Registration No. 333-

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

FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

ReWalk Robotics Ltd.

(Exact name of registrant as specified in its charter)

State of Israel (State or Other Jurisdiction of Incorporation or Organization) 3842 (Primary Standard Industrial Classification Code Number) Not Applicable (I.R.S. Employer Identification No.)

3 Hatnufa St., Floor 6 Yokneam Ilit 2069203, Israel +972 (4) 959-0123

(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

ReWalk Robotics, Inc. 200 Donald Lynch Blvd. Marlborough, MA 01752 (508) 251-1154

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies of all communications, including communications sent to agent for service, should be sent to:

Colin J. Diamond, Esq. White & Case LLP 1221 Avenue of the Americas New York, NY 10020 Tel: (212) 819-8200 Aaron M. Lampert, Adv. Goldfarb Seligman & Co. 98 Yigal Alon Street Tel Aviv 6789141, Israel Tel: +972 (3) 608-9999

Approximate date of commencement of proposed sale to the public: From time to time after this Registration Statement becomes effective as determined by market conditions.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ⊠

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. \square

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. \Box

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. \Box							
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an 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 □						

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered ⁽¹⁾	Proposed maximum offering price per unit ⁽²⁾		Proposed maximum aggregate offering price	Amount of registration fee	
Ordinary shares, par value NIS 0.25 per share	5,579,776	\$	1.34	\$ 7,476,899.84	\$	815.73
Ordinary shares, par value NIS 0.25 per share, issuable upon exercise of						
outstanding warrants	4,519,619	\$	1.34	\$ 6,056,289.46	\$	660.74
Total				\$13,533,189.30	\$	1,476.47

- (1) The Registrant is hereby registering for resale from time to time by the selling shareholders named herein of up to (i) 5,579,776 ordinary shares, par value NIS 0.25 per share, and (ii) 4,519,619 ordinary shares, par value NIS 0.25 per share, issuable upon exercise of the outstanding warrants. Pursuant to Rule 416 under the Securities Act of 1933, as amended (the "Securities Act"), the securities being registered hereunder also include such indeterminate number of additional securities as may be issuable to prevent dilution resulting from stock splits, stock dividends or similar transactions.
- (2) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(c) under the Securities Act, based on the average of the high and low prices of the registrant's ordinary shares as reported on Nasdaq Capital Market on December 14, 2020, which was approximately \$1.34 per share.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to such Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. The selling shareholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities, and neither we nor the selling shareholders are soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to completion, dated December 18, 2020

PRELIMINARY PROSPECTUS



5,579,776 Ordinary Shares

4,519,619 Ordinary Shares Issuable upon Exercise of Outstanding Warrants

To Be Sold by Selling Shareholders

This prospectus relates to the resale by the selling shareholders named herein, from time to time, of up to (i) 5,579,776 ordinary shares, par value NIS 0.25 per share (the "Ordinary Shares"), and (ii) 4,519,619 ordinary shares, par value NIS 0.25 per share (the "Purchaser Warrant Shares"), issuable upon exercise of outstanding warrants ("Purchaser Warrants"). The Ordinary Shares and the Purchaser Warrants were initially issued by us in a private placement (the "Private Placement"), pursuant to the securities purchase agreement, dated as of December 3, 2020, between us and certain selling shareholders. We are also registering ordinary shares, par value NIS 0.25 per share (the "Placement Agent Warrant Shares"), issuable upon exercise of outstanding warrants issued to designees of the placement agent of our Private Placement as compensation for its services (the "Placement Agent Warrants"). The Ordinary Shares, Purchaser Warrant Shares and Placement Agent Warrant Shares are referred to herein as the "Securities." We are not registering the resale of the Purchaser Warrants or Placement Agent Warrants.

We will not receive any proceeds from the sale of Securities by the selling shareholders. We will, however, receive the proceeds of any Warrants exercised for cash in the future, which will total up to approximately \$6.2 million, based on the Warrants' exercise prices. See "Use of Proceeds" in this prospectus.

The selling shareholders may offer and sell the Securities from time to time at varying prices and in a number of different ways as each selling shareholder may determine through public or private transactions or through other means described under "Plan of Distribution." Each selling shareholder may also sell shares under Rule 144 under the Securities Act of 1933, as amended, to the extent available pursuant to the restrictions thereunder, rather than under this prospectus.

The selling shareholders will bear all commissions, discounts and concessions, if any, attributable to the sale or disposition of the Securities. Other than in connection with our indemnification obligations with respect to the selling shareholders, we will bear only the costs, expenses and fees in connection with the registration of the Securities. We will not be paying any underwriting commissions or discounts in offerings under this prospectus. For more information, see "Plan of Distribution."

Our ordinary shares are traded on the Nasdaq Capital Market under the symbol "RWLK." The last reported sales price of our ordinary shares on the Nasdaq Capital Market on December 16, 2020 was \$1.49 per ordinary share.

INVESTING IN OUR SECURITIES INVOLVES A HIGH DEGREE OF RISK. SEE "RISK FACTORS" IN THIS PROSPECTUS.

None of the Securities and Exchange Commission, the Israel Securities Authority or any state securities commission has approved or disapproved of the securities being offered by this prospectus, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

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(i)

ABOUT THIS PROSPECTUS

This prospectus relates to the resale from time to time by selling shareholders of 5,579,776 ordinary shares, par value NIS 0.25 per share, and (ii) 4,519,619 ordinary shares, par value NIS 0.25 per share, issuable upon exercise of outstanding warrants. Before buying any of the ordinary shares that the selling shareholders are offering, we urge you to carefully read this prospectus. These documents contain important information that you should consider when making your investment decision.

You should rely only on the information we have provided in this prospectus. We have not authorized anyone to provide you with different information. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. You must not rely on any unauthorized information or representation. You should assume that the information in this prospectus is accurate only as of the dates on the front of this prospectus.

For investors outside the United States: We have not done anything that would permit offerings under this prospectus, or possession or distribution of this prospectus, in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the ordinary shares and the distribution of this prospectus outside of the United States.

Unless the context clearly indicates otherwise, references in this prospectus to "we," "our," "ours," "us," "the Company" and "ReWalk" refer to ReWalk Robotics Ltd. and its subsidiaries.

PROSPECTUS SUMMARY

Overview

We are an innovative medical device company that is designing, developing and commercializing robotic exoskeletons that allow individuals with mobility impairments or other medical conditions the ability to stand and walk once again. We have developed and are continuing to commercialize our ReWalk Personal and ReWalk Rehabilitation devices for individuals with Spinal Cord Injury, which are exoskeletons designed for individuals with paraplegia that use our patented tilt-sensor technology and an on-board computer and motion sensors to drive motorized legs that power movement. We began marketing ReWalk Rehabilitation for use in hospitals, rehabilitation centers and stand-alone training centers in the United States and Europe in 2011, and we received United States Food and Drug Administration ("FDA") clearance to market ReWalk Personal in the United States in June 2014. We have also developed and began commercializing our ReStore device in June 2019, following receipt of CE mark and FDA clearance in the second quarter of 2019. ReStore is a powered, lightweight soft exo-suit intended for use in the rehabilitation of individuals with lower limb disability due to stroke. Our principal markets are the United States and Europe. In Europe, we have a direct sales operation in Germany and the United Kingdom and work with distribution partners in certain other major countries. We operate our business from our offices in Marlborough, Massachusetts, Berlin, Germany and Yokneam, Israel.

Corporate Information

We were incorporated in 2001 under the laws of the State of Israel. Our principal executive offices are located at 3 Hatnufa St., Floor 6, Yokneam Ilit 2069203, Israel, and our telephone number is +972 (4) 959-0123. Our website address is www.rewalk.com. Information contained on, or that can be accessed through, our website does not constitute a part of this prospectus and is not incorporated by reference herein. We have included our website address in this prospectus solely for informational purposes. We have irrevocably appointed our subsidiary, ReWalk Robotics Inc., which is incorporated in Delaware, as our agent to receive service of process in any action against us in any U.S. federal or state court. The address of ReWalk Robotics Inc. is 200 Donald Lynch Blvd., Marlborough, MA 01752, and its telephone number is (508) 251-1154.

ReWalk® is our registered trademark in Israel and in the United States and Restore™ is our registered trademark in Europe and the United States. Other trademarks and service marks appearing in this prospectus are the property of their respective holders.

Outstanding Shares and Warrants Issued in the December 2020 Private Placement

The shares offered in this prospectus relate to the resale by selling shareholders of an aggregate of 5,579,776 ordinary shares and 4,519,619 ordinary shares issuable upon the exercise of outstanding warrants, which were issued in our private placement of shares and warrants on December 8, 2020 (the "December 2020 Private Placement"). We sold the 5,579,776 ordinary shares (the "December 2020 Shares") to institutional investors pursuant to a securities purchase agreement between us and the investors party thereto, dated December 3, 2020 (the "December 2020 Purchase Agreement"). The outstanding warrants include:

- warrants to purchase up to 4,184,832 ordinary shares at an exercise price of \$1.34 (the "December 2020 Institutional Warrants"), which were issued to institutional investors pursuant to the December 2020 Purchase Agreement; and
- warrants to purchase up to 334,787 ordinary shares at an exercise price of \$1.7922 per share (the "December 2020 HCW Warrants"), which were issued to designees of H.C. Wainwright & Co., LLC ("H.C. Wainwright"), the placement agent of the December 2020 Private Placement, as compensation for its services.

We refer to the December 2020 Institutional Warrants and the December 2020 HCW Warrants in this prospectus collectively as the "December 2020 Warrants." All December 2020 Shares and December 2020 Warrants were issued pursuant to the exemption from the registration requirements in Section 4(a)(2) of the Securities Act of 1933, as amended, and/or Regulation D thereunder. We are filing the registration statement on Form S-1, of which this prospectus is a part, to enable the holders of the December 2020 Shares to resell such ordinary shares and the holders of the December 2020 Warrants to resell the underlying ordinary shares after exercising the warrants for cash, as well as to satisfy our resale registration obligations under our registration rights agreement, dated December 3, 2020 (the "December 2020 Registration Rights Agreement"), with the investors party thereto.

The Offering

Securities offered by the selling shareholders 5,579,776 ordinary shares and 4,519,619 ordinary shares issuable upon exercise of the outstanding December 2020 Warrants.

> 24,757,225 ordinary shares, based on the number of shares outstanding as of December 8, 2020 (which includes 5,579,776 ordinary shares issued on December 8, 2020 in the December 2020 Private Placement).

Ordinary shares to be outstanding after this offering

Ordinary shares outstanding before this offering

29,276,844 shares (assuming the exercise of all the outstanding December 2020 Warrants and the resale of all underlying ordinary shares by the selling shareholders

in offerings under this prospectus).

Use of proceeds

We will not receive any proceeds from the sale of ordinary shares by the selling shareholders. We will, however, receive the proceeds of any Warrants exercised for cash in the future. Such net proceeds will be up to approximately \$6.2 million, based on the December 2020 Warrants' exercise prices. See "Use of Proceeds" in this prospectus.

Dividend policy

Risk factors

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.

You should carefully consider the risk factors described in the section of this prospectus entitled "Risk Factors," together with all of the other information included in this prospectus, before deciding to purchase our ordinary shares.

Ordinary Shares Outstanding and Other Outstanding Warrants

The total number of ordinary shares we disclose as outstanding before this offering excludes all 4,519,619 ordinary shares underlying the December 2020 Warrants, and the total number of shares we disclose as outstanding after this offering assumes that the selling shareholders will exercise all such December 2020 Warrants prior to reselling the ordinary shares issued upon such exercises. Additionally, unless otherwise stated in this prospectus, the total number of ordinary shares outstanding both before and after this offering is based on 24,757,225 shares outstanding as of December 8, 2020 (which includes 5,579,776 ordinary shares issued on December 8, 2020 in the December 2020 Private Placement) and excludes:

- as of December 8, 2020, 1,925,222 ordinary shares reserved for issuance under our equity incentive plans, of which there were outstanding options to purchase 69,606 ordinary shares at a weighted average exercise price of \$37.9 per share, (ii) 1,256,311 ordinary shares underlying unvested restricted stock units ("RSUs"), and (iii) 599,305 ordinary shares available for future grant;
- as of December 8, 2020, 97,496 ordinary shares issuable upon the exercise of warrants to purchase ordinary shares at an exercise price of \$118.75, which were issued on November 1, 2016 in a follow-on underwritten public offering and are exercisable until November 1, 2021, subject to the terms thereof (the "November 2016 Oppenheimer Warrants");
- as of December 8, 2020, 6,679 ordinary shares issuable upon the exercise of warrants to purchase ordinary shares at an exercise price of \$7.50 per share, which were granted on December 31, 2015 and December 28, 2016 to Kreos Capital V (Expert Fund) Limited ("Kreos V"), and are currently exercisable (in whole or in part) until the earlier of (i) December 30, 2025 or (ii) an "M&A Transaction," as defined in the warrant;
- as of December 8, 2020, 126,839 ordinary shares issued upon the exercise of warrants to purchase ordinary shares at an exercise price of \$7.5 per share, which were issued on November 20, 2018 in a follow-on underwritten public offering and may be exercised until November 20, 2023, subject to the terms thereof (the "November 2018 Common Warrants");
- as of December 8, 2020, 106,680 ordinary shares issuable upon the exercise of warrants to purchase ordinary shares at an exercise price of \$9.375 per share, which were issued to the underwriters of a separate follow-on underwritten public offering on November 20, 2018 and may be exercised until November 15, 2023, subject to the terms thereof (the "November 2018 HCW Warrants");
- as of December 8, 2020, 45,600 ordinary shares issuable upon the exercise of warrants to purchase ordinary shares at an exercise price of \$7.1875 per share, which were issued to the exclusive placement agents in a follow-on "best efforts" public offering on February 25, 2019 and may be exercised until February 21, 2024, subject to the terms thereof (the "February 2019 HCW Warrants");

- as of December 8, 2020, 408,457 ordinary shares issuable upon the exercise of warrants to purchase ordinary shares at an exercise price of \$5.14 per share, which were issued to certain institutional purchasers in a private placement on April 5, 2019 and may be exercised until October 7, 2024, subject to the terms thereof (the "April 2019 Institutional Warrants");
- as of December 8, 2020, 49,015 ordinary shares issuable upon the exercise of warrants to purchase ordinary shares at an exercise price of \$6.503125 per share, which were issued to the exclusive placement agents in the private placement on April 5, 2019 and may be exercised until April 3, 2024, subject to the terms thereof (the "April 2019 HCW Warrants");
- as of December 8, 2020, 1,464,665 ordinary shares issuable upon the exercise of warrants to purchase ordinary shares at an exercise price of \$7.50 per share, which were issued to certain institutional purchasers in a private placement on June 5 and 6, 2019 and may be exercised until June 5, 2024, subject to the terms thereof (the "June 2019 Private Placement Warrants");
- as of December 8, 2020, 87,880 ordinary shares issuable upon the exercise of warrants to purchase ordinary shares at an exercise price of \$9.375 per share, which were issued to designees of the placement agent in the private placement on June 5 and 6, 2019 and may be exercised until June 5, 2024, subject to the terms thereof (the "June 5, 2019 HCW Warrants");
- as of December 8, 2020, 416,667 ordinary shares issuable upon the exercise of warrants to purchase ordinary shares at an exercise price of \$6.00 per share, which were issued to certain institutional investors in a private placement of warrants on June 12, 2019 (concurrent with our registered direct offering of ordinary shares) and may be exercised until December 12, 2024, subject to the terms thereof (the "June 2019 Institutional Warrants");
- as of December 8, 2020, 50,000 ordinary shares issuable upon the exercise of warrants to purchase ordinary shares at an exercise price of \$7.50 per share, which were issued to designees of the placement agent in the private placement on June 12, 2019 and may be exercised until June 10, 2024, subject to the terms thereof (the "June 12, HCW Warrants");
- as of December 8, 2020, 4,343,500 ordinary shares issuable upon the exercise of warrants to purchase ordinary shares at an exercise price of \$1.25 per share, which were issued in a follow-on "best efforts" public offering on February 10, 2020 and may be exercised until February 5, 2025, subject to the terms thereof (the "February 2020 Common Warrants");
- as of December 8, 2020, 336,000 ordinary shares issuable upon the exercise of warrants to purchase ordinary shares at an exercise price of \$1.5625 per share, which were issued to designees of the placement agent in the follow-on "best efforts" public offering on February 10, 2020 and may be exercised until February 5, 2025, subject to the terms thereof (the "February 2020 HCW Warrants");
- as of December 8, 2020, 2,469,139 ordinary shares issuable upon the exercise of warrants to purchase ordinary shares at an exercise price of \$1.76 (the "July 2020 Institutional Warrants"), which were issued to institutional investors pursuant to a securities purchase agreement between us and the investors party thereto, dated July 1, 2020; and
- as of December 8, 2020, 296,297 ordinary shares issuable upon the exercise of warrants to purchase ordinary shares at an exercise price of \$2.2781 per share (the "July 2020 HCW Warrants"), which were issued to designees of the placement agent of the July 2020 Warrants Private Placement, as compensation for its services.

