscape and the potential clinical impact of this device. This product would be a complementary product to ReStore as it provides active assistance to the ankle during plantar flexion and dorsiflexion for gait and mobility improvement in the home environment, and it received Breakthrough Device Designation from the U.S. Food and Drug Administration ("FDA") in November 2021. Further investment in the development path of the ReBoot has been temporarily paused in 2023 pending further determination about the clinical and commercial opportunity of this device.

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 revenue 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 exoskeleton technologies such as the ReWalk Personal Exoskeleton, 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 updates with the Centers for Medicare and Medicaid Services (“CMS”), to clarify the Medicare coverage category (i.e., benefit category) applicable for personal exoskeletons. In 2021, the National Spinal Cord Injury Statistical Center (“NSCISC”) reported the Medicare and Medicaid are the primary payors for approximately 56% 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 Exoskeleton (effective October 1, 2020), which may be used for purposes of claim submission to Medicare, Medicaid, and other payors. We are currently seeking a nationwide Medicare benefit category determination from CMS to designate the relevant Medicare benefit category. CMS has stated that, until a nationwide benefit category determination is issued, coverage and payment can be adjudicated on a case-by-case basis by the Medicare Administrative contractors (“MACs”).

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 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 Exoskeleton 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.

Components of Our Statements of Operations

Revenue

We currently rely, and in the future will rely, on sales and rentals of our ReWalk Personal and ReWalk Rehabilitation Exoskeleton devices, and sales of our ReStore exo-suit device, additional Distributed Products such as the MyoCycle, and related extended service contracts for the SCI Products. Our revenue is generated from a combination of third-party payors, including private and government employers, institutions, and self-payors. Payments for our products by third party payors have been made primarily through case-by-case determinations. Third-party payors include, without limitation, private insurance plans and managed care programs, government programs including the VA, and worker’s compensation payments. We expect that third-party payors will be an increasingly important source of revenue in the future as we seek to clarify the Medicare coverage category (i.e., benefit category) applicable for personal exoskeletons. 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.

ReWalk Personal and ReWalk Rehabilitation systems are generally covered by a five-year warranty from the date of purchase, which is included in the purchase price. The warranty covers 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 range between one year to ten years depending on the specific product and part.

Cost of Revenue and Gross Profit

Cost of revenue consists primarily of systems purchased from our outsourced manufacturer, Sanmina. Cost of revenue also includes internal costs such as salaries and related personnel costs including non-cash share-based compensation, manufacturing and inventory management, training and inspection, warranty and service activities, freight costs, and reserves for excess and obsolete inventory, when necessary. The cost of revenue also includes royalties and expenses related to royalty-bearing research and development grants.

Our gross profit and gross margin (defined as gross profit as a percentage of revenue) are influenced by a number of factors, including primarily the volume and price of our products sold, fluctuations in the mix of products sold, and variability in our cost of revenue. We expect gross profit and gross margin will expand in the future as we increase our revenue volumes and realize operating efficiencies associated with greater scale which will reduce the cost of revenue as a percentage of revenue.

Operating Expenses

Research and Development Expenses, Net

Research and development expenses, net consist primarily of salaries and related personnel costs including share-based compensation, supplies, materials, and consulting expenses associated with to product design and development, clinical studies, regulatory submissions, patent costs, sponsored research and other related activities. 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 revenue. 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 and related personnel costs including share-based compensation for sales, sales support, marketing, and reimbursement related activities, travel, marketing, advertisement, tradeshows and conferences, lobbying, and public relations activities.

General and Administrative Expenses

Our general and administrative expenses consist primarily of salaries and 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 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, 2022, 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 \$220.9 million. After we utilize our net operating loss carryforwards, 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, 2022, we have received a total of \$2.3 million in funding from the IIA, \$1.6 million of which are royalty-bearing grants, \$400 thousand were received in consideration for an investment in our preferred shares while \$309 thousand was received without future obligation. Of the royalty-bearing grants received, we have paid royalties to the IIA in the total amount of \$110 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, 2022, the aggregate contingent liability to the IIA was \$1.6 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, 2022 Compared to Year Ended December 31, 2021

Revenue

Our revenue for 2022 and 2021 were as follows (dollars in thousands, except unit amounts)

	Years Ended December 31,	
	2022	2021
Personal unit revenue	\$ 4,762	\$ 4,820
Rehabilitation unit revenue	\$ 749	\$ 1,146
Revenue	\$ 5,511	\$ 5,966

Personal unit revenue consists of ReWalk Personal Exoskeleton and Distributed Products sale, rental, service, and warranty revenue for individual use.

Rehabilitation unit revenue 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.

Revenue was \$5.5 million, a decrease of \$0.5 million, or 8%, during 2022 as compared to 2021. The decrease was driven primarily by lower rehabilitation units sold in the United States due to a one time multiple-unit shipment to a medical academic center in 2021, partially offset by a higher number of distributed products units sold in the U.S. Additionally, we experienced an adverse impact to revenue from currency due to an erosion of the euro-dollar exchange rate.

In the future we expect our growth to be driven by sales of our ReWalk Personal device through expansion of coverage and reimbursement by commercial and government third-party payors, as well as sales of Distributed Products and the ReStore device to rehabilitation clinics and personal users.

Gross Profit

Our gross profit for 2022 and 2021 were as follows (in thousands):

	Years Ended December 31,	
	2022	2021
Gross profit	\$ 1,905	\$ 2,903

Gross profit was \$1.9 million, or 35% of revenue, for 2022, as compared to a gross profit of \$2.9 million, or 49% of revenue for 2021. Our gross profit declined because of a higher inventory reserve of ReStore finished goods and raw materials due to the obsolescence of electronic components. Gross profit decrease is also attributable to a decreased volume of ReWalk Personal Exoskeleton sales, increase of production costs and freight expense.

We expect gross profit and gross margin will increase in the future as we increase our revenue volumes and realize operating efficiencies associated with greater scale which will reduce the cost of revenue as a percentage of revenue. 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 material costs.

Research and Development Expense, Net

Our research and development expense, net for 2022 and 2021 was as follows (in thousands):

	Years Ended December 31,	
	2022	2021
Research and development expense, net	\$ 4,031	\$ 2,939

Research and development expense was \$4.0 million in 2022, an increase of \$1.1 million, or 37%, during 2022 as compared to 2021. The increase is attributable to increased personnel and personnel related expenses and subcontractors' expenses primarily due to development projects offset partially with grant received from the IIA.

We intend to focus our research and development expenses mainly on our current products maintenance and improvement as well as in support of the FDA submission for clearance of the stair walking capability of the ReWalk 6.0 and in support of the FDA submission for clearance of the ReWalk 7.0 next generation model.