RISK FACTORS

An investment in our securities involves risks. Our business, financial condition or results of operations could be materially and adversely affected by any of these risks. If any of these risks occur, the value of our ordinary shares and our other securities may decline. You should carefully consider the risk factors set forth herein, as well as other information contained or incorporated by reference herein or any applicable prospectus supplement hereto, before making a decision to invest in our securities. See "Incorporation of Certain Documents by Reference." Such risk factors include the following, among certain other factors:

- our management's conclusion, and our independent registered public accounting firm's statement in its opinion relating to our consolidated financial statements for the fiscal year ended December 31, 2019, that there is a substantial doubt as to our ability to continue as a going concern;
- the adverse effect that the current coronavirus (COVID-19) pandemic has had and may continue to have on our business and results of operations;
- our ability to have sufficient funds to meet certain future capital requirements, which could impair our efforts to develop and commercialize
 existing and new products;
- our ability to maintain compliance with the continued listing requirements of the Nasdaq Capital Market and the risk that our ordinary shares will be delisted if we cannot do so;
- the risk of a cybersecurity attack or breach of our IT systems significantly disrupting our business operations;
- · 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 for our products;
- our limited operating history and our ability to leverage our sales, marketing and training infrastructure;
- 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 repay our secured indebtedness;
- 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 ReWalk's ability to market
 and sell its products;
- our ability to gain and maintain regulatory approvals;
- our expectations as to the results of the FDA, potential regulatory developments with respect to our mandatory 522 postmarket surveillance study;
- our ability to maintain adequate protection of our intellectual property and to avoid violation of the intellectual property rights of others;
- our ability to establish a pathway to commercialize our products in China;
- 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; and
- market and other conditions.

Risks Related to Our Business and Our Industry

We have concluded that there are substantial doubts as to our ability to continue as a going concern.

As of September 30, 2020, we had an accumulated deficit in the total amount of approximately \$179 million and anticipate further losses in the development of our business. Those factors raise substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern depends upon our obtaining the necessary financing to meet our obligations and timely repay our liabilities arising from normal business operations. The financial statements have been prepared assuming that we will continue to operate as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Our auditors also included an explanatory paragraph to their audit opinion relating to our accompanying consolidated financial statements for the fiscal year ended December 31, 2019 regarding the substantial doubts about the Company's ability to continue as a going concern. If we are unable to secure additional capital, which might also be harder to obtain due to current market conditions and the COVID-19 pandemic, we may be required to take additional measures to reduce costs in order to conserve our cash in amounts sufficient to sustain operations and meet our obligations. If we become insolvent, investors in our securities may lose the entire value of their investment in our business. The accompanying financial statements do not include any adjustments that may be necessary should we be unable to continue as a going concern, and it is not possible for us to predict at this time the potential success of our business.

A pandemic, epidemic or outbreak of an infectious disease, such as COVID-19, has adversely affected and may continue to materially and adversely impact our business, our operations and our financial results.

The impact of the COVID-19 pandemic has resulted in and will likely continue to result in significant disruptions to the global economy, as well as businesses and capital markets around the world. In an effort to halt the outbreak of COVID-19, a number of countries, including the United States and Germany where we have key operations, placed significant restrictions on travel, and many businesses announced extended closures. It is unclear how long total or partial shutdowns may last and whether additional shutdowns will be necessary to the extent future outbreaks occur.

The COVID-19 outbreak has had, and a continuing outbreak or future outbreaks may have, several adverse effects on our business, results of operations and financial condition.

Sales. In particular, the steps we have taken to safeguard employees and patients have curtailed direct sales activities, including our ability to train patients and rehabilitation centers on how to use our system, which has adversely impacted our revenues in 2020. The overall impact of the limitations on our sales efforts are currently hard to determine because, in addition to the short-term impacts, we are unable to interact and test our system with potential new patients at the same levels that we have before the COVID-19 outbreak. It may take an extended period after current restrictions end for us to engage potential new clients. We continue to monitor our sales pipeline on a day-to-day basis in order to assess the quarterly effect of these limitations as some have short term effects and some affects our future pipeline development

Repairs. In addition, we have been unable to repair existing systems with the result that we have had to ship temporary replacement systems in some cases. We cannot be certain when social distancing restrictions will be fully lifted and, once they are fully lifted, whether sales of our systems will offset the revenue that we have forgone earlier in the year. We also cannot be certain that social distancing restrictions or other measures will not be reinstated in the event of a future outbreak of COVID-19 or similar outbreak.

Production and Supply Chain. Our manufacturing may be impacted due to supply chain delays or adverse impacts on our production capacity due to government directives or health protocols that might impact our production facility. In addition, given the impact of current limitations on our sales activities, it has become hard for us to effectively forecast our future requirements for systems. Accordingly, there is a greater risk that we may overproduce or underproduce compared to sales.

Regulatory and clinical trials. Limitations on travel and business closures recommended by federal, state, and local governments, could, among other things, impact our ability to enroll patients in clinical trials, recruit clinical site investigators, and obtain timely approvals from local regulatory authorities. In our postmarket study that we continue to conduct, we may face decreased ability to contact patients where a patient's COVID-19 status is unknown. Regulatory oversight and actions regarding our products have been and may continue to be disrupted or delayed in regions impacted by COVID-19, including the United States and Europe, which have been and may continue to impact review and approval timelines for products in development and/or changes to existing products that need regulatory review and approval.

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

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

We may not have sufficient funds to meet certain future capital requirements, which could impair our efforts to develop and commercialize existing and new products, and may need to take advantage of various forms of capital-raising transactions, future equity financings, strategic transactions or borrowings may also further dilute our shareholders or place us under restrictive covenants limiting our ability to operate.

We intend to finance operating costs over the next 12 months with existing cash on hand, continued close examination of our operating spend and potential reduction in specific areas, issuances of equity and/or debt securities, and other future public or private issuances of securities, or through a combination of the foregoing. Through equity transactions completed in 2019 and 2020 to date we have raised in the aggregate approximately \$60.7 million in gross proceeds. However, we will need to seek additional sources of financing if we require more funds than anticipated during the next 12 months or in later periods, including if we cannot make loan repayments under our loan agreement with Kreos V or we cannot raise sufficient funds from equity issuances. The alternative capital-raising transactions we may seek may entail significant downsides, due to limitations on use of our Form S-3 and under our at-the-market offering program with Piper Jaffray & Co., or the ATM Offering Program. For instance, under the Purchase Agreement, we have agreed for a period of one year following December 3, 2020 not to (i) issue or agree to issue equity or debt securities convertible into, or exercisable or exchangeable for, Ordinary Shares at a conversion price, exercise price or exchange price which floats with the trading price of the Ordinary Shares or which may be adjusted after issuance upon the occurrence of certain events or (ii) enter into any agreement, including an equity line of credit, whereby the Company may issue securities at a future-determined price, other than an at-the-market facility with the Placement Agent thirtyfive (35) days after the effective date of the registration statement of which this prospectus forms part. 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" in our Quarterly on Form 10-Q for the quarterly period ended September 30, 2020 filed with the SEC on November 10, 2020 (the "Q3 2020 Form 10-Q").

To raise additional capital in the public markets, including taking into account the limitations on our Form S-3 use as discussed above, we will likely be required to seek and are currently actively seeking other methods, such as a registration statement on Form S-1. The preparation of a registration statement on Form S-1 is more time-consuming and costly. We may also conduct fundraising transactions in the form of private placements, potentially with registration rights or priced at a discount to the market value of our ordinary shares, which could require shareholder approval under the rules of Nasdaq, or other equity raise transactions such as equity lines of credit. In addition to entailing increased capital costs, any such transactions could result in substantial dilution of our shareholders' interests, transfer control to a new investor and diminish the value of an investment in our ordinary shares.

We may also need to pursue strategic transactions, such as joint ventures, in-licensing transactions or the sale of our business or all or substantially all of our assets. We are in discussions routinely with such possible sources of additional funding. These private financings and 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. Agreements governing any borrowing arrangement may also contain covenants that could restrict our operations.

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. Further, external perceptions regarding our ability to continue as a going concern may make it more difficult for us to obtain financing for the continuation of our operations or require us to obtain financing on terms that are more favorable to investors, and could result in the loss of confidence by investors and suppliers. As such, our failure to continue as a going concern could harm our business, operating results and financial position and severely affect the value of your investment.

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

As previously disclosed, on March 24, 2020, we received a notification letter from Nasdaq stating that we failed to comply with the closing bid price requirement of Nasdaq Rule 5550(a) ("Rule 5550(a)"). If our closing bid price is less than \$1 per share for 30 consecutive business days, we will be deficient with Rule 5550(a). On May 11, 2020, we received a notice from Nasdaq stating that we have regained compliance with Rule 5550(a) since our share price was above \$1 for 10 consecutive business days and that the matter is now closed. Our closing share price as of December 14, 2020 was \$1.36 If we become noncompliant with Rule 5550(a) in the future (absent any relief, such as the temporary relief imposed by Nasdaq during the ongoing COVID-19 pandemic) and we fail to regain compliance with Rule 5550(a) during the rule's applicable cure period, Nasdaq will notify us that our ordinary shares are subject to delisting. In the case of non-compliance, there can be no assurance that we will be able to regain compliance with the applicable rules.

Additionally, as previously disclosed, in October 2018, we received a notification letter from Nasdaq stating that, under Nasdaq Rule 5550(b), or Rule 5550(b), we failed to comply with the minimum \$35 million market value of listed securities requirement for continued listing on the Nasdaq Capital Market as of October 26, 2018 and did not meet the rule's alternative \$2.5 million shareholders' equity and \$500,000 net income standards as of applicable balance sheet and income statement dates. We regained compliance with Rule 5550(b) in April 2019. Our shareholders' equity was \$16.8 million as of September 30, 2020. However, if our quarterly or annual report for a subsequent fiscal period does not evidence such compliance, we may become immediately subject to delisting without a cure period. For example, if we cannot maintain the requisite cash levels for a compliant amount of shareholders' equity, our ordinary shares may be at serious risk of immediate delisting.

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

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

We are currently engaged in research and development efforts to address the needs of patients with mobility impairments besides paraplegia, such as stroke, and, in the future, we may engage in efforts to address these needs in patients with other conditions such as multiple sclerosis, cerebral palsy Parkinson's disease and elderly assistance. We also began commercializing in 2019 our first product for stroke patients, the ReStore. For more information, see "Part, Item 1. Business—ReStore Products" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, as filed with the SEC on February 20, 2020 (the "2019 Form 10-K"). In addition to other research and development projects, we currently collaborate with Harvard University's Wyss Institute for Biologically Inspired Engineering to design, research and develop lightweight exoskeleton system technologies for lower limb disabilities intended to treat stroke, multiple sclerosis, mobility limitations for the elderly and other medical applications. As part of the collaboration, Harvard has also licensed to us certain of its intellectual property relating to lightweight exoskeleton system technologies for lower limb disabilities. We are obligated to use commercially reasonable efforts to develop products under the license in accordance with an agreed-upon development plan and to introduce and market such products commercially.

We expect that a portion of our revenues will be derived, in the next few years, from the ReStore soft suit exoskeleton product and, in later years, if we chose to advance the current designs, from other new products such as a home use device for stroke patients or new products of ours aimed at addressing other medical indications which affect the ability to walk, including multiple sclerosis, cerebral palsy, Parkinson's disease and elderly assistance. As such, our future results will depend on our ability to successfully develop and commercialize such new products. We cannot ensure you that we will be able to introduce new products, products currently under development and products contemplated for future development for additional indications in a timely manner, or at all as it depends on our available resources to fund such projects While we received governmental clearance to market our ReStore product on the anticipated timetable in 2019, obtaining clearance for any other soft suit exoskeleton products we may develop could involve an extensive, costly and time-consuming process, which would delay any planned commercialization. For more information on the clearance processes, see "Part I, Item 1. Business—Government Regulation" in our 2019 Form 10-K.

Harvard may also terminate its license agreement with us if we fail to obtain 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. 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 the customer. We may also be unable to gain necessary regulatory approvals to enable us to market new products for additional indications or the regulatory process may be more costly and time-consuming than expected, which could adversely impact us given our cash position and ongoing capital requirements. We might also terminate or change our research collaboration agreement with Harvard if we see limited market to the current developed products or seek to focus our available resources to other areas of the business.

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

While our new products currently under development will share some aspects of the core technology platform in our current products, their design features and components may differ from our current products. Accordingly, these products will also be subject to the risks described under "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 or generate sufficient revenues from such contracts." To the extent we are unable to successfully develop and commercialize products to address indications other than paraplegia, we will not meet our projected results of operations and future growth.

We rely on sales of our ReWalk and ReStore systems and related service contracts and extended warranties for our revenue. We may not be able to achieve or maintain market acceptance of our ReWalk or ReStore systems, or to generate sufficient revenues from these current and future products.

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

• ReWalk. We have sold only a limited number of ReWalk systems, and market acceptance and adoption depend on educating people with limited upright mobility and health care providers as to the distinct features, ease-of-use, positive lifestyle impact and other benefits of ReWalk compared to alternative technologies and treatments. ReWalk may not be perceived to have sufficient potential benefits compared with these alternatives. Users may also choose other therapies due to disadvantages of ReWalk, including the time it takes for a user to put on ReWalk, the slower pace of ReWalk compared to a wheelchair, the weight of ReWalk when carried, which makes it more burdensome for a companion to transport than a wheelchair, and the requirement that users be accompanied by a trained companion. Also, we believe that healthcare providers tend to be slow to change their medical treatment practices because of perceived liability risks arising from the use of new products and the uncertainty of third-party reimbursement. Accordingly, healthcare providers may not recommend ReWalk until there is sufficient evidence to convince them to alter the treatment methods they typically recommend, such as prominent healthcare providers or other key opinion leaders in the spinal cord injury community recommending ReWalk as effective in providing identifiable immediate and long-term health benefits.

In addition, we may be unable to sell on a profitable basis current ReWalk systems or other future products for home and community use if third-party payors deny coverage, limit reimbursement or reduce their levels of payment, or if our costs of production increase faster than increases in reimbursement levels. Several private and national insurers in the United States and Europe have provided reimbursement for ReWalk in certain cases to date, the VA maintains its policy of covering the cost of ReWalk devices for qualifying veterans across the United States and German insurers such as Germany's national social accident insurance provider, Deutsche Gesetzliche Unfallversicherung (the "DGUV") indicated that its member payers will approve the supply of exoskeleton systems for qualifying beneficiaries on a case-by-case basis as the ReWalk device was issued a code in the medical device directory in Germany and in 2020 we announced that we accepted a binding offer with the DGUV to supply our ReWalk Personal 6.0 to qualified patients as well as with other payors in Germany. However, no broad uniform policy of coverage and reimbursement for electronic exoskeleton medical technology exists among third-party payors in the United States and Germany. Health insurance companies and other third-party payors in the future may also not deliver adequate coverage or reimbursement for our current or future products designed for home and community use. The VA or DGUV or other payors may cancel or materially curtail their current policy of providing coverage ReWalk devices in the United States and Germany for qualifying individuals who have suffered spinal cord injury, or we may not place enough units through to make our sales profitable under the their policies. For more information, see "-Risks Related to our Business and our Industry- We may fail to secure or maintain adequate insurance coverage or reimbursement for our products by third-party payors, which risk may be heightened if insurers find the products to be investigational or experimental or if new government regulations change existing reimbursement policies. Additionally, such coverage or reimbursement, even if maintained, may not produce revenues that are high enough to allow us to sell our products profitably."

• *ReStore*. The ReStore system is designed to provide advantages to stroke rehabilitation clinics and therapists as compared to other traditional therapies and devices by minimizing setup time, improving patients' clinical results during therapy, supplying real-time analytics to optimize session productivity and generating ongoing data reports to assist with tracking patient progress. Other potential secondary benefits for rehabilitation clinics include reducing staffing requirements, staff fatigue and the risk for potential staff injuries. Since the ReStore device is currently being used only in the rehabilitative clinical setting, its market reception will depend heavily on our ability to demonstrate to clinics and therapists the systemic and economic benefits of using the ReStore device, its clinical advantage when compared to other devices or manual therapy, the functionality of the device for a significant portion of the patients that they treat and the overall advantages that the device provides to their patients compared to other technologies.

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

We obtained FDA clearance for our ReStore system in June 2019. This clearance permits 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 contraindicates 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, 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, or NSCISC, estimates that as of 2019 there were 291,000 people in the United States living with SCI, and that the annual incidence of SCI cases is approximately 17,730 new cases per year. Based on information from a 2017 report by the NSCISC, 40.6% of the total U.S. population of SCI patients suffered injuries between levels T4 and L5. Three published ReWalk trials with respect to such eligible SCI patients had an aggregate screening acceptance rate of 79% considering all current FDA limitations, resulting in an estimated 33% of the total population of SCI patients being medically qualified candidates for current ReWalk products under its medical labeling criteria. There are other factors that affect the market size such as patient motivation, ability to use the device in the user's current home environment and companion support, which limits the number of potential eligible users. 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, skilled nursing facilities and rehabilitation clinics providing therapy in the U.S. for example we believe that only a portion of the clinics will decide 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" in our 2019 Form 10-K.

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

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

We expect that in the future a significant source of payment for ReWalk systems will be private insurance plans and managed care programs, government programs such as the VA, Medicare and Medicaid, worker's compensation and other third-party payors. We have similar expectations for our ReStore product, although we possess less information regarding the payment by third-party payors for this product as we only began commercializing it in 2019.

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

Generally, private insurance companies do not cover or provide reimbursement for any medical exoskeleton products for personal use, including ReWalk Personal, and may ultimately provide no coverage at all. For instance, during 2017 we submitted a proposal to a large U.S. national insurance provider for a broader coverage policy for the ReWalk Personal device. While we believe there was support for a change, the insurer was unable to reach internal consensus and therefore elected not change its existing non-coverage policy. Additionally, there is limited clinical data related to 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. For example, Aetna has determined that certain lower-limb prostheses, including ReWalk, are experimental and investigational because there is inadequate evidence of their effectiveness. Additionally, the majority of independent medical review decisions made following the denial of ReWalk coverage have determined that ReWalk is experimental and/or investigational, citing a lack of clinical data.

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

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

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

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

Although we were incorporated in 2001, we did not begin selling ReWalk Rehabilitation until 2011, and we did not begin selling ReWalk Personal in Europe until 2012. We began selling ReWalk Personal in the United States in the third quarter of 2014, as we received FDA clearance to do so in June 2014. We began selling our ReStore product in the United States and Europe in June 2019 following receipt of FDA and CE mark clearance, respectively. Therefore, we have limited operating history upon which you can evaluate our business plan and prospects. Our business plan and prospects must be considered in light of the potential problems, delays, uncertainties and complications encountered in connection with a more newly established business. The risks include, but are not limited to, that:

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

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

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

A key element of our long-term business strategy is the continued leveraging of our sales, marketing, training and reimbursement infrastructure, through the training, retaining and motivating of skilled sales and marketing representatives and reimbursement personnel with industry experience and knowledge. Our ability to derive revenue from sales of our products depends largely on our ability to market the products and obtain reimbursements for them. In order to continue growing our business efficiently, we must therefore coordinate the development of our sales, marketing, training and reimbursement infrastructure with the timing of regulatory approvals, decisions regarding reimbursements, limited resources consideration and other factors in various geographies. Managing and maintaining our sales and marketing infrastructure is expensive and time consuming, and an inability to leverage such an organization effectively, or in coordination with regulatory or other developments, could inhibit potential sales and the penetration and adoption of our products into both existing and new markets. However, certain decisions we make regarding staffing in these areas in our efforts to maintain an adequate spending level could have unintended negative effects on our revenues, such as by weakening our sales infrastructure, impairing our reimbursement efforts and/or harming the quality of our customer service. As we have done throughout the past several years, we intend to continue to evaluate our spending throughout 2020 and focus our resources in areas we believe will support our growth.

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

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

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

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

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

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

We also rely on third-party suppliers, which contract directly with Sanmina, to supply certain components of our products, and in some cases we purchase these components ourselves. Sanmina does not have long-term supply agreements with most of its suppliers and, in many cases, makes purchases on a purchase order basis. Sanmina's ability to secure adequate quantities of such products may be limited. Suppliers may encounter problems that limit their ability to manufacture components for our products, including financial difficulties or damage to their manufacturing equipment or facilities. If Sanmina fails to obtain sufficient quantities of high quality components to meet demand on a timely basis, we could lose customer orders, our reputation may be harmed and our business could suffer.

Our results of operations and liquidity could be adversely impacted by supply chain disruptions and operational challenges faced by our manufacturer or suppliers. Sanmina generally uses a small number of suppliers for ReWalk and ReStore. Depending on a limited number of suppliers exposes us to risks, including limited control over pricing, availability, quality and delivery schedules. Such risks are heightened in light of the interruptions in supply chains and distribution networks related to the COVID-19 pandemic. If any one or more of our suppliers ceases to provide sufficient quantities of components in a timely manner or on acceptable terms, Sanmina would have to seek alternative sources of supply. It may be difficult to engage additional or replacement suppliers in a timely manner. Failure of these suppliers to deliver products at the level our business requires would limit our ability to meet our sales commitments, which could harm our reputation and could have a material adverse effect on our business. Sanmina also may have difficulty obtaining similar components from other suppliers that are acceptable to the FDA or other regulatory agencies, and the failure of Sanmina's suppliers to comply with strictly enforced regulatory requirements could expose us to regulatory action including warning letters, product recalls, termination of distribution, product seizures or civil penalties. It could also require Sanmina to cease using the components, seek alternative components or technologies and we could be forced to modify our products to incorporate alternative components or technologies, which could result in a requirement to seek additional regulatory approvals. Any disruption of this nature or increased expenses could harm our commercialization efforts and adversely affect our operating results.

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

There are several other companies developing technology and devices that compete with our products. Our principal competitors in the medical exoskeleton market consist of Ekso Bionics, Parker Hannifin, FREE Bionics, Rex Bionics, Cyberdyne, and others. These companies have products currently available for institutional use and in some cases personal use. We expect some of such products to become available for personal use in the next few years. In addition, we compete with alternative devices and alternative therapies, including treadmill-based gait therapies, such as those offered by Hocoma, AlterG, Aretech, Reha Technology and Bioness. Our competitor base may change or expand as we continue to develop and commercialize our soft suit exoskeleton product in the future. These or other medical device or robotics companies, academic and research institutions, or others, may develop new technologies or therapies that provide a superior walking 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.

In the event that we default under the Loan Agreement with Kreos, Kreos could foreclose on its lien and take possession over all of our assets.

On December 30, 2015, we entered into the Loan Agreement with Kreos, pursuant to which Kreos extended a line of credit to us in the amount of \$20.0 million. On January 4, 2016, we drew down \$12.0 million and on December 28, 2016, we drew down the remaining \$8.0 million. The principal amount of each drawdown was initially repayable monthly over a period of 24 months commencing 12 months after the applicable drawdown date, which period would be extended to 36 months if we raise \$20.0 million or more in connection with the issuance of shares of our capital stock (including debt convertible into shares of our capital stock) before the respective 24-month period expires. Interest on each drawdown is payable monthly in arrears at a rate of 10.75% per year from the applicable drawdown date through the date on which all such principal is repaid. In mid-2017, the Company had raised more than \$20.0 million and therefore the repayment period was extended by an additional 12 months to 36 months. On November 20, 2018, the Company and Kreos amended the Loan Agreement, where the Company repaid Kreos the \$3.6 million covering a convertible note under the loan and "end of loan" payments by issuing equity interest to Kreos as part of the Company's public offering. The Company and Kreos also agreed to revise the principal and the repayment schedule under the Kreos Loan Agreement to account for payment deferrals, for total deferred payments of \$3.9 million compared to the prior repayment schedule. As of September 30, 2020, the outstanding principal amount under the Kreos Loan Agreement was \$3.0 million, with the loan scheduled to be repaid in full by March 31, 2021.

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 our subsidiaries, subject to certain permitted security interests. For more information, see "Part 2. Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources" and our consolidated financial statements and the related notes thereto, in each case, in our Q3 2020 Form 10-Q. In the event that we are unable to make the interest payments when due under the Loan Agreement or to pay the outstanding principal amount following the termination of the Loan Agreement, Kreos could take actions under the Loan Agreement and seek to take possession of or sell our assets to satisfy our obligations thereunder. Any of these actions would have an immediate material adverse effect on our business, operating results and financial condition.

We utilize independent distributors who are free to market products that compete with 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 a meaningful percentage of our sales will continue to be generated by independent distributors in the future. None of our independent distributors has been required to sell our products exclusively. Our distributor agreements generally have one-year initial terms and automatic renewals for an additional year. If any of our key independent distributors were to cease to distribute our products, our sales could be adversely affected. In such a situation, we may need to seek alternative independent distributors or increase our reliance on our other independent distributors or our direct sales representatives, which may not prevent our sales from being adversely affected. Additionally, to the extent that we enter into additional arrangements with independent distributors to perform sales, marketing, or distribution services, the terms of the arrangements could cause our product margins to be lower than if we directly marketed and sold our products.

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

All manufacturing and assembly of our products is conducted at a single facility of our contract manufacturer, Sanmina, located in Ma'alot, Israel. Accordingly, we are highly dependent on the uninterrupted and efficient operation of this facility. If operations at this facility were to be disrupted as a result of equipment failures, earthquakes and other natural disasters, fires, accidents, work stoppages, power outages, acts of war or terrorism or other reasons, our business, financial condition and results of operations could be materially adversely affected. In particular, this facility is located in the north of Israel within range of rockets that have from time to time been fired into the country during armed conflicts with Hezbollah and other armed groups in Lebanon, 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 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 two-year warranty for parts and services, other than for normal wear and tear. We also provide customers with the option to purchase an extended warranty for up to an additional three years. In the beginning of 2018 we updated our service policy for new devices sold to include a 5-year warranty. 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.

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 approvals.

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

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

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

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

- identify the product features that people with paraplegia or paralysis, their caregivers and healthcare providers are seeking in a medical device that restores upright mobility and successfully incorporate those features into our products;
- 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 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 or partnerships with third-parties that may not result in the development of commercially viable products or the generation of significant future revenues.

In the ordinary course of our business, we may enter into collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships 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. We may not identify, secure, or complete any such transactions or arrangements in a timely manner, on a cost-effective basis, on acceptable terms or at all. We have limited institutional knowledge and experience with respect to these business development activities, and we may also not realize the anticipated benefits of any such transaction or arrangement. In particular, these collaborations may not result in the development of products that achieve commercial success or result in significant revenues and could be terminated prior to developing any products. For example, we have entered into agreements with MediTouch and Myolyn for the distribution of their products in the U.S. We also collaborate with Harvard University's Wyss Institute for Biologically Inspired Engineering for the research, design, development and commercialization of lightweight exoskeleton system technologies for lower limb disabilities, aimed to treat stroke, multiple sclerosis, mobility limitations for the elderly and other medical applications. Our arrangements with MediTouch, Myolyn and Harvard, may not be as productive or successful as we hope.

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

Timwell's and its affiliates' material breaches of their agreements with us will force us to find alternative financing and alternative means to penetrate the Chinese market.

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

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

The closings of the Second Tranche and Third Tranche were subject to specified closing conditions, including the formation of a joint venture, the signing of a license agreement and a supply agreement, and the successful production of certain ReWalk products. The Third Tranche Closing was to have occurred by December 31, 2018 and no later than April 1, 2019. We believe that Timwell committed various material breaches of the Investment Agreement, including failure to consummate its second and third investment tranches in the Company for a total of \$15 million, failure to enter into a detailed joint venture with the Company, and failure to make payments for product-related commitments. Nevertheless, until March 2020 we continued to engage in a dialogue with Timwell (and its affiliate RealCan) on alternative pathways to allow us to commercialize our products in China through RealCan and its affiliates, and also provide for RealCan or an affiliate to invest in us. In late March 2020, Timwell notified us that it would not invest the second and third tranches under the Investment Agreement. In response, in early April 2020, our Board of Directors also removed Timwell's designee, who was appointed pursuant to the Investment Agreement, from the Board of Directors, due to this breach pursuant to the terms of the Investment Agreement. Due to these developments with Timwell, we could face further financial losses stemming from threatened or actual claims brought against us and/or reputational harm. Although no such claims have been asserted to date, we cannot make any assurance that we will not face them in the future.

We continue to view China as a market with key opportunities for products designed for stroke patients, and therefore we continue to evaluate potential relationships with other groups to penetrate the Chinese market. We are also evaluating potential relationships with other groups to penetrate the Chinese market. However, downturns in trade between the United States and China and the impact of public health epidemics like the coronavirus could have an adverse effect on our ability to penetrate the Chinese market and a material impact on the success of any ventures in China. For more information, see "—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."

Risks Related to Government Regulation

We have submitted medical device reports, or MDRs, to the FDA (and equivalent authorities outside of the United States) for numerous serious injuries relating to use of the ReWalk Personal system, and conducted a voluntary correction related to certain use instructions in the device's labeling, which the FDA classified as a Class II recall. If our product may have caused or contributed to a death or a serious injury, or if our product malfunctioned and the malfunction's recurrence would be likely to cause or contribute to a death or serious injury, we must comply with the FDA's MDR regulations (and equivalent authorities outside of the United States), which could result in voluntary corrective actions or enforcement actions, such as mandatory recalls.