Sales and Marketing Expenses

Our sales and marketing expense for 2022 and 2021 was as follows (in thousands):

	Years Ended December 31,	
	2022	2021
Sales and marketing expense	\$ 9,842	\$ 6,993

Sales and marketing expense was \$9.8 million in 2022, an increase of \$2.8 million, or 41%, during 2022 as compared to 2021. The increase was driven by higher consulting expenses related to CMS reimbursement progress, an increase in tradeshow and travel expenses since Covid-19 restrictions are being lifted and personnel and personnel-related expenses.

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

General and Administrative Expense

Our general and administrative expense for 2022 and 2021 was as follows (in thousands):

	Years Ended December 31,	
	2022	2021
General and administrative	\$ 7,134	\$ 5,626

General and administrative expense was \$7.1 million, an increase of \$1.5 million, or 27%, during 2022 as compared to 2021. The increase was mainly driven by increased professional services expenses related to the 2022 proxy process, partially offset by a decrease in insurance costs.

Financial Expenses (income), Net

Our financial expense, net for 2022 and 2021 was as follows (in thousands):

	Years Ended December 31,	
	2022	2021
Financial expense (income), net	\$ (*)	\$ (13)

Financial expense (income), net, decreased by \$13 thousand during 2022 as compared to 2021. The decrease is mainly due to exchange rate fluctuations.

*) Represents an amount lower than \$1.

Income Tax

Our income tax for 2022 and 2021 was as follows (in thousands):

	Years Ended December 31,	
	2022	2021
Taxes on income	\$ 467	\$ 94

Income tax increased by \$373 thousand during 2022 as compared to 2021 due to the application of a valuation allowance to our deferred tax assets.

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

A discussion of changes in our results of operations in 2022 compared to 2021 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, 2021, filed with the SEC on February 24, 2022, which is available free of charge on the SEC's website at www.sec.gov and at 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 revenue 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

Our revenue is recognized in accordance with ASC Topic 606 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. 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.

For the majority of sales of Rehabilitation systems, we include insignificant training and consider the elements in the arrangement to be a single performance obligation. 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.

SCI Products include a five-year warranty. The first two years are considered as an assurance type warranty and the additional period is considered an extended service arrangement, which is a service type warranty. A service type warranty is either sold with a unit or separately for a unit for which the warranty has expired. A service type warranty is accounted as a separate performance obligation and revenue is 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 from between one year to ten years, depending on the specific product and part.

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. Expected volatility is calculated based on actual historical stock price movements over the most recent periods ending on the grant date, equal to the expected term of the options, or based on certain peer companies that the Company considered to be comparable, in case there is no sufficient trading volume to rely on market volatility.

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, 2022, the Company incurred a consolidated net loss of \$19.6 million and has an accumulated deficit in the total amount of \$213.8 million. Our cash and cash equivalent on December 31, 2022, totaled \$67.9 million. The Company's negative operating cash flow for the full year ended December 31, 2022, was \$17.9 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, 2022.

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 revenue 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.

Our anticipated primary uses of cash are funding (i) sales, marketing, and promotion activities related to market development for our ReWalk Personal and ReWalk Rehabilitation Exoskeleton devices and other product lines added through distribution agreements; (ii) payor education activities to establish or broaden coverage by third-party payors and CMS for our ReWalk Personal Exoskeleton device; (iii) development of our lightweight exo-suit technology for potential home personal health utilization for multiple indications and future generation designs for our exoskeleton device; (iv) routine product updates; (v) general corporate purposes, including working capital needs; (vi) share repurchase programs; and (vii) potential acquisitions of businesses. 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 with respect to 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, 2022, on February 23, 2023, we were subject to these limitations, because our public float did not reach at least \$75 million in the 60 days preceding the filing of this annual report. We will continue to be subject to these limitations for the remainder of the 2023 fiscal year and until the earlier of such time as our public float reaches at least \$75 million or when we file our next annual report for the year ended December 31, 2023, at which time we will be required to re-test our status under these rules. If our public float is 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 continue to be subject to these limitations, 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 registration statement on Form S-3, which was declared effective by the SEC in May 2022.

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 3, 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 shares 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.

As of December 31, 2022, 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. During the twelve months that ended December 31, 2022, no warrants were exercised.

Share Repurchase Program

In June 2022, we announced that our Board approved a program to repurchase up to \$8.0 million of our ordinary shares, par value NIS 0.25 per share, subject to receipt of Israeli court approval. In July 2022, we announced that we had received approval from an Israeli court for the share repurchase program, valid through January 20, 2023.

On December 19, 2022, our board of directors approved the extension of our on-going share repurchase program, with such extension to be in the aggregate amount of up to \$5.8 million. The extension was approved by an Israeli court on February 9, 2023, and will expire on the earlier of August 9, 2023, or reaching the additional \$5.8 million of repurchases of our ordinary shares.

Under the program, share repurchases may be made from time to time using a variety of methods, including open market transactions or in privately negotiated transactions. Such repurchases will be made in accordance with all applicable securities laws and regulations, including restrictions relating to volume, price and timing under applicable law, including Rule 10b-18 under the United States Securities Exchange Act of 1934, as amended (the "Exchange Act"). The timing and amount of shares repurchased will be determined by our management, within guidelines to be established by the Board or a committee thereof, based on its ongoing evaluation of our capital needs, market conditions, the trading price of our ordinary shares, trading volume and other factors, subject to applicable law. For all or a portion of the authorized repurchase amount, we may enter into a plan compliant with Rule 10b5-1 under the Exchange Act that is designed to facilitate these repurchases.

The repurchase program does not require us to acquire a specific number of shares and may be suspended or discontinued at any time. There can be no assurance as to the timing or number of shares of any repurchases in the future, and any such share repurchases will be funded from available working capital. As of December 31, 2022, we have repurchased approximately 2.9 million of our ordinary shares at an aggregate amount of \$2.6 million under the repurchase program.

Cash Flows

	Years Ended December 31,		
	2022	2021	2020
Net cash used in operating activities	\$ (17,891)	\$ (11,469)	\$ (12,589)
Net cash used in investing activities	(25)	(47)	(73)
Net cash (used in) provided by financing activities	(2,500)	79,512	16,724
Effect of Exchange rate changes on Cash, Cash Equivalents and Restricted Cash	(79)	—	—
Net cash flow	\$ (20,495)	\$ 67,996	\$ 4,062

Year Ended December 31, 2022 to Year Ended December 31, 2021

Net Cash Used in Operating Activities

Net cash used in operating activities was \$17.9 million in 2022, an increase of \$6.4 million as compared to 2021 mainly due to lower revenue collection, higher consulting, professional services expenses and personnel and personnel related expenses.