Under the FDA's MDR regulations, we are required to report to the FDA information that reasonably suggests a product we market may have caused or contributed to a death or serious injury or malfunctioned and our product or a similar device marketed by us would be likely to cause or contribute to death or serious injury if the malfunction were to recur. In addition, all manufacturers placing medical devices on the market in the European Union are legally bound to report any serious or potentially serious incidents involving devices they produce or sell to the relevant authority in whose jurisdiction the incident occurred. Between 2013 and 2017, we submitted a number of MDRs to the FDA to report incidents in which ReWalk Personal users sustained falls or fractures. The FDA sent us letters requesting additional information relating to these MDRs submitted in 2017, including a request for a failure analysis. In August 2017, we initiated a voluntary correction for the ReWalk device that related to certain use instructions to reduce the risk of tibia/fibula fractures and submitted a report to the FDA under 21 CFR Part 806. Under Part 806, manufacturers and importers are required to make a report to the FDA of any correction or removal of a device if the correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the U.S. Federal Food, Drug, and Cosmetic Act caused by the device that may present a risk to health.

In June 2018, we received a letter from the FDA agreeing with our decision to initiate a corrective action for the ReWalk, classifying the recall action as a Class II recall, and requesting that we make regular status reports to the FDA regarding our progress. While the FDA has statutory authority to require a recall, most recalls are undertaken voluntarily when a medical device is defective, when it could present a risk to health, or when it is both defective and presents a risk to health. In January 2019, we submitted a recall termination request to the FDA. In November 2019 the FDA informed us that it considered the recall action terminated. In September 2018, we submitted to the FDA revised labeling that incorporates the revised use instructions intended to prevent the tibia/fibula fractures as a special 510(k). The special 510(k) was not accepted by FDA because it was administratively incomplete, and we withdrew the submission. In January 2020 we submitted a new 510(k) to the FDA for both the revised labeling/use instructions and additional changes to the device. This new 510(k) was not accepted by FDA because it was administratively incomplete and, accordingly, FDA notified ReWalk on January 22, 2020 of the Refuse-to-Accept (RTA) designation. The company was in communication with the FDA and has resubmitted an updated 510(k) in February 2020 which was cleared on May 27, 2020. In September 2019, we also submitted a revised technical file with the additional device changes to the EU notified body and were notified in December 2019 that the extension of our certification had been granted.

In 2018, we submitted additional MDRs for tibia/fibula fractures that occurred in foreign countries between 2015 and 2018. In addition, in 2018 and 2019 we submitted MDRs for tibia/fibula fractures that occurred in the United States and Europe. In 2020 we submitted an MDR for tibial fractures that occurred in the United States. Additional fractures or other adverse events may occur in the future that may require us to report to the FDA pursuant to the MDR regulations (or other governmental authorities pursuant to equivalent outside of the United States regulations), and/or to initiate a removal, correction, or other action. Any adverse event involving our products could result in future voluntary corrective actions, such as recalls or customer letters, or in an FDA enforcement action, such as a mandatory recall, notification to healthcare professionals and users, warning letter, seizure, injunction or import alert. 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.

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

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

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

While we addressed the observations that the FDA cited in a 2015 warning letter related to our mandatory post-market surveillance study and initiated the study, we are currently experiencing enrollment issues that make our study progress inadequate and our modified protocol (intended to overcome the enrollment issues so that we may complete the study, as required) has not yet been approved by FDA. Going forward, if we cannot meet certain FDA requirements and enrollment criteria for the study or otherwise satisfy FDA requests promptly, or if our study produces unfavorable results, we could be subject to additional FDA warnings letters or more significant enforcement action, which could materially and adversely affect our commercial success.

We are conducting an ongoing mandatory FDA postmarket surveillance study on our ReWalk Personal 6.0, which began in June 2016. Before we began the current study, the FDA sent us a warning letter on September 30, 2015, ("the September 2015 Warning Letter"), threatening potential regulatory action against us for violations of Section 522 of the U.S. Federal Food, Drug, and Cosmetic Act, based on our failure to initiate a postmarket surveillance study by the September 28, 2015 deadline, our allegedly deficient protocol for that study, and the lack of progress and communication regarding the study. Between June 2014 and our receipt of the September 2015 Warning Letter, we had responded late to certain of the FDA's requests related to our study protocol. In February 2016, the FDA sent us an additional information request, or the February 2016 Letter, requesting additional changes to our study protocol and asking that we amend the study within 30 days. This letter also discussed the FDA's request, as further discussed in later communications with the FDA, for a new premarket notification for our ReWalk device, or a special 510(k), linked to what the FDA viewed as changes to the labeling and the device, including to a computer included with the device. In late March 2016, following multiple discussions with the FDA, including an in-person meeting, the FDA confirmed that the agency would permit the continued marketing of the ReWalk device conditioned upon our timely submitting a special 510(k) and initiating our postmarket surveillance study by June 1, 2016. The special 510(k) was timely submitted on April 8, 2016, and the FDA's substantial equivalence determination was received by us on July 22, 2016, granting us permission to continue marketing the ReWalk device. Additionally, we submitted a protocol to the FDA for the postmarket surveillance study that was approved by the FDA on May 5, 2016.

We began the study on June 13, 2016, with Stanford University as the lead investigational site. In August 2016, the FDA sent us a letter stating that, based on its evaluation of our corrective and preventive actions in response to the September 2015 Warning Letter, it appeared we had adequately addressed the violations cited in the September 2015 Warning Letter. As part of our study, we provided the FDA with the required periodic reports on the study's progress, in a few cases with delay, and we intend to continue providing the FDA with periodic reports as required. Through these reports, we made the FDA aware that due to enrollment issues, we were unable to satisfy the target enrollment specified in the original study protocol. As of December 8, 2020, we had three active centers participating in the study (one site is closed and another site is on hold), but only two sites have successfully enrolled patients. Twelve subjects have enrolled in the study, two have completed the study, and three are using the device in the community. This is substantially below the required number of patients included in our original study protocol.

In March 2020, FDA approved a modified postmarket study protocol that will supplement data from the clinical study with real-world evidence and the study status was updated to progress adequate in September 2020. ReWalk is actively collecting the real-world evidence in order to fulfill the postmarket study order requirements. However, despite the revised study protocol there can be no assurance that we will be able to satisfy the post-market study requirements. Additionally, we are experiencing some study disruptions due to COVID-19 pandemic If we cannot meet FDA requirements for the post-market study or timely address requests from the FDA related to the study, or if the results of the study are not as favorable as we expect, the FDA may issue additional warning letters to us, impose limitations on the labeling of our device or require us to stop marketing the ReWalk Personal device in the United States. We derived 41.4% of our revenues in the year ended December 31, 2019 from sales of the ReWalk device in the United States and, if we are unable to market the ReWalk device in the United States, we expect that these sales would be adversely impacted, which could materially adversely affect our business and overall results of operations.

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

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

Our marketing and promotional materials are subject to FDA scrutiny to ensure that the device is being marketed in compliance with these requirements. If the FDA investigates our marketing and promotional materials and finds that any of our current or future commercial products were being marketed for unapproved or 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 ReWalk.

Our products are regulated as medical devices in the United States under the FFDCA as implemented and enforced by the FDA. Under the FFDCA, medical devices are classified into one of three classes (Class I, Class II or Class III) depending on the degree of risk associated with the medical device, what is known about the type of device, and the extent of control needed to provide reasonable assurance of safety and effectiveness. Classification of a device is important because the class to which a device is assigned determines, among other things, the necessity and type of FDA review required prior to marketing the device. For more information, see "Part I, Item 1. Business—Government Regulation" in our 2019 Form 10-K.

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

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

Following the introduction of a product, the governmental agencies will periodically review our manufacturing processes and quality controls, and we are under a continuing obligation to ensure that all applicable regulatory requirements continue to be met. The process of complying with the applicable good manufacturing practices, adverse event reporting and other requirements can be costly and time consuming, and could delay or prevent the production, manufacturing or sale of our devices. In addition, if we fail to comply with applicable regulatory requirements, it could result in fines or delays of regulatory clearances, closure of manufacturing sites, seizures or recalls of products and damage to our reputation, as well as enforcement actions against us.

For example, the FDA could request that we recall our ReWalk Personal 6.0 device. For more information on certain deficiencies previously identified by the FDA in our mandatory post-market surveillance study on our ReWalk Personal 6.0, see "—Risks Related to Government Regulation—While we addressed the observations that FDA cited in a 2015 warning letter related to our mandatory post-market surveillance study and initiated the study, we are currently experiencing enrollment issues that make our study progress inadequate. Going forward, if we cannot meet certain FDA requirements and enrollment criteria for the study or otherwise satisfy FDA requests promptly, or if our study produces unfavorable results, we could receive additional FDA warnings, which could materially and adversely affect our commercial success."

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

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

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

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

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

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

Medical device companies such as ours have faced lawsuits and investigations pertaining to alleged violations of numerous statutes and regulations, including anti-corruption laws and health care "fraud and abuse" laws, such as the federal False Claims Act, the federal Anti-Kickback Statute and the U.S. Foreign Corrupt Practices Act, or the FCPA. See "Part I, Item 1. Business-Government Regulation" in our 2019 Form 10-K. U.S. federal and state laws, including the federal Physician Payments Sunshine Act, or the Sunshine Act, and the implementation of Open Payments regulations under the Sunshine Act, require medical device companies to disclose certain payments or other transfers of value made to healthcare providers and teaching hospitals or funds spent on marketing and promotion of medical device products. It is widely believed that public reporting under the Sunshine Act and implementing Open Payments regulations results in increased scrutiny of the financial relationships between industry, physicians and teaching hospitals. Further, some state laws require medical device companies to report information related to payments to physicians and other health care providers or marketing expenditures. These anti-kickback, anti-bribery, public reporting and aggregate spending laws affect our sales, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, rehabilitation centers, physicians or other potential purchasers or users of ReWalk or ReStore. They also impose additional administrative and compliance burdens on us. In particular, these laws influence, among other things, how we structure our sales offerings, including discount practices, customer support, education and training programs and physician consulting and other service arrangements, including those with marketers and sales agents. We may face significant costs in attempting to comply with these laws and regulations. If we are found to be in violation of any of these requirements or any actions or investigations are instituted against us, those actions could be costly to defend and could have a significant impact on our business, including the imposition of significant criminal and civil fines and penalties, exclusion from federal healthcare programs or other sanctions, and damage to our reputation or business.

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

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

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

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

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

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

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

Our management team consists of few employees, as the majority of our employees are engaged in sales and marketing and research and development activities. For more information, see "Part I, Item 1. Business—Employees" in our 2019 Form 10-K. In light of such constraints on its time, personnel and finances, our management may not be able to implement programs and policies in an effective and timely manner to respond adequately to the heightened legal, regulatory and reporting requirements applicable to us. In the past, for example, we have not always been able to respond on a timely basis to requests from regulators, although we have not to date experienced any long-term material adverse consequences as a result. For more information, see "—Risks Related to Government Regulation—While we addressed the observations that FDA cited in a 2015 warning letter related to our mandatory post-market surveillance study and initiated the study, we are currently experiencing enrollment issues that make our study progress inadequate. Going forward, if we cannot meet certain FDA requirements and enrollment criteria for the study or otherwise satisfy FDA requests promptly, or if our study produces unfavorable results, we could receive additional FDA warnings, which could materially and adversely affect our commercial success" above. Similar deficiencies, weaknesses or lack of compliance with public company, medical device and other regulations could harm our reputation in the capital markets or for quality and safety, negatively affect our ability to maintain our public company status and to develop, commercialize or continue selling our products on a timely and effective basis, and cause us to incur sanctions, including fines, injunctions and penalties.

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

Risks Related to Our Intellectual Property

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

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

In the current environment, there are numerous and evolving risks to cybersecurity and privacy, including criminal hackers, hacktivists, state-sponsored intrusions, industrial espionage, employee malfeasance and human or technological error. High-profile security breaches at other companies and in government agencies have increased in recent years, and security industry experts and government officials have warned about the risks of hackers and cyberattacks targeting businesses such as ours. Computer hackers and others routinely attempt to breach the security of technology products, services and systems, and to fraudulently induce employees, customers, or others to disclosure information or unwittingly provide access to systems or data. A 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" in our 2019 Form 10-K. 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, upon the expiration of our current patents, we may be unable to adequately develop new technologies and obtain future patent protection to preserve our competitive advantage. If we are unable to maintain a competitive advantage, our business and results of operations may be materially adversely affected.

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to an Investment in 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 December 8, 2020, 14,817,854 ordinary shares were issuable pursuant to the exercise of warrants, with exercise prices ranging from \$1.25 to \$118.75 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 and December 2020. There were also 6,679 ordinary shares issuable pursuant to the exercise of warrants granted to Kreos in connection with the Loan Agreement in January and December 2016, with an exercise price 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, in our Q3 2020 Form 10-Q

All shares sold pursuant to an offering covered by a registration statement would be freely transferable. With respect to the outstanding warrants, there may be certain restrictions on the holders to sell the underlying ordinary shares to the extent they are restricted securities, held by "affiliates" or would exceed certain ownership thresholds. Certain of our largest shareholders, may also have limitations under Rule 144 under the Securities Act on the resale of certain ordinary shares they hold unless they are registered for resale under the Securities Act. Despite these limitations, if we, our existing shareholders or their affiliates sell a substantial number of the above-mentioned ordinary shares in the public market, the market price of our ordinary shares could decrease significantly. 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.

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 8, 2020, 1,925,222 ordinary shares remained available for issuance to our and our affiliates' respective employees, non-employee directors and consultants under our equity incentive plans, including 1,325,917 ordinary shares subject to outstanding awards (consisting of outstanding options to purchase 69,606 ordinary shares and 1,256,311 ordinary shares underlying unvested RSUs. For more information, see Note 8c to our consolidated financial statements for the year ended December 31, 2019.

Additionally, the number of ordinary shares available for issuance under our 2014 Incentive Compensation Plan, or our 2014 Plan, may increase each year due to the operation of an "evergreen" provision previously approved by our shareholders. Pursuant to this provision, the 2014 Plan's reserve increases on January 1 of each calendar year during the plan's term by the lesser of (i) 38,880, (ii) 4% of the total number of shares outstanding on December 31 of the immediately preceding calendar year and (iii) an amount determined by our board of directors.

Additionally, to the extent registered on a Form S-8, ordinary shares granted or issued under our equity incentive plans will, subject to vesting provisions, lock-up restrictions and Rule 144 volume limitations applicable to our "affiliates," be available for sale in the open market immediately upon registration. Sales of a substantial number of the above-mentioned ordinary shares in the public market could result in a significant decrease in the market price of our ordinary shares and have a material adverse effect on an investment in our ordinary shares.

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. If our results of operations are below the estimates or expectations of our sole analyst 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 2020).

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 we cannot be certain whether the reduced requirements applicable to smaller reporting companies will make our ordinary shares less attractive to investors.

We are a "smaller reporting company" under the rules of the Securities Act and the Exchange Act. As a result, we may choose to take advantage of certain scaled disclosure requirements available specifically to smaller reporting companies. For example, we are not required to provide market risk disclosures, a contractual obligations table in our management's discussion and analysis of our financial condition and results of operations or selected financial data in our annual report. Additionally, as long as we continue to be a smaller reporting company, 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 both (i) a smaller reporting company and "non-accelerated filer" until the last day of the fiscal year in which we have at least \$100 million in revenue and at least \$700 million in aggregate market value of ordinary shares held by non-affiliated persons and entities (known as "public float"), or, alternatively, if our revenues exceed \$100 million, (ii) a smaller reporting company until the last day of the fiscal year in which our public float was at least \$250.0 million and a "non-accelerated filer" until the last day of the fiscal year in which our public float was at least \$75.0 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).

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. 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.

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). Under proposed Treasury Regulations, however, if we are treated as publicly traded for a majority of the relevant taxable year, our assets would generally be required to be measured at their fair market value, even if we are a CFC.

The proposed Treasury Regulations have not yet been adopted as final Treasury Regulations. Until such time as they are adopted as final Treasury Regulations, taxpayers may choose whether or not to apply them, provided (if they choose to apply them) they apply them consistently and in their entirety. The remainder of this discussion ignores the potential application of the proposed Treasury Regulations to the determination of whether we are a PFIC.

Based on our gross income and assets, the market price of our ordinary shares, and the nature of our business, we believe that we may have been a PFIC for the taxable year ended December 31, 2019. 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, 2019, 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.

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 \$0.82 per share through December 8, 2020. 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 offering completed in November 2016, and we do not expect one to develop, our ordinary shares will be issuable pursuant to exercise of these warrants. Because the warrants are exercisable into our ordinary shares, volatility or a reduction in the market price of our ordinary shares could have an adverse effect on the trading price of the warrants. Factors which may cause fluctuations in the price of our ordinary shares include, but are not limited to:

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

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

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

Recent political uprisings, social unrest and violence in various countries in the Middle East and North Africa, including Israel's neighbors Egypt and Syria, are affecting the political stability of those countries. This instability may lead to deterioration of the political relationships that exist between Israel and these countries and has raised concerns regarding security in the region and the potential for armed conflict. Our commercial insurance does not cover losses that may occur as a result of an event associated with the security situation in the Middle East. Any losses or damages incurred by us could have a material adverse effect on our business. In addition, Iran has threatened to attack Israel and is widely believed to be developing nuclear weapons. Iran is also believed to have a strong influence among parties hostile to Israel in areas that neighbor Israel, such as the Syrian government, Hamas in Gaza and Hezbollah in Lebanon. Any armed conflicts, terrorist activities or political instability in the region could materially and adversely affect our business, financial condition and results of operations.

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

Many Israeli citizens are obligated to perform one month, and in some cases more, of annual military reserve duty until they reach the age of 45 (or older, for reservists with certain occupations) and, in the event of a military conflict, may be called to active duty. In response to terrorist activity, there have been periods of significant call-ups of military reservists. For example, the Israeli armed forces called up a significant number of reservists to active duty in connection with the recent conflict in the Gaza Strip. It is possible that there will be additional military reserve duty call-ups in the future in connection with this conflict or otherwise. 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" in our 2019 Form 10-K.

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 September 30, 2020, we received a total of \$1.97 million from the Israel Innovation Authority, or the IIA. We may in the future apply to receive additional grants from the IIA to support our research and development activities. With respect to such grants we are committed to pay royalties at a rate of 3.0% to 3.5% on sales proceeds up to the total amount of grants received, linked to the dollar and bearing interest at an annual rate of LIBOR applicable to dollar deposits. Even after payment in full of these amounts, we will still be required to comply with the requirements of the Israeli Encouragement of Industrial Research, 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.

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

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

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

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

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

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

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

In late March 2019, following the receipt of shareholder approval, we filed the Third Amended and Restated Articles of Association of the Company with the Registrar of Companies of the State of Israel to increase the Company's authorized share capital after the effect of the reverse share split (as well as to reflect the reverse share split itself). As a result of the amendment, the total number of ordinary shares the Company is authorized to issue changed from 250,000,000 shares to 60,000,000 shares and the authorized share capital of the Company changed from NIS 2,500,000 to NIS 15,000,000 (representing proportional increases after giving effect to the reverse share split that was effected on April 1, 2019). The objective of the increase in authorized share capital was to maintain our flexibility following the reverse share split to conduct future issuances of our ordinary shares, in the ordinary course from time to time, to fund our operations, consistent with our historical practice of raising financing through equity and debt issuances.

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, giving rise to further opportunities for dilution. Future issuances of ordinary shares will dilute the voting power and ownership of our existing shareholders, and, depending on the amount of consideration received in connection with the issuance, could also reduce shareholders' equity on a per-share basis. Due to the increase in authorized capital, the dilution to the ownership interest of our existing shareholders may be greater than would occur had the increase not been effected.

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

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

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

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. Responding to these types of actions by activist shareholders could be costly and time-consuming, disrupting our operations and diverting the attention of management and our employees. Such activities could interfere with our ability to execute our strategic plan. In addition, a proxy contest for the election of directors at our annual meeting would require us to incur significant legal fees and proxy solicitation expenses and require significant time and attention by management and our board of directors. The perceived uncertainties as to our future direction also could affect the market price and volatility of our securities.

General Risks

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

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

We cannot predict any future trends in the rate of inflation in Israel or the rate of devaluation (if any) of the shekel against the dollar. For example, while the shekel appreciated against the dollar at a rate of approximately 8% during the fiscal year of 2019, the rate of devaluation of the shekel against the dollar was approximately 7% in 2017. This had the effect of increasing the dollar cost of our operations in Israel. If the dollar cost of our operations in Israel increases once again, our dollar-measured results of operations will be adversely affected. Our operations also could be adversely affected if we are unable to effectively hedge against currency fluctuations in the future.

We have in the past engaged in limited hedging activities, and we may enter into other hedging arrangements with financial institutions from time to time. Any hedging strategies that we may implement in the future to mitigate currency risks, such as forward contracts, options and foreign exchange swaps related to transaction exposures may not eliminate our exposure to foreign exchange fluctuations. For further information, see "—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 presidential administration has imposed tariffs on imports from China, Mexico, Canada and other countries, and has 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.

The economic effects of Brexit may affect relationships with existing and future customers and could have an adverse impact on our business and operating results.

On June 23, 2016, the United Kingdom, or the U.K., held a referendum in which voters approved Brexit. On January 31, 2020, the U.K. formally ceased to be part of the EU. Although negotiations between the U.K. and EU regarding Brexit began in June 2017 and the UK has passed legislation regarding the immediate impact of the U.K.'s withdrawal from the EU, it is still unclear what terms, if any, may be agreed within the U.K. and between the U.K. and other countries on many aspects of fiscal policy, cross-border trade and international relations, both in the final outcome and for any transitional period. The withdrawal of the U.K from the E.U. could potentially disrupt the free movement of goods, services and people between the U.K. and the E.U., undermine bilateral cooperation in key geographic areas and significantly disrupt trade between the U.K. and the E.U. or other nations as the U.K. pursues independent trade relations. Because this is an unprecedented event, it is unclear what long-term economic, financial, trade and legal implications Brexit would have and how it would affect the regulation applicable to our business globally and in the region. The impact on us will depend, in part, on the outcome of tariff, trade, regulatory and other negotiations. Any of these developments, along with any political, economic and regulatory changes that may occur, could cause political and economic uncertainty in Europe and internationally and could adversely affect our sales in Europe. The impact on us from Brexit will depend, in part, on the outcome of tariff, trade, regulatory and other negotiations.

As a result of Brexit, the global markets and currencies have been adversely impacted, including a decline in the value of the British pound as compared to the U.S. dollar. A potential devaluation of the local currencies of our international buyers relative to the U.S. dollar may impair the purchasing power of our international buyers and could cause international buyers to decrease their participation in our marketplaces or use of our products. Further, volatility in exchange rates resulting from Brexit is expected to continue in the short term as the U.K. negotiates its exit from the E.U. We translate sales and other results of our activities in the U.K. denominated in British pounds into U.S. dollars for our financial statements. During periods of a strengthening dollar, our reported international sales and earnings could be reduced because foreign currencies may translate into fewer U.S. dollars. Finally, Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the U.K. determines which E.U. laws to replace or replicate, and those laws and regulations may be cumbersome, difficult or costly in terms of compliance. In addition, Brexit may lead other E.U. member countries to consider referendums regarding their E.U. membership. Any of these effects of Brexit, among others, could adversely affect our business, financial condition, operating results and cash flows.

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

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

While to date we believe the effect of the TCJA in our Consolidated Financial Statements the application of accounting guidance for various items, and the ultimate impact of the TCJA on our business are not material, the final impacts of the TCJA could be materially different from our analysis. For example, adverse changes in the underlying profitability and financial outlook of our operations or changes in tax law could lead to changes in our valuation allowances against deferred tax assets on our consolidated balance sheets, which could materially affect our results of operations. The U.S. Treasury Department, the Internal Revenue Service (the "IRS"), and other standard-setting bodies could interpret or issue guidance on how provisions of the TCJA will be applied or otherwise administered that is different from our interpretation which may materially affect our results of operations. Finally, foreign governments may enact tax laws in response to the TCJA that could result in further changes to global taxation and materially affect our financial position and results of operations. The uncertainty surrounding the effect of the reforms on our financial results and business could also weaken confidence among investors in our financial condition. This could, in turn, have a materially adverse effect on the price of our ordinary shares.

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

From time to time, we may consider opportunities to acquire 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;
- · unanticipated costs associated with acquisitions;
- diversion of management's attention from our existing business;
- · risks associated with entering new markets in which we have limited or no experience; and
- · increased legal and accounting costs relating to the acquisitions or compliance with regulatory matters.

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

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

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

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

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

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

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

We have benefited substantially from the leadership and performance of our senior management. For example, we depend on our Chief Executive Officer's experience successfully scaling an early stage medical device company, as well as the experience of other members of management. Our success will depend on our ability to retain our current management. Competition for senior management in our industry is intense and we cannot guarantee that we will be able to retain our personnel. Additionally, we do not carry key man insurance on any of our current executive officers. The loss of the services of certain members of our senior management could prevent or delay the implementation and completion of our strategic objectives, or divert management's attention to seeking qualified replacements.

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, over the last several years 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.

Uncertainty relating to the LIBOR calculation process and potential phasing out of LIBOR in the future may adversely affect the value of any outstanding debt instruments.

National and international regulators and law enforcement agencies have conducted investigations into a number of rates or indices known as "reference rates." Actions by such regulators and law enforcement agencies may result in changes to the manner in which certain reference rates are determined, their discontinuance, or the establishment of alternative reference rates. In particular, on July 27, 2017, the Chief Executive of the U.K. Financial Conduct Authority (the "FCA"), which regulates LIBOR, announced that the FCA will no longer persuade or compel banks to submit rates for the calculation of LIBOR after 2021. Such announcement indicates that the continuation of LIBOR on the current basis cannot and will not be guaranteed after 2021. As a result, it appears highly likely that LIBOR will be discontinued or modified by 2021.

At this time, it is not possible to predict the effect that these developments, any discontinuance, modification or other reforms to LIBOR or any other reference rate, or the establishment of alternative reference rates may have on LIBOR, other benchmarks, or LIBOR-based debt instruments. Uncertainty as to the nature of such potential discontinuance, modification, alternative reference rates or other reforms may materially adversely affect the trading market for securities linked to such benchmarks. Furthermore, the use of alternative reference rates or other reforms could cause the interest rate calculated for the LIBOR-based debt instruments to be materially different than expected.

FORWARD-LOOKING STATEMENTS

In addition to historical information, this prospectus and the documents incorporated by reference into this prospectus contain forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, Section 27A of the U.S. Securities Act of 1933, and Section 21E of the U.S. Securities Exchange Act of 1934. Such forward-looking statements may include projections regarding ReWalk's future performance and other statements that are not statements of historical fact and, in some cases, may be identified by words like "anticipate," "assume," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "future," "will," "should," "would," "seek" and similar terms or phrases.

These forward-looking statements are based on our management's current expectations, which are subject to uncertainty, risks and changes in circumstances that are difficult to predict, and many of which are outside of our control. Important factors that could cause our actual results to differ materially from those indicated in the forward-looking statements include, among others, the factors discussed in the list above under "Risk Factors" and other factors discussed under the heading "Risk Factors" in the 2019 Form 10-K and other documents subsequently filed with or furnished to the SEC.

Any forward-looking statements made in this prospectus and the documents incorporated by reference into this prospectus speak only as of the date of the particular statement. Factors or events that could cause the Company's actual results to differ from the statements contained herein or therein may emerge from time to time, and it is not possible for the Company to predict all of them. Except as required by law, the Company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

USE OF PROCEEDS

We are not selling any securities under this prospectus and will not receive any proceeds from the sale of ordinary shares by the selling shareholders. We will, however, receive the proceeds of any December 2020 Warrants exercised for cash in the future. Such net proceeds will be up to approximately \$6.2 million, based on the December 2020 Warrants' exercise prices.

We intend to use the net proceeds for: (i) sales, marketing and reimbursement expenses related to market development activities of our ReStore device, broadening third-party payor coverage for our ReWalk Personal device and commercializing our new product lines added through distribution agreements; (ii) research and development activities; and (iii) general corporate purposes, including working capital needs.

We will not be paying any underwriting discounts or commissions in offerings under this prospectus. The selling shareholders will bear discounts or commissions, if any, attributable to their sale or disposition of the ordinary shares. Other than in connection with our indemnification obligations with respect to the selling shareholders, we will bear all costs, expenses and fees in connection with the registration of the shares (which do not include the fees and expenses of any selling shareholder counsel).

DESCRIPTION OF OUR ORDINARY SHARES

This description is a summary and is qualified in its entirety by reference to the third amended and restated articles of association, or the Articles of Association, a copy of which is filed as Exhibit 3.1 to our 2019 Form 10-K.

General

Our authorized share capital currently consists solely of 60,000,000 ordinary shares, par value NIS 0.25 per share. 24,757,225 ordinary shares were issued and outstanding as of October 8, 2020.

All of our issued and outstanding ordinary shares are validly issued, fully paid and non-assessable. Our ordinary shares are not redeemable and do not have any preemptive rights.

For information about deduction of the withholding tax or other duties from dividend payments, see "Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities" and "Item 1A. Risk Factors. Risks Relating to Our Incorporation and Location in Israel" of our 2019 Form 10-K.

Ordinary Shares

Quorum requirements

The quorum required for our general meetings of shareholders consists of at least two holders of our ordinary shares present in person or by proxy and holding among them at least 33 1/3% of the total outstanding voting rights.

Vote Requirements

Pursuant to our Articles of Association, holders of our ordinary shares have one vote for each ordinary share held on all matters submitted to a vote before the shareholders at a general meeting. Shareholders may vote at a general meeting either in person, by proxy or by written ballot.

Our Articles of Association provide that all resolutions of our shareholders require a simple majority vote, unless otherwise required by the Israel Companies Law, 5799-1999, or the Israel Companies Law, or by our Articles of Association. Under the Israel Companies Law, each of (i) the approval of an extraordinary transaction with a controlling shareholder and (ii) the terms of employment or other engagement of the controlling shareholder of the company or such controlling shareholder's relative (even if not extraordinary) requires special approval. For more information, see our Registration Statement on Form 8-A as filed with the SEC on September 2, 2014 under the heading "Item 1. Description of Registrant's Securities to be Registered." Under our Articles of Association, the alteration of the rights, privileges, preferences or obligations of any class of our shares requires a simple majority vote of all classes of shares voting together as a single class at a shareholder meeting. Our Articles of Association also require that the removal of any director from office (other than our external directors) or the amendment of the provisions of our amended articles relating to our staggered board requires the vote of 65% of the total voting power of our shareholders. In addition, the voluntary winding up, or approval of a scheme of arrangement or reorganization, of the company pursuant to Section 350 of the Israel Companies Law, requires the approval of a majority of those represented at the meeting, in person, by proxy or by voting deed and voting on the resolution, who must be the holders of at least 75% of the voting rights.