Net Cash Used in Investing Activities

Net cash used in investing activities decreased to \$25 thousand in 2022 as compared 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

Net cash (used in) provided by financing activities was a cash use of \$2.5 million in 2022, a decrease of \$82 million, as compared to cash provided of \$79.5 million in 2021. The decline was a result of a share repurchase plan that was initiated in the second half of 2022, while in 2021 the source of cash consisted primarily of proceeds from the issuance of common stock and warrants, as well as the exercise of warrants issued in prior years.

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

A discussion of changes in our cash flows in 2021 compared to 2020 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, 2021, filed with the SEC on February 24, 2022, which is available free of charge on the SEC’s website at www.sec.gov and at 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, 2022:

Contractual obligations	Payments due by period (in dollars, in thousands)		
	Total	Less than 1 year	1-3 years
Purchase obligations (1)	\$ 1,935	\$ 1,935	\$ —
Collaboration Agreement and License Agreement obligations (2)	57	57	—
Operating lease obligations (3)	1,006	603	403
Total	\$ 2,998	\$ 2,595	\$ 403

- (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 with Harvard was originally for a term of five years, commencing in May 2016, and was subsequently amended in April 2018 to extend the term by one additional year. The Collaboration Agreement concluded as of March 31, 2022. Under the Collaboration Agreement, we were required to pay in quarterly installments the funding of our joint research collaboration with Harvard, subject to a minimum funding commitment under applicable circumstances. Our License Agreement with Harvard consists of patent reimbursement expenses payments and 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. All product development milestones contemplated by the License Agreement have been met as of December 31, 2022; however, there are still outstanding commercialization milestones under the License Agreement that 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 3.519:\$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:\$1.07, both of which were the applicable exchange rates as of December 31, 2022.

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 euro, until 2018 most of our revenue was denominated in U.S. dollars and the remainder of our revenue was denominated in euro and British pound whereas in the last four years our euro revenue is higher than our U.S. dollar revenue. Accordingly, changes in the value of the NIS and Euro relative to the U.S. dollar in each of the years 2022, 2021, and 2020 impacted amounts recorded on our consolidated statements of operations for these periods. We expect that the denominations of our revenue and expenses in 2023 will be consistent with what we experienced in 2022.

The following table presents information about the devaluation in the exchange rates of the NIS and euro against the U.S. dollar in 2022, 2021 and 2020:

Period	Change in Average Exchange Rate	
	NIS against the U.S. Dollar (%)	Euro against the U.S. Dollar (%)
2022	3.70	10.84
2021	(6.38)	3.46
2020	3.76	2.07

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 the devaluation 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 \$429 thousand in 2022. 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 \$13 thousand in 2022.

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, 2022. 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, 2022 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, 2022, 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 23, 2022:

Name	Age	Position
Larry Jasinski	65	Chief Executive Officer and Director
Michael Lawless	55	Chief Financial Officer
Jeannine Lynch	58	Vice President of Market Access
Almog Adar	39	Vice President of Finance

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.

Michael Lawless has served as the Company's Chief Financial Officer since September 2022. Prior to ReWalk Robotics Mr. Lawless served as a CFO consultant for Danforth Advisors, LLC, a provider of outsourced services to the life sciences industry, starting in 2021. Previously, Mr. Lawless served as a Division CFO of Azenta, Inc. (formerly known as Brooks Automation, Inc.), a leading provider of life sciences solutions worldwide, from 2017 to 2020, and as Senior Director of Financial Planning and Analysis at Azenta from 2015 to 2017. Among other positions, Mr. Lawless also held several financial leadership roles for PerkinElmer, Inc. from 2007 to 2012. Mr. Lawless has a Bachelor of Arts degree in Economics from Swarthmore College, a Master of Business Administration degree from the Tuck School of Business at Dartmouth College and is a Certified Public Accountant.

Jeannine Lynch has served as the Company's Vice President of Market Access and Strategy since August 2021. Prior to ReWalk, Ms. Lynch served as Senior Director of Patient Access Services at BioMarin Pharmaceuticals from April 2009 to September 2021. In addition to her work with BioMarin, Ms. Lynch has worked for industry leaders such as Genentech and Pfizer/Agouron. She has held leadership roles in commercial management, product launches and built customized patient services to address several different rare and ultrarare medical conditions. Ms. Lynch also sits on the Board of Directors for MVP, a non-profit organization to help young people of color prepare, perform, progress, and prosper in their education, leadership and early professional careers. Ms. Lynch is a graduate of the University of California Berkeley and holds a Master of Public Health from the University of Michigan.

Almog Adar became has served as the Vice President of Finance since December 2022. From 2020 to 2022, Mr. Adar served as our Director of Finance and Corporate Financial Controller. Prior to ReWalk Robotics Mr. Adar served as Controller of Infynya recycling Ltd (Previously Ammir Recycling), from January 2018 until December 2019. From January 2016 until December 2017, Mr. Adar served as Assistant Controller of Delta Galil Industries. Mr. Adar has a Bachelor of Arts degree in Accounting and Economics from the Open University of Israel and is a Certified Public Accountant licensed by the Israeli Ministry of Justice.

The remaining information required by this Item will be included in, and is incorporated herein by reference from, our definitive proxy statement for our 2022 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, 2022 (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.

PART IV

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

3.1	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).
4.1	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).
4.2	Description of the registrant's securities registered pursuant to Section 12 of the Securities Exchange Act of 1934 (incorporated by reference to Exhibit 4.2 to the Company's Annual Report on Form 10-K filed with the SEC on February 24, 2022).
4.3	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).
4.4	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).
4.5	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).
4.6	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).
4.7	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).
4.8	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).

4.9	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).
4.10	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).
4.11	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).
4.12	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).
4.13	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).
4.14	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).
4.15	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).
4.16	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).
4.17	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).
4.18	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).
4.19	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).
4.20	Form of purchaser warrant from February 2021 private placement (incorporated by reference to Exhibit of the Company's Current Report on Form 8-K filed with the SEC on February 25, 2021).
4.21	Form of placement agent warrant from February 2021 private placement (incorporated by reference to Exhibit of the Company's Current Report on Form 8-K filed with the SEC on February 25, 2021).
4.22	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).
4.23	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).
4.24	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).