Preferred Stock

We may, from time to time, by shareholders resolution, provide for shares with such preferred or deferred rights or rights of redemption or other special rights and such restrictions, whether in regard to dividends, voting, repayment of share capital or otherwise, as may be stipulated in such resolution (subject to the provisions of the Israel Companies Law). The rights of the holders of ordinary shares will be subject to, and may be adversely affected by, the rights of holders of any preferred stock that may be issued in the future. As of October 8, 2020, we had no shares of preferred stock outstanding.

Transfer of Shares; Share Ownership Restrictions

Our fully paid ordinary shares are issued in registered form and may be freely transferred under our Articles of Association, unless the transfer is restricted or prohibited by another instrument, applicable law or the rules of a stock exchange on which the shares are listed for trade. The ownership or voting of our ordinary shares by non-residents of Israel is not restricted in any way by our Articles of Association or the laws of the State of Israel, except for ownership by nationals of some countries that are, or have been, in a state of war with Israel.

Election of Directors

Our ordinary shares do not have cumulative voting rights for the election of directors. As a result, the holders of a majority of the voting power represented at a shareholders meeting have the power to elect all of our directors, subject to the special approval requirements for external directors.

Under our Articles of Association, our board of directors must consist of not less than five but no more than thirteen directors, including two external directors as and if required by the Israel Companies Law. Pursuant to our Articles of Association, other than the external directors, for whom special election requirements apply under the Israel Companies Law, the vote required to appoint a director is a simple majority vote of holders of our voting shares, participating and voting at the relevant meeting. In addition, our directors, other than the external directors, are divided into three classes that are each elected at a general meeting of our shareholders every three years, in a staggered fashion (such that one class is elected each year), and serve on our board of directors unless they are removed by a vote of 65% of the total voting power of our shareholders at a general or special meeting of our shareholders or upon the occurrence of certain events, in accordance with the Israel Companies Law and our Articles of Association. In addition, our Articles of Association allow our board of directors to appoint new directors and appoint directors to fill vacancies on the board of directors to serve for a term of office equal to the remaining period of the term of office of the directors(s) whose office(s) have been vacated.

External directors are elected for an initial term of three years, may be elected for additional terms of three years each under certain circumstances and may be removed from office pursuant to the terms of the Israel Companies Law. Pursuant to regulations promulgated under the Israel Companies Law, as a company that does not have a controlling shareholder and that complies with U.S. securities laws and the corporate governance rules of the Nasdaq Stock Market ("Nasdaq"), we are permitted to "opt out" of the requirement to appoint external directors. In February 2018, we opted out of the requirement to have external directors.

Dividend and Liquidation Rights

Subject to the Israel Companies Law, we may declare a dividend to be paid to the holders of our ordinary shares in proportion to their respective shareholdings. Under the Israel Companies Law, dividend distributions are determined by the board of directors and do not require the approval of the shareholders of a company unless the company's articles of association provide otherwise. Our Articles of Association do not require shareholder approval of a dividend distribution and provide that dividend distributions may be determined by our board of directors.

Pursuant to the Israel Companies Law, a company may make a distribution of dividends out of its profits on the condition that there is no reasonable concern that the distribution may prevent the company from meeting its existing and expected obligations when they fall due. The Israel Companies Law defines such profits as retained earnings or profits accrued in the last two years, whichever is greater, according to the last reviewed or audited financial statements of the company, provided that the date of the financial statements is not more than six months before the distribution.

In the event of our liquidation, after satisfaction of liabilities to creditors, our assets will be distributed to the holders of our ordinary shares in proportion to their shareholdings. This right, as well as the right to receive dividends, may be affected by the grant of preferential dividend or distribution rights to the holders of a class of shares with preferential rights that may be authorized in the future.

Exchange Controls

There are currently no Israeli currency control restrictions on payments of dividends or other distributions with respect to our ordinary shares or the proceeds from the sale of the shares, except for the obligation of Israeli residents to file reports with the Bank of Israel regarding certain transactions. However, legislation remains in effect pursuant to which currency controls can be imposed by administrative action at any time.

Shareholder Meetings

Under Israeli law, we are required to hold an annual general meeting of our shareholders once every calendar year and no later than 15 months after the date of the previous annual general meeting. All meetings other than the annual general meeting of shareholders are referred to in our Articles of Association as extraordinary general meetings. Our board of directors may call extraordinary general meetings whenever it sees fit, at such time and place, within or outside of Israel, as it may determine. In addition, the Israel Companies Law provides that our board of directors is required to convene an extraordinary general meeting upon the written request of (i) any two of our directors or one-quarter of the members of our board of directors or (ii) one or more shareholders holding, in the aggregate, either (a) five percent or more of our outstanding issued shares and one percent of our outstanding voting power.

Subject to the provisions of the Israel Companies Law and the regulations promulgated thereunder, shareholders entitled to participate and vote at general meetings are the shareholders of record on a date to be decided by the board of directors, which may be between four and 40 days prior to the date of the meeting. Furthermore, the Israel Companies Law requires that resolutions regarding the following matters be passed at a general meeting of our shareholders:

- amendments to our Articles of Association;
- appointment or termination of our auditors;
- appointment of external directors;
- approval of certain related party transactions;
- increases or reductions of our authorized share capital;
- · a merger; and

• the exercise of our board of directors' powers by a general meeting, if our board of directors is unable to exercise its powers and the exercise of any of its powers is required for our proper management.

The Israel Companies Law and our Articles of Association require that notice of any annual general meeting or extraordinary general meeting be provided to shareholders at least 21 days prior to the meeting and if the agenda of the meeting includes the appointment or removal of directors, the approval of transactions with office holders or interested or related parties, or an approval of a merger, notice must be provided at least 35 days prior to the meeting.

Under the Israel Companies Law and under our Articles of Association, our shareholders are not permitted to take action via written consent in lieu of a meeting.

Access to Corporate Records

Under the Israel Companies Law, shareholders generally have the right to review: minutes of our general meetings; our shareholders register and principal shareholders register; our Articles of Association; our annual financial statements; and any document that we are required by law to file publicly with the Israel Companies Registrar or the Israel Securities Authority. In addition, shareholders may request to be provided with any document related to an action or transaction with a related party that requires shareholder approval under the related party transaction provisions of the Israel Companies Law. We may deny a request to review a document if we believe it has not been made in good faith, that the document contains a trade secret or patent or that the document's disclosure may otherwise impair our interests.

Acquisitions Under Israeli Law

Full Tender Offer. A person wishing to acquire shares of an Israeli public company and who would as a result hold over 90% of the target company's issued and outstanding share capital (or of a class thereof) is required by the Israel Companies Law to make a tender offer to all of the company's shareholders for the purchase of all of the issued and outstanding shares of the company (or the applicable class). If as a result of a full tender offer the purchaser would own more than 95% of the issued and outstanding share capital of the company or of the applicable class, and more than half of the shareholders who do not have a personal interest in the offer accept the offer, all of the shares that the purchaser offered to purchase will be transferred to the acquirer by operation of law. The law provides for appraisal rights if any shareholder files a request in court within six months following the consummation of a full tender offer, provided that the purchaser is entitled to stipulate that tendering shareholders forfeit their appraisal rights. If as a result of a full tender offer the purchaser would own 95% or less of the issued and outstanding share capital of the company or of the applicable class, the purchaser may not acquire shares that will cause its shareholding to exceed 90% of the issued and outstanding share capital of the company or of the applicable class.

Special Tender Offer. The Israel Companies Law provides that an acquisition of shares of an Israeli public company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of 25% or more of the voting rights in the company, unless there is already another holder of at least 25% of the voting rights in the company. Similarly, the Israel Companies Law provides that an acquisition of shares in a public company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of more than 45% of the voting rights in the company, if there is no other shareholder of the company who holds more than 45% of the voting rights in the company, subject to certain exceptions.

A special tender offer must be extended to all shareholders of a company but the offeror is not required to purchase shares representing more than 5% of the voting power attached to the company's outstanding shares, regardless of how many shares are tendered by shareholders. A special tender offer may be consummated only if (i) at least 5% of the voting power attached to the company's outstanding shares will be acquired by the offeror and (ii) the number of shares tendered in the offer exceeds the number of shares whose holders objected to the offer (excluding the purchaser, controlling shareholders, holders of 25% or more of the voting rights in the company or any person having a personal interest in the acceptance of the tender offer). If a special tender offer is accepted, then the purchaser or any person or entity controlling it or under common control with the purchaser or such controlling person or entity may not make a subsequent tender offer for the purchase of shares of the target company and may not enter into a merger with the target company for a period of one year from the date of the offer, unless the purchaser or such person or entity undertook to effect such an offer or merger in the initial special tender offer.

Merger. The Israel Companies Law permits merger transactions if approved by each party's board of directors and, unless certain requirements described under the Israel Companies Law are met, by a majority vote of each party's shares, and, in the case of the target company, a majority vote of each class of its shares, voted on the proposed merger at a shareholders meeting.

For purposes of the shareholder vote, unless a court rules otherwise, the merger will not be deemed approved if a majority of the votes of shares represented at the shareholders meeting that are held by parties other than the other party to the merger, or by any person (or group of persons acting in concert) who holds (or hold, as the case may be) 25% or more of the voting rights or the right to appoint directors of the other party, vote against the merger. If, however, the merger involves a merger with a company's own controlling shareholder or if the controlling shareholder has a personal interest in the merger, then the merger is instead subject to the same special majority approval that governs all extraordinary transactions with controlling shareholders.

If the transaction would have been approved by the shareholders of a merging company but for the separate approval of each class or the exclusion of the votes of certain shareholders as provided above, a court may still approve the merger upon the request of holders of at least 25% of the voting rights of a company, if the court holds that the merger is fair and reasonable, taking into account the value of the parties to the merger and the consideration offered to the shareholders of the company.

Upon the request of a creditor of either party to the proposed merger, the court may delay or prevent the merger if it concludes that there exists a reasonable concern that, as a result of the merger, the surviving company will be unable to satisfy the obligations of the merging entities, and may further give instructions to secure the rights of creditors.

In addition, a merger may not be consummated unless at least 50 days have passed from the date on which a proposal for approval of the merger was filed by each party with the Israeli Companies Registrar and at least 30 days have passed from the date on which the merger was approved by the shareholders of each party.

Anti-takeover Measures Under Israeli Law

The Israel Companies Law allows us to create and issue shares having rights different from those attached to our ordinary shares, including shares providing certain preferred rights with respect to voting, distributions or other matters and shares having preemptive rights. Upon the closing of our IPO, our Articles of Association were amended to provide that no preferred shares are authorized. In the future, if we do authorize, create and issue a specific class of preferred shares, such class of shares, depending on the specific rights that may be attached to it, may have the ability to frustrate or prevent a takeover or otherwise prevent our shareholders from realizing a potential premium over the market value of their ordinary shares. The authorization and designation of a class of preferred shares will require an amendment to our Articles of Association, which requires the prior approval of the holders of a majority of the voting power attaching to our issued and outstanding shares at a general meeting. The convening of the meeting, the shareholders entitled to participate and the majority vote required to be obtained at such a meeting will be subject to the requirements set forth in the Israel Companies Law as described above in "—Voting Rights."

Transfer Agent and Registrar

The transfer agent and registrar for our ordinary shares is American Stock Transfer & Trust Company, LLC. Its address is 6201 15th Avenue, Brooklyn, New York 11219, and its telephone number is (800) 937-5449.

MARKET INFORMATION AND DIVIDEND POLICY

Our ordinary shares began trading publicly on the Nasdaq Global Market on September 12, 2014 and were transferred for listing on the Nasdaq Capital Market effective May 25, 2017. Prior to the initial listing in September 2014, there was no public market for our ordinary shares. Our ordinary shares trade under the trading symbol "RWLK." The last reported sales price of our ordinary shares as reported by the Nasdaq Capital Market on October 16, 2020 was \$1.49 per share.

No dividends have been declared or paid on our ordinary shares. We do not anticipate paying any cash dividends on any of our ordinary shares in the foreseeable future. We currently intend to retain any earnings to finance the development and expansion of our business. Any future determination to pay dividends will be at the discretion of our board of directors and will be dependent upon then-existing conditions, including our earnings, capital requirements, results of operations, financial condition, business prospects and other factors that our board of directors considers relevant. Further, the loan agreement between the Company and Kreos V, dated November 20, 2018 contains provisions that limit our ability to pay dividends on our ordinary shares.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

As of December 8, 2020, there were 24,757,225 ordinary shares outstanding, excluding ordinary shares issuable in connection with the exercise of outstanding warrants (including the December 2020 Warrants) or outstanding options or upon the vesting of RSUs. The voting rights of all shareholders are the same.

The following table sets forth certain information as of December 8, 2020 concerning the number of ordinary shares beneficially owned, directly or indirectly, by:

- (1) each person, or group of affiliated persons, known to us to beneficially own more than 5% of our outstanding ordinary shares;
- (2) each of our directors;
- (3) each of our Named Executive Officers (as defined in "Executive and Director Compensation—Summary Compensation Table" in Amendment No. 1 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the SEC on December 18, 2020); and
- (4) all of our directors and executive officers serving as of December 8, 2020, as a group.

As of December 8, 2020, there were 26 holders of record of our ordinary shares, including Cede & Co., the nominee of the Depositary Trust Company. The actual number of beneficial holders of ordinary shares is greater than this number of record holders, because it includes beneficial owners whose shares are held in street name by brokers and other nominees.

Beneficial ownership is determined in accordance with the rules of the SEC based on voting and investment power with respect to such shares. Shares subject to options or warrants that are currently exercisable or exercisable within 60 days of December 8, 2020 (subject, in the case of warrants, to beneficial ownership limitations of 4.99% or 9.99%), and shares subject to RSUs that were vested as of or will vest within 60 days of December 8, 2020, are deemed to be outstanding and to be beneficially owned by the person holding such options, RSUs or warrants for the purpose of computing the percentage ownership of such person. However, such shares are not deemed to be outstanding and to be beneficially owned for the purpose of computing the percentage ownership of any other person.

Under the terms of the terms of certain outstanding warrants, a holder may not exercise the warrants to the extent that such shareholder, together with its affiliates, would beneficially own, after such exercise, more than 4.99% or 9.99% of the ordinary shares then outstanding, as applicable (subject to the right of the shareholder with a 4.99% ownership limitation to increase or decrease such beneficial ownership limitation upon notice to us, provided that such limitation cannot exceed 9.99%), and provided that any increase in the beneficial ownership limitation shall not be effective until 61 days after such notice is delivered. Consistent with beneficial ownership reporting principles under Section 13(d) of the Exchange Act, the below table only shows ordinary shares underlying warrants that are deemed to be beneficially owned, assuming compliance with these ownership limitations. This is in contrast with the table under "Selling Shareholders," which discloses these beneficial ownership limitations but otherwise shows as owned all shares held by selling shareholders regardless of compliance with these beneficial ownership limitations.

All information with respect to the beneficial ownership of shareholders below has been furnished by such shareholder to the Company or is based on our filings with the SEC and, unless otherwise indicated below, we believe that persons named in the table have sole voting and sole investment power with respect to all the ordinary shares shown as beneficially owned, subject to community property laws, where applicable. The ordinary shares beneficially owned by our directors and officers may include shares owned by their respective family members, as to which such directors and officers disclaim beneficial ownership. Unless otherwise noted below, each shareholder's address is c/o ReWalk Robotics Ltd., 3 Hatnufa Street, Floor 6, Yokneam Ilit 2069203, Israel.