10.1	Letter of Agreement, dated July 11, 2013, between the Company and Sanmina Corporation (incorporated by reference to Exhibit 10.1 to the Company's Annual Report on Form 10-K filed with the SEC on February 18, 2021).*
10.2	License Agreement, dated May 16, 2016, between the Company and the President and Fellows of Harvard College (incorporated by reference to Exhibit 10.8 to the Company's Annual Report on Form 10-K filed with the SEC on February 18, 2021).*
10.3	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).**
10.4	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).**
10.5	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).**
10.6	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).**
10.7	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).**
10.8	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).**
10.9	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).**
10.10	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).**
10.11	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).**
10.12	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).**
10.13	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).**
10.14	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).**
10.15	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).**
10.16	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).**

10.17	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).**
10.18	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).**
10.19	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).*
10.20	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).
10.21	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).**
10.22	Employment Agreement dated December 10, 2019, by and between the Company and Almog Adar (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on May 13, 2022).* **
10.23	Employment Agreement, dated September 2, 2022, by and between the Company and Michael A. Lawless (incorporated by reference to Exhibit 10.1 to the Company's Quarterly report on Form 10-Q filed with the SEC on November 7, 2022) * **
10.24	Form of Restricted Share Unit Award (Inducement Award) for non-Israeli employees and executives (incorporated by reference to Exhibit 10.2 to the Company's Quarterly report on Form 10-Q filed with the SEC on November 7, 2022).**
21.1	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).
23.1	Consent of Kost Forer Gabbay & Kasierer, a member of Ernst & Young Global Limited.
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act 2002.
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act 2002.
32.1	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 ***
32.2	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.***
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 23, 2023

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 Mike Lawless 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 23, 2023
<u>/s/ Mike Lawless</u> Mike Lawless	Chief Financial Officer (Principal Financial Officer)	February 23, 2023
<u>/s/ Almog Adar</u> Almog Adar	Vice President of Finance (Principal Accounting Officer)	February 23, 2023
<u>/s/ Jeff Dykan</u> Jeff Dykan	Chairman of the Board	February 23, 2023
<u>/s/ Yohanan R Engelhardt</u> Yohanan R Engelhardt	Director	February 23, 2023
<u>/s/ Dr. John William Poduska</u> Dr. John William Poduska	Director	February 23, 2023
<u>/s/ Wayne B. Weisman</u> Wayne B. Weisman	Director	February 23, 2023
<u>/s/ Yasushi Ichiki</u> Yasushi Ichiki	Director	February 23, 2023
<u>/s/ Aryeh Dan</u> Aryeh Dan	Director	February 23, 2023
<u>/s/ Randel Richner</u> Randel Richner	Director	February 23, 2023
<u>/s/ Joseph Turk</u> Joseph Turk	Director	February 23, 2023
<u>/s/ Hadar Levy</u> Hadar Levy	Director	February 23, 2023

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

	<u>Page</u>
Report of Registered Public Accounting Firm (PCAOB ID 1281)	F-2
Consolidated Balance Sheets	F-4
Consolidated Statements of Operations	F-6
Statements of Changes in Shareholders' Equity	F-7
Consolidated Statements of Cash Flows	F-8
Notes to Consolidated Financial Statements	F-10



REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the 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, 2022 and 2021, 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, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, 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 the 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 accounts or disclosures 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 recognized ratably over the life of the warranty. 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.

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 23, 2023

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

	December 31,	
	2022	2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 67,896	\$ 88,337
Trade receivable, net	1,036	585
Prepaid expenses and other current assets	649	610
Inventories	2,929	2,989
Total current assets	72,510	92,521
LONG-TERM ASSETS		
Restricted cash and other long-term assets	694	1,064
Operating lease right-of-use assets	836	881
Property and equipment, net	196	284
Total long-term assets	1,726	2,229
Total assets	\$ 74,236	\$ 94,750

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,	
	2022	2021
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current maturities of operating leases liability	\$ 564	\$ 641
Trade payables	1,950	1,384
Employees and payroll accruals	1,282	1,142
Deferred revenue	301	316
Other current liabilities	685	555
Total current liabilities	4,782	4,038
LONG-TERM LIABILITIES		
Deferred revenue	890	866
Non-current operating leases liability	333	418
Other long-term liabilities	66	45
Total long-term liabilities	1,289	1,329
Total liabilities	6,071	5,367
COMMITMENTS AND CONTINGENT LIABILITIES		
Shareholders' equity:		
Share capital		
Ordinary share of NIS 0.25 par value-Authorized: 120,000,000 shares at December 31, 2022 and 2021; Issued: 63,023,506 and 62,480,163 shares at December 31, 2022 and December 31, 2021, respectively; Outstanding: 60,090,298 and 62,480,163 shares as of December 31, 2022 and December 31, 2021 respectively	4,489	4,661
Additional paid-in capital	279,857	278,903
Treasury Shares at cost, 2,933,208 ordinary shares at December 31, 2022	(2,431)	-
Accumulated deficit	(213,750)	(194,181)
Total shareholders' equity	68,165	89,383
Total liabilities and shareholders' equity	\$ 74,236	\$ 94,750

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,		
	2022	2021	2020
Revenue	\$ 5,511	\$ 5,966	\$ 4,393
Cost of revenue	3,606	3,063	2,204
Gross profit	1,905	2,903	2,189
Operating expenses:			
Research and development, net	4,031	2,939	3,459
Sales and marketing, net	9,842	6,993	5,754
General and administrative	7,134	5,626	4,980
Total operating expenses	21,007	15,558	14,193
Operating loss	(19,102)	(12,655)	(12,004)
Financial expenses (income), net	*)	(13)	921
Loss before income taxes	(19,102)	(12,642)	(12,925)
Taxes on income	467	94	51
Net loss	\$ (19,569)	\$ (12,736)	\$ (12,976)
Net loss per ordinary share, basic and diluted	\$ (0.31)	\$ (0.27)	\$ (0.82)
Weighted average number of shares used in computing net loss per ordinary share, basic and diluted	62,378,797	47,935,652	15,764,980

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

*) Represents an amount lower than \$1.

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	Treasury Shares	Accumulated deficit	Total shareholders' equity
	Number	Amount				
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 vesting of 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
Share-based compensation to employees and non-employees	-	-	993	-	-	993
Issuance of ordinary shares upon vesting of RSUs by employees and non-employees	543,343	39	(39)	-	-	-
Treasury shares at cost	(2,933,208)	(211)	-	(2,431)	-	(2,642)
Net loss	-	-	-	-	(19,569)	(19,569)
Balance as of December 31, 2022	60,090,298	\$ 4,489	\$ 279,857	\$ (2,431)	\$ (213,750)	\$ 68,165

(1) See Note 8a.

(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,		
	2022	2021	2020
Cash flows used in operating activities:			
Net loss	\$ (19,569)	\$ (12,736)	\$ (12,976)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	202	266	285
Share-based compensation	993	833	749
Deferred taxes	316	(29)	(44)
Gain on PPP forgiveness	-	-	(392)
Foreign currency remeasurement loss	79	-	-
Changes in assets and liabilities:			
Trade receivables, net	(408)	99	110
Prepaid expenses, operating lease right-of-use assets and other assets	94	592	166
Inventories	(117)	432	(469)
Trade payables	566	(884)	(506)
Employees and payroll accruals	140	275	197
Deferred revenue	(34)	74	264
Operating lease liabilities and other liabilities	(153)	(391)	27
Net cash used in operating activities	<u>(17,891)</u>	<u>(11,469)</u>	<u>(12,589)</u>
Cash flows used in investing activities:			
Purchase of property and equipment	(25)	(47)	(73)
Net cash used in investing activities	<u>(25)</u>	<u>(47)</u>	<u>(73)</u>
Cash flows from financing activities:			
Repayment of long-term loan	-	-	(6,965)
Proceeds from PPP loan (3)	-	-	392
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
Purchase of treasury shares	(2,500)	-	-
Net cash (used in) provided by financing activities	<u>(2,500)</u>	<u>79,512</u>	<u>16,724</u>
Effect of Exchange rate changes on Cash, Cash Equivalents and Restricted Cash	(79)	-	-
(Decrease) increase in cash, cash equivalents, and restricted cash	(20,495)	67,996	4,062
Cash, cash equivalents, and restricted cash at beginning of period	89,050	21,054	16,992
Cash, cash equivalents, and restricted cash at end of period	<u>\$ 68,555</u>	<u>\$ 89,050</u>	<u>\$ 21,054</u>

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,		
	2022	2021	2020
Supplemental disclosures of non-cash flow information			
Expenses related to offerings not yet paid (1)	\$ -	\$ -	\$ 76
Classification of other current assets to property and equipment, net	\$ 22	\$ 34	\$ 98
Classification of inventory to property and equipment	\$ 67	\$ 32	\$ 50
Classification of inventory to property and equipment	\$ 142	\$ -	\$ -
Supplemental disclosures of cash flow information:			
Cash paid for income taxes	\$ 113	\$ 40	\$ 13
Cash paid for interest	\$ -	\$ -	\$ 862
Reconciliation of cash, cash equivalents and restricted cash as shown in the consolidated statements of cash flows			
Cash and cash equivalents	\$ 67,896	\$ 88,337	\$ 20,350
Restricted cash included in other long-term assets	\$ 659	\$ 713	\$ 704
Total Cash, cash equivalents, and restricted cash	\$ 68,555	\$ 89,050	\$ 21,054

(1) See Note 8a.

(2) See Note 8f.

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 a medical device company that is designing, developing, and commercializing innovative technologies that enable mobility and wellness in rehabilitation and daily life for individuals with neurological conditions. Our initial product offerings were the ReWalk Personal and ReWalk Rehabilitation Exoskeleton devices for individuals with spinal cord injury. These devices are robotic exoskeletons that are 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. These SCI Products allow individuals with spinal cord injury the ability to stand and walk again during everyday activities at home or in the community.

We have sought to expand our product offerings beyond the SCI Products through internal development and distribution agreements. We have developed our ReStore Exo-Suit device, which we began commercializing in June 2019. The ReStore is a powered, lightweight soft exo-suit intended for use during the rehabilitation of individuals with lower limb disability due to stroke. During the second quarter of 2020, we signed two separate agreements to distribute additional product lines in the United States. We are the exclusive distributor of the MYOLYN MyoCycle FES Pro cycles to U.S. rehabilitation clinics and for the MyoCycle Home cycles available to US veterans through VA hospitals. In the second quarter of 2020, we also became the exclusive distributor of the MediTouch Tutor movement biofeedback systems in the United States; however, due to unsatisfactory sales performance of the MediTouch product lines, we terminated this agreement as of January 31, 2023. We will continue to evaluate other products for distribution or acquisition that can broaden our product offerings further to help individuals with neurological injury and disability.

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.

- 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, and could potentially continue to result in, significant disruptions to the global economy and the capital markets, as well as our business. This has resulted in a negative impact on the Company’s sales and results of operations since the start of the pandemic, 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. 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, 2022 the Company incurred a consolidated net loss of \$19.6 million and has an accumulated deficit in the total amount of \$213.8 million. The Company’s negative operating cash flow for the full year ended December 31, 2022 was \$17.9 million. Our cash and cash equivalent on December 31, 2022 totaled \$67.9 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, 2022.

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 establishment of contracts for the distribution of new product lines, or the acquisition of additional product lines, any of which, or in combination, would contribute to the achievement of a level of revenue 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 existing 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.

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 revenue 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, 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 Shekels ("NIS") and Euros. Until 2018 most of the Company's revenue was denominated in U.S. dollars and the remainder of our revenue was denominated in Euros and British pound, whereas, in the last four years our Euro-denominated revenue is higher than our dollar-denominated revenue. 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 subsidiary's 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.

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 net realizable 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 net realized value.

Cost is determined as follows:

Finished products - based on 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. If actual demand for the Company's products deteriorates, or market conditions are less favorable than those projected, additional inventory reserves may be required. In the years ended December 31, 2022, 2021 and 2020, the Company applied inventory reserves in the amount of \$502 thousand, \$252 thousand, and \$215 thousand, respectively. The inventory reserves were recorded in cost of revenue.

f. Balances and transactions with related parties:

In September 2013, the Company entered into a share purchase agreement and a strategic alliance with Yaskawa Electric Corporation ("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. 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.

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:

	%
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, 2022, 2021 and 2020, 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. Treasury shares

The Company repurchased its ordinary shares and holds them as treasury shares. The Company presents the cost to repurchase treasury shares as a reduction of shareholders' equity.

k. Revenue Recognition:

The Company generates revenue 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 activities, or under 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 good or service 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 a purchase order or a signed quote to be a contract with a customer. 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.

Determining the transaction price requires of level judgment, which is discussed by revenue category in further detail below.

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. 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 insignificant 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 Revenue (in thousands)

	Year Ended December 31,		
	2022	2021	2020
Units placed	\$ 5,034	\$ 5,449	\$ 3,620
Spare parts and warranties	477	517	773
Total Revenue	\$ 5,511	\$ 5,966	\$ 4,393

Units placed

During 2022, the Company offered five products: (1) ReWalk Personal, (2) ReWalk Rehabilitation, (3) ReStore, (4) MyoCycle and (5) MediTouch. Due to unsatisfactory sales performance of the MediTouch product lines, we terminated this agreement as of January 31, 2023.

ReWalk Personal and ReWalk Rehabilitation are SCI Products, which are currently designed for everyday use by paraplegic individuals at home and in their communities. The SCI Products 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 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.

The 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.

The Company also sells Distributed Products that include the MyoCycle, which uses Functional Electrical Stimulation ("FES") technology, and MediTouch tutor movement biofeedback devices. 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 revenue 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 an assurance type or a service type warranty. A warranty is considered an assurance type warranty if it provides the customer with assurance that the product will function as intended for a limited period of time. An assurance type warranty is not accounted for as a separate performance obligation under the revenue model.