Name	Number of Shares	Percentage of Shares
5%-or-More Beneficial Owners:		
Intracoastal Capital, LLC ⁽¹⁾	2,450,965	9.99%
Armistice Capital Master Fund, Ltd. ⁽²⁾	1,394,944	5.63%
Named Executive Officers and Directors:		
Larry Jasinski ⁽³⁾	36,842	*
Jeff Dykan ^{(4) (5)}	66,479	*
Yohanan Engelhardt ⁽⁶⁾	11,223	*
Wayne B. Weisman ⁽⁴⁾ (7)	71,787	*
Aryeh (Arik) Dan ⁽⁷⁾	11,784	*
Yasushi Ichiki ⁽⁷⁾	11,784	*
Randel Richner ⁽⁸⁾	6,874	*
Dr. John William Poduska ⁽⁹⁾	12,285	*
Ofir Koren ⁽¹⁰⁾	6,118	*
Ori Gon ⁽¹¹⁾	17,044	*
All directors and executive officers as a group (10 persons) ⁽¹²⁾	192,217	*

- * Ownership of less than 1%.
- Holds (i) 871,840 ordinary shares, all of which are December 2020 Shares and ordinary shares underlying currently exercisable warrants to purchase up to an aggregate of 1,972,122 ordinary shares, including 653,880 ordinary shares underlying the December 2020 Warrants, with the remaining ordinary shares underlying the February 2020 Institutional Warrants, the November 2016 Oppenheimer Warrants, April 2019 Institutional Warrants, June 2019 Institutional Warrants and July 2020 Institutional Warrants. However, as a result of beneficial ownership limitations in the outstanding warrants, Intracoastal is only deemed to beneficially own for purposes of this table 2,450,965 ordinary shares, or 9.99% of our total outstanding ordinary shares. For more information regarding these ownership limitations, see "Selling Shareholders." Mitchell P. Kopin and Daniel B. Asher, each of whom are managers of Intracoastal LLC ("Intracoastal"), have shared voting control and investment discretion over the securities held by Intracoastal. As a result, each of Mr. Kopin and Mr. Asher may be deemed to have beneficial ownership over such shares of Intracoastal. The principal business address of Intracoastal is 245 Palm Trail, Delray Beach, FL 33482.
- (2) Holds (i) 1,394,944 ordinary shares, all of which are December 2020 Shares and (ii) ordinary shares underlying currently exercisable warrants to purchase up to an aggregate of 4,253,021 ordinary shares, including 1,046,208 ordinary shares underlying the December 2020 Warrants, with the remaining ordinary shares underlying the June 2019 Institutional Warrants, February 2020 Common Warrants and July 2020 Institutional Warrants. However, as a result of 4.99% beneficial ownership limitations in the outstanding warrants, Armistice Capital Master Fund, Ltd. ("Armistice") is only deemed to beneficially own 1,394,944 ordinary shares for purposes of this table. For more information regarding these ownership limitations, see "Selling Shareholders." Armistice Capital, LLC, the investment manager of Armistice, and Steven Boyd, the managing member of Armistice Capital, LLC, hold shared voting and dispositive power over the shares held by Armistice. The principal business address of Armistice is c/o Armistice Capital, LLC 510 Madison Avenue, 7th Floor New York, NY 10022.
- (3) Consists of 5,451 ordinary shares, and exercisable options to purchase 31,391 ordinary shares.
- Based on filings made with the SEC, consists of 40,707 ordinary shares beneficially owned by SCP Vitalife Partners II, L.P., or SCP Vitalife Partners II, a limited partnership organized in the Cayman Islands, 13,596 ordinary shares beneficially owned by SCP Vitalife Partners (Israel) II, L.P., or SCP Vitalife Partners Israel II, a limited partnership organized in Israel, 2,480 ordinary shares beneficially owned by Vitalife Partners (Overseas) L.P., or Vitalife Partners Overseas, 820 ordinary shares beneficially owned by Vitalife Partners (Israel) L.P., or Vitalife Partners Israel, 829 ordinary shares beneficially owned by Vitalife Partners (D.C.M) L.P., or Vitalife Partners DCM, and 1,571 ordinary shares currently held by the Israel Innovation Authority (formerly known as the Office of the Chief Scientist of the State of Israel), or the IIA, that Vitalife Partners Overseas, Vitalife Partners Israel and Vitalife Partners DCM have the right to acquire from IIA. SCP Vitalife II Associates, L.P., or SCP Vitalife Associates, a limited partnership organized in the Cayman Islands, is the general partner of the SCP Vitalife Partners II and SCP Vitalife Partners Israel II, and SCP Vitalife II GP, Ltd., or SCP Vitalife GP, organized in the Cayman Islands, is the general partner of SCP Vitalife Associates. As such, SCP Vitalife GP may be deemed to beneficially own the 54,303 ordinary shares beneficially owned by SCP Vitalife Partners II and SCP Vitalife Israel Partners II. Jeff Dykan and Wayne B. Weisman are the directors of SCP Vitalife GP and, as such, share voting and dispositive power over the shares held by the foregoing entities. As such, they may be deemed to beneficially own 60,003 ordinary shares, consisting of the 54,303 ordinary shares beneficially owned by SCP Vitalife GP, as well as the ordinary shares beneficially owned by each of Vitalife Partners Overseas, Vitalife Partners Israel and Vitalife Partners DCM and held by IIA. The principal business address of SCP Vitalife Partners II, SCP Vitalife Associates, SCP Vitalife GP, and Messrs. Churchill and Weisman is c/o SCP Vitalife Partners II, L.P., 1200 Liberty Ridge Drive, Suite 300, Wayne, Pennsylvania 19087. The principal business address of SCP Vitalife Partners Israel II, Vitalife Partners Israel, Vitalife Partners Overseas, Vitalife Partners DCM, Mr. Dykan and Dr. Ludomirski is c/o SCP Vitalife Partners (Israel) II, L.P., 32B Habarzel Street, Ramat Hachayal, Tel Aviv 69710, Israel.

- (5) Consists of 5,975 ordinary shares, including 1,897 shares underlying RSUs vesting within 60 days, and exercisable options to purchase 501 ordinary shares.
- (6) Consists of 11,223 ordinary shares, including 2,737 shares underlying RSUs vesting within 60 days.
- (7) Consists of 11,283 ordinary shares, including 2,737 shares underlying RSUs vesting within 60 days, and exercisable options to purchase 501 ordinary shares.
- (8) Consists of 6,874 ordinary shares, including 6,874 shares underlying RSUs vesting within 60 days.
- (9) Consists of 11,283 ordinary shares, including 2,737 shares underlying RSUs vesting within 60 days, and exercisable options to purchase 1,002 ordinary shares.
- (10) Consists of 2,157 ordinary shares and exercisable options to purchase 3,961 ordinary shares. Mr. Ofir Koren informed us that he intends to resign as Vice President, Research & Development and Regulatory, effective January 17, 2021. Mr. Koren will continue to support the Company until February 28, 2021 in certain regulatory matters.
- (11) Consists of 12,586 ordinary shares and exercisable options to purchase 4,458 ordinary shares.
- (12) Consists of (i) 126,945 ordinary shares directly or beneficially owned by our directors and executive officers; (ii) 42,816 ordinary shares constituting the cumulative aggregate number of options granted to the executive officers and directors; and (iii) 22,456 shares underlying RSUs vesting within 60 days.

MATERIAL TAX CONSIDERATIONS

The following description is not intended to constitute a complete analysis of all tax consequences relating to the acquisition, ownership and disposition of our ordinary shares. You should consult your own tax advisor concerning the tax consequences of your particular situation, as well as any tax consequences that may arise under the laws of any state, local, foreign or other taxing jurisdiction.

Israeli Tax Considerations

The following is a discussion of the material Israeli tax consequences concerning the ownership and disposition of our securities. This summary does not discuss all the aspects of Israeli tax law that may be relevant to a particular investor in light of his or her personal investment circumstances or to some types of investors subject to special treatment under Israeli law. Examples of such investors include residents of Israel or traders in securities who are subject to special tax regimes not covered in this discussion. Because parts of this discussion are based on new tax legislation that has not yet been subject to judicial or administrative interpretation, we cannot assure you that the appropriate tax authorities or the courts will accept the views expressed in this discussion. The discussion below is subject to change, including due to amendments under Israeli law or changes to the applicable judicial or administrative interpretations of Israeli law, which change could affect the tax consequences described below.

Sale, Exchange or Other Taxable Disposition of Ordinary Shares

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

However, non-Israeli corporations will not be entitled to the foregoing exemption if Israeli residents: (i) have a controlling interest of more than 25% in such non-Israeli corporation or (ii) are the beneficiaries of, or are entitled to, 25% or more of the revenues or profits of such non-Israeli corporation, whether directly or indirectly. Such exemption is not applicable to a person whose gains from selling or otherwise disposing of the securities are deemed to be a business income.

Additionally, a sale of securities by a non-Israeli resident may be exempt from Israeli capital gains tax under the provisions of an applicable tax treaty. For example, under the United States-Israel Tax Treaty, the disposition of shares by a shareholder who (i) is a U.S. resident (for purposes of the treaty), (ii) holds the shares as a capital asset, and (iii) is entitled to claim the benefits afforded to such person by the treaty, is generally exempt from Israeli capital gains tax. Such exemption will not apply if: (i) the capital gain arising from the disposition can be attributed to a permanent establishment in Israel; (ii) the shareholder holds, directly or indirectly, shares representing 10% or more of the voting capital during any part of the 12-month period preceding the disposition, subject to certain conditions; or (iii) such U.S. resident is an individual and was present in Israel for 183 days or more during the relevant taxable year. In such case, the sale, exchange or disposition of our ordinary shares should be subject to Israeli tax, to the extent applicable; however, under the United States-Israel Tax 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 United States-Israel Tax Treaty does not relate to U.S. state or local taxes.

In some instances where our holders may be liable for Israeli tax on the sale of their securities, 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 capital gains derived from the sale of securities, 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 for 2020 and thereafter. 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. "Means of control" generally include the right to vote, receive profits, nominate a director or an executive officer, receive assets upon liquidation, or instruct someone who holds any of the aforesaid rights how to act, regardless of the source of such right (which source may include shares and rights to shares such as warrants). 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 sale he or she was a substantial shareholder.

As of January 1, 2020, holders that are individuals with taxable income exceeding NIS 651,600 in a tax year (linked to the Israeli consumer price index each year) will be subject to an additional tax, referred to as High Income Tax, at the rate of 3% on their taxable income for such tax year which is in excess of such threshold. For this purpose, taxable income will also include taxable capital gains from the sale of our securities and taxable income from dividend distributions.

If the above exemptions from capital gains tax are not available, corporations will be subject to the corporate tax rate (23% for 2020 and thereafter) on capital gains derived from the sale of securities.

Exercise of Warrants

Purchasers will generally not recognize gain or loss for Israeli tax purposes on the exercise of a warrant and related receipt of an ordinary share, unless cash is received in lieu of the issuance of a fractional ordinary share. A purchaser's initial tax basis in such ordinary share received on the exercise of a warrant should be equal to the sum of (i) the purchaser's tax basis in such warrant (that is, an amount equal to the purchase price of the warrant) plus (ii) the exercise price paid by the purchaser upon the exercise of the warrant. Also, for tax purposes, the date of purchase of such ordinary share will be considered to be the date of purchase of the warrants (excluding the portion of tax basis in the ordinary share attributed to the exercise price of the warrant (as described above) for which the relevant date of purchase will be the date of exercise of the warrant).

The Israeli income tax treatment of a cashless exercise of warrants into ordinary shares is unclear, and the tax consequences of a cashless exercise could differ from the consequences upon the exercise of a warrant described in the preceding paragraph.

Taxation of Non-Israeli Shareholders on Receipt of Dividends

Dividends paid on publicly traded shares, like our ordinary shares, to non-Israeli residents are generally subject to Israeli withholding tax at a rate of 25%, unless a lower rate is provided under an applicable tax treaty and 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 United States-Israel Tax Treaty) is 25%. The United States Israel Tax 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 (certain Israeli tax-benefit programs that may apply to us) 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 United States federal income tax purposes in the amount of the taxes withheld, subject to detailed rules contained in U.S. tax legislation.

Israel Innovation Authority

We have received grants from the Israel Innovation Authority, or the IIA, for research and development programs in the aggregate amount of approximately \$1.97 million as of September 30, 2020. We may in the future apply to receive additional grants from the IIA to support our research and development activities. With respect to such grants we are committed to pay 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. As of September 30, 2020, the amount of royalties that we paid to the IIA was \$0.9 million and the remaining aggregate amount to be returned to the IIA through royalties on future sales was about \$1.6 million. If we transfer our manufacturing outside of Israel the rate of royalties and the aggregate amount to be repaid can be increased significantly. 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, 5744-1984, or the R&D Law, and related regulations and IIA guidelines, 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 of such know-how to third parties or outside of Israel, 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 technology 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 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, we are required to notify the IIA of any change in our means of control (e.g. equity or the right to nominate board members) and if any non-Israeli entity becomes an interested party in us (e.g. (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) or if an existing foreign interested party purchases or is issued any means of control in us, we will be required to have such foreign interested party to sign an undertaking to comply with the rules and regulations applicable to the grant programs of the IIA and the R&D Law.

U.S. Federal Income Tax Considerations

The following is a description of the material U.S. federal income tax consequences relating to the acquisition, ownership and disposition of our ordinary shares by a U.S. Holder (as defined below). This description addresses only the U.S. federal income tax consequences to U.S. Holders that will hold such ordinary shares as capital assets. This description does not address tax considerations applicable to U.S. Holders that may be subject to special tax rules, including, without limitation:

- banks, financial institutions or insurance companies;
- real estate investment trusts, regulated investment companies or grantor trusts;
- brokers, dealers or traders in securities, commodities or currencies;
- tax-exempt entities or organizations, including an "individual retirement account" or "Roth IRA" as defined in Section 408 or 408A of the Code
 (as defined below), respectively;
- certain former citizens or long-term residents of the United States;
- persons that received our shares as compensation for the performance of services;
- persons that will hold our shares as part of a "hedging," "integrated" or "conversion" transaction or as a position in a "straddle" for U.S. federal income tax purposes;
- partnerships (including entities classified as partnerships for U.S. federal income tax purposes) or other pass-through entities, or holders that will hold our shares through such an entity;
- S corporations;
- holders that acquire ordinary shares as a result of holding or owning our preferred shares;
- holders whose "functional currency" is not the U.S. Dollar;
- persons subject to special tax accounting rules as a result of any item of gross income with respect to the common stock being taken into account in an applicable financial statement; or
- holders that own directly, indirectly or through attribution 10.0% or more of the voting power or value of our shares.

Moreover, this description does not address the U.S. federal estate, gift or alternative minimum tax consequences, or any state, local or foreign tax consequences, of the acquisition, ownership and disposition of our ordinary shares.

This description is based on the U.S. Internal Revenue Code of 1986, as amended (the "Code"), existing, proposed and temporary United States Treasury Regulations and judicial and administrative interpretations thereof, in each case as in effect and available on the date hereof. All of the foregoing is subject to change, which change could apply retroactively and could affect the tax consequences described below. There can be no assurances that the U.S. Internal Revenue Service (the "IRS"), will not take a different position concerning the tax consequences of the acquisition, ownership and disposition of our ordinary shares or that such a position would not be sustained. Holders should consult their own tax advisors concerning the U.S. federal, state, local and foreign tax consequences of purchasing, owning and disposing of our ordinary shares in their particular circumstances.