SCI Products include a five-year warranty. The first two years are considered as an assurance type warranty and the additional period is considered an extended service arrangement, which is a service type warranty. A service type warranty is either sold with a unit or separately for a unit for which the warranty has expired. A service type warranty is accounted as a separate performance obligation and revenue is 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 from between one year to ten years, depending on the specific product and part.

Contract balances (in thousands)

	<u>December 31,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
Trade receivable, net (1)	\$ 1,036	\$ 585
Deferred revenue (1) (2)	\$ 1,191	\$ 1,182

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

(2) \$352 thousands of the December 31, 2021 deferred revenue balance was recognized as revenue during the year ended December 31, 2022.

Deferred revenue is composed primarily of unearned revenue related to service type warranty obligations as well as other advances and payments which the Company received from customers prior to satisfying the performance obligation, for which revenue has not yet been recognized. The Company's unearned performance obligations as of December 31, 2022 and the estimated revenue expected to be recognized in the future related to the service type warranty amounts to \$1.2 million, which will be fulfilled over one to five years.

l. 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.

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 account for forfeitures as they occur.

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 is calculated based on actual historical stock price movements over the most recent periods ending on the grant date, equal to the expected term of the options, or based on certain peer companies that the Company considered to be comparable, in case there is no sufficient trading volume to rely on market volatility. 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.

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.

There were no options granted during the twelve months ended December 31, 2022, 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, 2022, 2021 and 2020 amounted to \$993 thousand, \$833 thousand and \$749 thousand respectively.

m. Warrants to Acquire Ordinary Shares:

During the twelve-month ended December 31, 2021, the Company issued warrants to acquire up to 15,083,611 ordinary shares. There were no issued warrants during the twelve months ended December 31, 2022. The Company assessed the warrants pursuant to ASC 480 "Distinguishing Liabilities from Equity" and ASC 815 "Derivatives and Hedging" and determined that the warrants should be accounted for as equity and not as a derivative liability. Refer to Note 8f for additional information.

n. 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.

o. 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, 2022, and 2021, the Company did not identify any significant uncertain tax positions.

p. Warranty:

For assurance-type warranty, the Company 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, 2021	\$ 112
Provision	314
Usage	(334)
Balance at December 31, 2022	<u>\$ 92</u>

q. 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. The bank deposits are held in financial institutions which management believes are institutions with high credit standing, and accordingly, minimal credit risk from geographic or credit concentration exists with respect to these deposits.

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

	December 31,	
	2022	2021
Customer A	27%	12%
Customer B	13%	16%
Customer C	13%	*)
Customer D	11%	*)
Customer E	*)	20%
Customer F	*)	18%
Customer G	*)	10%

*) 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, 2022, and 2021 trade receivables are presented net of \$26 thousand and \$42 thousand allowance for doubtful accounts, respectively.

r. **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 \$113 thousand, \$104 thousand and \$125 thousand for the years ended December 31, 2022, 2021 and 2020, respectively.

s. **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.

t. **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 loss per share is computed based on the weighted average number of ordinary shares outstanding during the period, plus dilutive potential shares considered outstanding during the period.

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,		
	2022	2021	2020
Net loss	\$ (19,569)	\$ (12,736)	\$ (12,976)
Net loss attributable to ordinary shares	(19,569)	(12,736)	(12,976)
Shares used in computing net loss per ordinary shares, basic and diluted	62,378,797	47,935,652	15,764,980
Net loss per ordinary share, basic and diluted	\$ (0.31)	\$ (0.27)	\$ (0.82)

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.

For the twelve months ended December 31, 2022, the total number of ordinary shares related to the outstanding warrants and share option plans aggregated to 19,464,888, was excluded from the calculations of diluted loss per ordinary share since it would have an anti-dilutive effect.

u. 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.

v. 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).

w. Leases

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 at commencement date 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. The lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise such options.

Leases with an initial term of 12 months or less are not recorded on the balance sheet.

x. New Accounting Pronouncements

Recently Implemented Accounting Pronouncements

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 did not have a material impact on the Company's consolidated financial statements.

Recent Accounting Pronouncements Not Yet Adopted

i. 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 adoption 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,	
	2022	2021
Government institutions	\$ 81	\$ 207
Prepaid expenses	242	335
Advances to vendors	174	5
Other assets	152	63
	<u>\$ 649</u>	<u>\$ 610</u>

NOTE 4:- INVENTORIES

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

	December 31,	
	2022	2021
Finished products	\$ 2,421	\$ 2,284
Raw materials	508	705
	<u>\$ 2,929</u>	<u>\$ 2,989</u>

During the twelve months ended December 31, 2022, 2021, and 2020, the Company recognized, at cost of revenues, reserves for excess and obsolete in the amount of \$502 thousand, \$252 thousand, and \$215 thousand, respectively.

NOTE 5:- PROPERTY AND EQUIPMENT, NET

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

	December 31,	
	2022	2021
Cost:		
Computer equipment	\$ 743	\$ 741
Office furniture and equipment	308	301
Machinery and laboratory equipment	621	620
Field service units	1,816	1,712
Leasehold improvements	333	333
	<u>\$ 3,821</u>	<u>\$ 3,707</u>
	2022	2021
Accumulated depreciation	<u>3,625</u>	<u>3,423</u>
Property and equipment, net	<u>\$ 196</u>	<u>\$ 284</u>

Depreciation expenses amounted to \$202 thousand, \$266 thousand, and \$285 thousand for the years ended December 31, 2022, 2021 and 2020, 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 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, 2022, non-cancelable outstanding obligations amounted to approximately \$1.9 million.

b. Operating lease commitment:

(i) The Company operates from leased facilities in Israel, the United States and Germany. These leases expire between 2023 and 2025. 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 2023 and 2025. 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 \$21 thousand as of December 31, 2022.

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, 2022 are as follows (in thousands):

2023	\$ 603
2024	356
2025	47
Total lease payments	<u>1,006</u>
Less: imputed interest	<u>(109)</u>
Present value of future lease payments	897
Less: current maturities of operating leases	<u>(564)</u>
Non-current operating leases	<u>\$ 333</u>
Weighted-average remaining lease term (in years)	1.43
Weighted-average discount rate	12.3%

Total lease expenses for the years ended December 31, 2022, 2021 and 2020 were \$739 thousand, \$730 thousand, and \$764 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, 2022, the Company received funding from the IIA in the total amount of \$2.3 million. Out of the \$2.3 million in funding from the IIA, a total amount of \$1.6 million were royalty-bearing grants, \$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, while \$309 thousand was received without future obligation. 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.

As of December 31, 2022, the Company paid royalties to the IIA in the total amount of \$110 thousand.

Royalties expenses in cost of revenue were \$7 thousand, \$14 thousand and \$46 thousand, for the years ended December 31, 2022, 2021 and 2020, respectively.