For purposes of this description, a "U.S. Holder" is a beneficial owner of our ordinary shares that, for United States federal income tax purposes, is:

- An individual holder that is a citizen or resident of the United States;
- a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States or any state thereof, including the District of Columbia;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust if such trust has validly elected to be treated as a United States person for U.S. federal income tax purposes or if (1) a court within the United States is able to exercise primary supervision over its administration and (2) one or more United States persons have the authority to control all of the substantial decisions of such trust.

If a partnership (or any other entity treated as a partnership for U.S. federal income tax purposes) holds our ordinary shares, the tax treatment of a partner in such partnership will generally depend on the status of the partner and the activities of the partnership. Such a partner or partnership should consult its tax advisor as to the particular U.S. federal income tax consequences of acquiring, owning and disposing of our ordinary shares in its particular circumstance.

You should consult your tax advisor with respect to the U.S. federal, state, local and foreign tax consequences of acquiring, owning and disposing of our ordinary shares.

Distributions

As noted above, we do not anticipate paying any cash dividends in the foreseeable future. Nevertheless, subject to the discussion below under "Passive Foreign Investment Company Considerations," the gross amount of any distribution made to you with respect to our ordinary shares before reduction for any Israeli taxes withheld therefrom, other than certain distributions, if any, of our ordinary shares distributed pro rata to all our shareholders, generally will be includible in your income as dividend income to the extent such distribution is paid out of our current or accumulated earnings and profits as determined under U.S. federal income tax principles. Subject to applicable limitations (and assuming that we are not a passive foreign investment company for our taxable year in which the dividend is paid or the preceding taxable year), dividends paid to certain noncorporate U.S. Holders may qualify for the preferential rates of taxation with respect to dividends on ordinary shares if certain requirements, including stock holding period requirements, are satisfied by the recipient and either we are eligible for the benefits of the United States-Israel Tax Treaty or our ordinary shares are readily tradable on an established market in the United States. However, such dividends will not be eligible for the dividends received deduction generally allowed to corporate U.S. Holders. To the extent that the amount of any distribution by us exceeds our current and accumulated earnings and profits as determined under U.S. federal income tax principles, it will be treated first as a return of your adjusted tax basis in our ordinary shares to the extent thereof and thereafter as either long-term or short-term capital gain depending upon whether your holding period for our ordinary shares exceeds one year as of the time such distribution is received. However, we do not expect to maintain calculations of our earnings and profits under U.S. federal income tax principles. Therefore, you should expect that the entire amount of any distribution generally will be reported as dividend income to you.

Subject to certain conditions and limitations, Israeli tax withheld on dividends may be deducted from your taxable income or credited against your U.S. federal income tax liability. Dividends paid to you with respect to our ordinary shares will generally be treated as foreign source income, which may be relevant in calculating your foreign tax credit limitation. However, for periods in which we are a "United States-owned foreign corporation," a portion of dividends paid by us may be treated as U.S. source solely for purposes of the foreign tax credit. We will be treated as a United States-owned foreign corporation if 50% or more of the total value or total voting power of our stock is owned, directly, indirectly or by attribution, by United States persons. To the extent any portion of our dividends is treated as U.S. source income pursuant to this rule, the ability of a U.S. Holder to claim a foreign tax credit for any Israeli withholding taxes payable in respect of our dividends may be limited. In addition, a corporate U.S. Holder that owns 10% or more of our ordinary shares (actually or constructively) may not be able to claim a foreign tax credit for any Israeli withholding taxes payable in respect of our dividends. You should consult your tax advisor about the impact of, and any exception available to, the special sourcing rule described in this paragraph, and the desirability of making, and the method of making, any applicable elections relating to this rule.

The rules relating to the determination of the foreign tax credit are complex, and you should consult your tax advisor to determine whether and to what extent you will be entitled to this credit.

Sale, Exchange or Other Taxable Disposition of Ordinary Shares

Subject to the discussion below under "Passive Foreign Investment Company Considerations," you generally will recognize gain or loss on the sale, exchange or other taxable disposition of our ordinary shares equal to the difference between the amount realized on such sale, exchange or other taxable disposition and your adjusted tax basis in such shares (taking into account the rules discussed above). Any such gain or loss generally will be long-term capital gain or loss if the U.S. Holder's holding period in the ordinary shares is more than one year at the time of the taxable disposition. Long-term capital gains recognized by certain non-corporate U.S. Holder may be eligible for preferential rates of taxation. The deductibility of capital losses for U.S. federal income tax purposes is subject to limitations under the Code. Any recognized gain or loss of a U.S. Holder generally will be treated as U.S. source income or loss for foreign tax credit limitation purposes.

Passive Foreign Investment Company Considerations

If we were to be classified as a PFIC in any taxable year, a U.S. Holder would be subject to special rules generally intended to reduce or eliminate any benefits from the deferral of U.S. federal income tax that a U.S. Holder could derive from investing in a non-U.S. company that does not distribute all of its earnings on a current basis.

A non-U.S. corporation will be classified as a PFIC for federal income tax purposes in any taxable year in which, after applying certain look-through rules with respect to the income and assets of subsidiaries, either:

- at least 75% of its gross income is "passive income"; or
- at least 50% of the average quarterly value of its total gross assets (which may be measured in part by the market value of our ordinary shares, which is subject to change as discussed below) is attributable to assets that produce "passive income" or are held for the production of passive income.

Passive income for this purpose generally includes dividends, interest, royalties, rents, gains from commodities and securities transactions, the excess of gains over losses from the disposition of assets which produce passive income, and includes amounts derived by reason of the temporary investment of funds raised in offerings of our ordinary shares. If a non-U.S. corporation owns directly or indirectly at least 25% by value of the stock of another corporation, the non-U.S. corporation is treated for purposes of the PFIC tests as owning its proportionate share of the assets of the other corporation and as receiving directly its proportionate share of the other corporation's income.

Our status as 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). Under recently released final Treasury Regulations, which are not yet effective, however, if we are treated as publicly traded for at least twenty 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 and the nature of our business, we believe that we may have been a PFIC for the taxable year ended December 31, 2019. This determination, however, 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, 2019, and also expresses no opinion with respect to our predictions or past determinations regarding our PFIC status in the past or in the future.

Under certain attribution rules, if we are a PFIC, U.S. Holders will be deemed to own their proportionate share of our PFIC subsidiaries, such subsidiaries referred to as "lower-tier PFICs," and will be subject to U.S. federal income tax in the manner discussed below on (1) a distribution to us on the shares of a "lower-tier PFIC" and (2) a disposition by us of shares of a "lower-tier PFIC," both as if the holder directly held the shares of such "lower-tier PFIC."

If an entity is treated as a PFIC for any taxable year during which a U.S. Holder holds (or, as discussed in the previous paragraph, is deemed to hold) its ordinary shares, such holder will be subject to adverse U.S. federal income tax rules. In general, if a U.S. Holder disposes of shares of a PFIC (including an indirect disposition or a constructive disposition of shares of a "lowertier PFIC"), gain recognized or deemed recognized by such holder would be allocated ratably over such holder's holding period for the shares. The amounts allocated to the taxable year of disposition and to years before the entity became a PFIC, if any, would be treated as ordinary income. The amount allocated to each other taxable year would be subject to tax at the highest rate in effect for such taxable year for individuals or corporations, as appropriate, and an interest charge would be imposed on the tax attributable to such allocated amounts. Further, any distribution in respect of shares of a PFIC (or a distribution by a lower-tier PFIC to its shareholders that is deemed to be received by a U.S. Holder) in excess of 125% of the average of the annual distributions on such shares received or deemed to be received during the preceding three years or the U.S. Holder's holding period, whichever is shorter, would be subject to taxation in the manner described above. In addition, dividend distributions made to you will not qualify for the preferential rates of taxation applicable to long-term capital gains discussed above under "Distributions."

If we are a PFIC for any year during which a U.S. Holder holds our ordinary shares, we must generally continue to be treated as a PFIC by that holder for all succeeding years during which the U.S. Holder holds the ordinary shares, unless we cease to meet the requirements for PFIC status and the U.S. Holder makes a "deemed sale" election with respect to the ordinary shares. If such election is made, the U.S. Holder will be deemed to have sold the ordinary shares it holds 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 subject to the consequences described above. After the deemed sale election, the U.S. Holder's ordinary shares with respect to which the deemed sale election was made will not be treated as shares in a PFIC, unless we subsequently again become a PFIC.

Where a company that is a PFIC meets certain reporting requirements, a U.S. Holder can avoid certain adverse PFIC consequences described above by making a "qualified electing fund," or QEF, election to be taxed currently on its proportionate share of the PFIC's ordinary income and net capital gains. However, we do not intend to comply with the necessary accounting and record keeping requirements that would allow a U.S. Holder to make a QEF election with respect to us if we are classified as a PFIC.

If we are a PFIC and our ordinary shares are "regularly traded" on a "qualified exchange," a U.S. Holder may make a mark-to-market election with respect to our ordinary shares (but not the shares of any lower-tier PFICs), which may help to mitigate the adverse tax consequences resulting from our PFIC status (but not that of any lower-tier PFICs). Our ordinary shares will be treated as "regularly traded" in any calendar year in which more than a de minimis quantity of the ordinary shares are traded on a qualified exchange on at least 15 days during each calendar quarter (subject to the rule that trades that have as one of their principal purposes the meeting of the trading requirement are disregarded). The Nasdaq Capital Market is a qualified exchange for this purpose and, consequently, if the ordinary shares are regularly traded, the mark-to-market election will be available to a U.S. Holder; however, there can be no assurance that trading volumes will be sufficient to permit a mark-to-market election. In addition, because a mark-to-market election with respect to us does not apply to any equity interests in "lower-tier PFICs" that we own, a U.S. Holder generally will continue to be subject to the PFIC rules with respect to its indirect interest in any investments held by us that are treated as equity interests in a PFIC for U.S. federal income tax purposes.

If a U.S. Holder makes the mark-to-market election, for each year in which we are a PFIC, the holder will generally include as ordinary income the excess, if any, of the fair market value of ordinary shares at the end of the taxable year over their adjusted tax basis, and will be permitted an ordinary loss in respect of the excess, if any, of the adjusted tax basis of our ordinary shares over their fair market value at the end of the taxable year (but only to the extent of the net amount of previously included income as a result of the mark-to-market election). If a U.S. Holder makes the election, the holder's tax basis in our ordinary shares will be adjusted to reflect any such income or loss amounts. Any gain recognized on a sale or other disposition of our ordinary shares will be treated as ordinary income. Any losses recognized on a sale or other disposition of our ordinary shares will be treated as ordinary loss to the extent of any net mark-to-market gains for prior years. U.S. Holders should consult their tax advisors regarding the availability and consequences of making a mark-to-market election in their particular circumstances. In particular, U.S. Holders should consider carefully the impact of a mark-to-market election with respect to our ordinary shares if we have "lower-tier PFICs" for which such election is not available. Once made, the mark-to-market election cannot be revoked without the consent of the IRS unless our ordinary shares cease to be "regularly traded."

If a U.S. Holder owns ordinary shares during any year in which we are a PFIC, the U.S. Holder generally will be required to file an IRS Form 8621 (Information Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund) with respect to the company, generally with the U.S. Holder's federal income tax return for that year. A failure to file such form may result in penalties and may suspend the running of the statute of limitations on the tax return. If our company were a PFIC for a given taxable year, then you should consult your tax advisor concerning your annual filing requirements.

The U.S. federal income tax rules relating to PFICs are very complex. Prospective U.S. investors are strongly urged to consult their own tax advisors with respect to the impact of these rules on the purchase, ownership and disposition of our ordinary shares, the consequences to them of an investment in a PFIC, any elections available with respect to the ordinary shares and the IRS information reporting obligations with respect to the purchase, ownership and disposition of the ordinary shares.

Medicare Tax

Certain U.S. Holders that are individuals, estates or trusts are subject to a 3.8% tax on all or a portion of their "net investment income," which may include all or a portion of their dividend income and net gains from the disposition of ordinary shares. Each U.S. Holder that is an individual, estate or trust is urged to consult its tax advisors regarding the applicability of the Medicare tax to its income and gains in respect of its investment in our ordinary shares.

Backup Withholding Tax and Information Reporting Requirements

United States backup withholding tax and information reporting requirements may apply to certain payments to certain holders of stock. Information reporting generally will apply to payments of dividends on, and to proceeds from the sale or redemption of, our ordinary shares made within the United States, or by a United States payor or United States middleman, to a holder of our ordinary shares, other than an exempt recipient (including a payee that is not a United States person that provides an appropriate certification and certain other persons). A payor will be required to withhold backup withholding tax from any payments of dividends on, or the proceeds from the sale or redemption of, ordinary shares within the United States, or by a United States payor or United States middleman, to a holder, other than an exempt recipient, if such holder fails to furnish its correct taxpayer identification number or otherwise fails to comply with, or establish an exemption from, such backup withholding tax requirements. Any amounts withheld under the backup withholding rules will be allowed as a credit against the beneficial owner's U.S. federal income tax liability, if any, and any excess amounts withheld under the backup withholding rules may be refunded, provided that the required information is timely furnished to the IRS.

Foreign Asset Reporting

Certain U.S. Holders are required to report information relating to an interest in our ordinary shares, subject to certain exceptions (including an exception for shares held in accounts maintained by U.S. financial institutions) by filing IRS Form 8938 (Statement of Specified Foreign Financial Assets) with their federal income tax return. U.S. Holders are urged to consult their tax advisors regarding their information reporting obligations, if any, with respect to their ownership and disposition of our ordinary shares.

The above description is not intended to constitute a complete analysis of all tax consequences relating to the acquisition, ownership and disposition of our ordinary shares. You should consult your tax advisor concerning the tax consequences of the acquisition, ownership and disposition of our ordinary shares in your particular situation.

SELLING SHAREHOLDERS

The ordinary shares being offered by the selling shareholders include the December 2020 Shares and shares underlying the December 2020 Warrants. For additional information regarding the issuances of those ordinary shares and warrants, see "Outstanding Shares and Warrants Issued in the December 2020 Private Placement" above. We are registering the December 2020 Shares and shares underlying the December 2020 Warrants in order to permit the selling shareholders to offer the shares for resale from time to time (in the case of the December 2020 Warrants, after exercising such warrants for cash), as well as to satisfy our resale registration obligations to such shareholders under our December 2020 Registration Rights Agreement. When we refer to the "selling shareholders" in this prospectus, we mean the persons and entities listed in the table below, and their respective transferees, donees, pledgees, assignees and successors-in-interest who later come to hold any of the selling shareholders' interests in ordinary shares other than through a public sale.

The table below lists the selling shareholders and other information regarding the beneficial ownership of the ordinary shares by each of the selling shareholders. The second column lists the number of ordinary shares beneficially owned by each selling shareholder, based on its ownership of the ordinary shares and warrants (including the December 2020 Shares, December 2020 Warrants and other ordinary shares and warrants), as of December 8, 2020, assuming exercise of the December 2020 Warrants held by the selling shareholders on that date, without regard to any limitations on exercises. The fourth column lists the ordinary shares being offered by this prospectus by the selling shareholders.

This prospectus covers the resale of the sum of (i) the number of December 2020 Shares issued to the selling shareholders and (