As of December 31, 2022, the contingent liability to the IIA amounted to \$1.6 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, 2022, an amount of \$659 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. Equity raise:

Follow-on offerings

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, 2022, 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, 2022, 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, 2022, 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.

As of December 31, 2022, a total of 9,814,754 outstanding warrants with exercise prices ranging from \$1.25 to \$1.79 were exercised, for total gross proceeds of approximately \$13.8 million. During the twelve months that ended December 31, 2022 no warrants were exercised.

b. 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 ("RSUs"), 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 RSU 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, 2022 and 2021, the Company had reserved 2,934,679 and 233,957 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 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 2022 is as follows:

	Number	Weighted average exercise price	Weighted average remaining contractual life (years)	Aggregate intrinsic value (in thousands)
Options outstanding at the beginning of the year	61,832	\$ 38.34	4.55	\$ -
Granted	-	-	-	-
Exercised	-	-	-	-
Forfeited	(17,838)	31.13	-	-
Options outstanding at the end of the year	43,994	\$ 41.27	4.39	\$ -
Options exercisable at the end of the year	43,217	\$ 41.91	4.36	\$ -

There were no options granted during the fiscal year ended December 31, 2022, 2021 and 2020. 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, 2022, 2021 and 2020, no options were exercised.

A summary of employee and non-employee RSUs activity during the fiscal year ended 2022 is as follows:

	Number of shares underlying outstanding RSUs	Weighted- average grant date fair value
Unvested RSUs at the beginning of the year	1,356,284	1.61
Granted	2,152,757	1.00
Vested	(543,343)	1.51
Forfeited	(210,641)	1.53
Unvested RSUs at the end of the year	<u>2,755,057</u>	<u>1.16</u>

The weighted average grant date fair values of RSUs granted during the fiscal year ended December 31, 2022, 2021 and 2020, were \$1.00, \$1.69 and \$1.44, respectively.

Total fair value of shares vested during the year ended December 31, 2022, 2021 and 2020 were \$860 thousand, \$802 thousand, and \$676 thousand, respectively. As of December 31, 2022, there were \$2.7 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 2.7 years.

The number of options and RSUs outstanding as of December 31, 2022 is set forth below, with options separated by range of exercise price:

Range of exercise price	Options and RSUs Outstanding as of December 31, 2022	Weighted average remaining contractual life (years) (1)	Options Exercisable as of December 31, 2022	Weighted average remaining contractual life (years) (1)
RSUs only	2,755,057	-	-	-
\$5.37	12,425	6.24	11,648	6.24
\$20.42- \$33.75	13,317	5.21	13,317	5.21
\$37.14-\$38.75	8,946	0.98	8,946	0.98
\$50-\$52.5	6,731	4.46	6,731	4.46
\$182.5-\$524.25	2,575	2.85	2,575	2.85
	<u>2,799,051</u>	<u>4.39</u>	<u>43,217</u>	<u>4.36</u>

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

c. Equity compensation issued to consultants:

The Company granted 47,522 fully vested RSUs during the fiscal year ended December 31, 2022, to non-employee consultants. As of December 31, 2022, there are no outstanding options or RSUs held by non-employee consultants.

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

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

	Year Ended December 31,		
	2022	2021	2020
Cost of revenue	\$ 16	\$ 10	\$ 8
Research and development, net	94	55	136
Sales and marketing, net	250	171	163
General and administrative	633	597	442
Total	\$ 993	\$ 833	\$ 749

e. Treasury shares:

On June 2, 2022, the Company's Board of Directors approved a share repurchase program to repurchase up to \$8 million of its Ordinary Shares, par value NIS 0.25 per share. On July 21, 2022, the Company received approval from an Israeli court for the share repurchase program. The program was scheduled to expire on the earlier of January 20, 2023, or reaching \$8.0 million of repurchases. On December 22, 2022, the Company's Board of Directors approved an extension of the repurchase program, with such extension to be in the aggregate amount of up to \$5.8 million. The extension was approved by an Israeli court on February 9, 2023, and will expire on the earlier of August 9, 2023, or reaching the additional \$5.8 million of repurchases of ordinary shares.

As of December 31, 2022, pursuant to the Company's share repurchase program, the Company had repurchased a total of 2,933,208 of its outstanding ordinary shares at a total cost of \$2.6 million.

As to ordinary shares repurchased after December 31, 2022, see Note 14.

f. Warrants to purchase ordinary shares:

The following table summarizes information about warrants outstanding and exercisable as of December 31, 2022:

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, 2022.

- (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. As of December 31, 2022, 3,740,100 warrants were exercised for total consideration of \$4,675,125. During the twelve months that ended December 31, 2022, no warrants were exercised.
- (13) Represents warrants that were issued to the placement agent as compensation for its role in the Company's February 2020 best efforts offering. As of December 31, 2022, 230,160 warrants were exercised for total consideration of \$359,625. During the twelve months that ended December 31, 2022, no warrants were exercised.
- (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. As of December 31, 2022, 2,020,441 warrants were exercised for total consideration of \$3,555,976. During the twelve months that ended December 31, 2022, no warrants were exercised.
- (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. As of December 31, 2022, 3,598,072 warrants were exercised for total consideration of \$4,821,416. During the twelve months that ended December 31, 2022, no warrants were exercised.

- (17) Represents warrants that were issued to the placement agent as compensation for its role in the Company's December 2020 private placement. As of December 31, 2022, 225,981 warrants were exercised for total consideration of \$405,003. During the twelve months that ended December 31, 2022, no warrants were exercised.
- (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 Collaboration Agreement (as amended, the “Collaboration Agreement”) and an Exclusive License Agreement (as amended, the “License Agreement”) with Harvard. The Collaboration Agreement concluded on March 31, 2022.

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, 2022, 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 \$74 thousand, \$293 thousand, and \$762 thousand as research and development expenses related to the License Agreement and to the Collaboration Agreement for the years ended December 31, 2022, 2021 and 2020, respectively. No withholding tax was deducted from the Company’s payments to Harvard in respect of the Collaboration Agreement and the 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 2020-2022:

The Israeli statutory corporate tax rate and real capital gains were 23% in the years 2020-2022.

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

	Year Ended December 31,		
	2022	2021	2020
Domestic	\$ (19,110)	\$ (12,780)	\$ (12,992)
Foreign	8	138	67
	<u>\$ (19,102)</u>	<u>\$ (12,642)</u>	<u>\$ (12,925)</u>

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

	Year Ended December 31,		
	2022	2021	2020
Current	\$ 151	\$ 123	\$ 95
Deferred	316	(29)	(44)
	<u>\$ 467</u>	<u>\$ 94</u>	<u>\$ 51</u>

	Year Ended December 31,		
	2022	2021	2020
Domestic	\$ -	\$ -	\$ -
Foreign	467	94	51
	<u>\$ 467</u>	<u>\$ 94</u>	<u>\$ 51</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, 2022 and 2021 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, 2022 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,	
	2022	2021
Deferred tax assets:		
Carry forward tax losses	\$ 50,833	\$ 47,323
Research and development carry forward expenses-temporary differences	844	718
Accrual and reserves	392	373
Share based compensation	456	-
Lease liabilities	214	261
Total deferred tax assets	<u>52,739</u>	<u>48,675</u>
Deferred tax liabilities:		
Right-of-use asset	(214)	(261)
Net deferred tax assets	<u>52,525</u>	<u>48,414</u>
Valuation allowance	<u>(52,525)</u>	<u>(48,098)</u>
Net deferred tax assets	<u>\$ -</u>	<u>\$ 316</u>

The net changes in the total valuation allowance for each of the years ended December 31, 2022, 2021 and 2020, are comprised as follows (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Balance at beginning of year	\$ (48,098)	\$ (42,941)	\$ (36,392)
Changes due to exchange rate differences	1,418	(1,488)	(2,929)
Adjustment previous year loss	(14)	-	-
Additions during the year	<u>(5,831)</u>	<u>(3,669)</u>	<u>(3,620)</u>
Balance at end of year	<u>\$ (52,525)</u>	<u>\$ (48,098)</u>	<u>\$ (42,941)</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,		
	2022	2021	2020
Loss before taxes, as reported in the consolidated statements of operations	\$ (19,102)	\$ (12,642)	\$ (12,925)
Statutory tax rate	23.0%	23.0%	23.0%
Theoretical tax benefits on the above amount at the Israeli statutory tax rate	\$ (4,393)	\$ (2,908)	\$ (2,973)
Income tax at rate other than the Israeli statutory tax rate	(2)	7	3
Non-deductible expenses including equity-based compensation expenses and other	262	102	185
Operating losses and other temporary differences for which valuation allowance was provided	5,375	3,669	3,620
Permanent differences	(775)	(784)	(706)
Other	-	8	(78)
Actual tax expense	\$ 467	\$ 94	\$ 51

f. Foreign tax rates:

Taxable income of RRI was subject to tax at the rate of 21% in 2022, 2021 and 2020.

Taxable income of RRG was subject to tax at the rate of 30% in 2022, 2021, and 2020.

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.

h. Tax assessments:

RRL and RRG has had final tax assessments up to and including the 2016 tax year.

RRI has had final tax assessments up to and including the 2018 tax year.

i. Net operating carry-forward losses for tax purposes:

As of December 31, 2022, RRL has carry-forward losses amounting to approximately \$220.9 million, which can be carried forward for an indefinite period.

NOTE 12: - FINANCIAL EXPENSES (INCOME), NET

The components of financial expenses (income), net were as follows (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Foreign currency transactions and other	\$ (22)	\$ (38)	\$ (9)
Financial expenses related to loan agreement with Kreos	-	-	907
Bank commissions	22	25	23
	<u>\$ *</u>	<u>\$ (13)</u>	<u>\$ 921</u>

*) Represent an amount lower than \$1.

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 based on one reportable segment and derives revenue from selling systems and services (see Note 1 for a brief description of the Company's business). The following is a summary of revenue within geographic areas (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Revenue based on customer's location:			
Israel	\$ 32	\$ -	\$ -
United States	2,303	2,519	1,746
Europe	3,057	3,381	2,631
Asia-Pacific	115	60	8
Latin America	-	-	6
Africa	4	6	2
Total revenue	<u>\$ 5,511</u>	<u>\$ 5,966</u>	<u>\$ 4,393</u>

	December 31,	
	2022	2021
Long-lived assets by geographic region:		
Israel	\$ 757	\$ 629
United States	231	493
Germany	44	43
	<u>\$ 1,032</u>	<u>\$ 1,165</u>

(*) Long-lived assets are comprised of property and equipment, net, and operating lease right-of-use assets.

Major customers data as a percentage of total revenue:

	Year Ended December 31,		
	2022	2021	2020
Customer A	14.2%	*)	10.0%
Customer B	*)	11.0%	*)

*) Less than 10%

NOTE 14: SUBSEQUENT EVENTS

In January 2023, the Company repurchased an additional 730,350 of its ordinary shares for an aggregate consideration of \$628 thousand.



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CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

- (1) Registration Statements (Form S-3 No. 333-231305, 333-260382 and 333-263984) of ReWalk Robotics Ltd.,
- (2) Registration Statements (Form S-1 No. 333-235931, 333-239733, 333-251454 and 333-254147) of ReWalk Robotics Ltd., and
- (3) Registration Statements (Form S-8 No. 333-199688, 333-221357, 333-230485, 333-239258 and 333-267284) pertaining to the ReWalk Robotics Ltd. 2006 Stock Option Plan, ReWalk Robotics Ltd. 2012 Equity Incentive Plan and ReWalk Robotics Ltd. 2014 Incentive Compensation Plan;

of our report dated February 23, 2023, with respect to the consolidated financial statements of ReWalk Robotics Ltd. included in this Annual Report (Form 10-K) of ReWalk Robotics Ltd. for the year ended December 31, 2022.

/s/ KOST FORER GABBAY & KASIERER
A Member of EY Global

February 23, 2023
Tel-Aviv

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO
EXCHANGE ACT RULE 13A-14(A)/15D-14(A)
AS ADOPTED PURSUANT TO SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002**

I, Larry Jasinski, certify that:

1. I have reviewed this annual report on Form 10-K of ReWalk Robotics Ltd. (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

/s/ Larry Jasinski
Larry Jasinski
Chief Executive Officer
(Principal Executive Officer)

Date: February 23, 2023

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO
EXCHANGE ACT RULE 13A-14(A)/15D-14(A)
AS ADOPTED PURSUANT TO SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002**

I, Mike Lawless, certify that:

1. I have reviewed this annual report on Form 10-K of ReWalk Robotics Ltd. (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

/s/ Mike Lawless
Mike Lawless
Chief Financial Officer
(Principal Financial Officer)

Date: February 23, 2023

**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**

In connection with the Annual Report of ReWalk Robotics Ltd. (the "Company") on Form 10-K for the period ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Larry Jasinski, do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Larry Jasinski

Larry Jasinski
Chief Executive Officer
(Principal Executive Officer)

Date: February 23, 2023

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

**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**

In connection with the Annual Report of ReWalk Robotics Ltd. (the "Company") on Form 10-K for the period ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Mike Lawless, do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Mike Lawless

Mike Lawless
Chief Financial Officer
(Principal Financial Officer)

Date: February 23, 2023

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.
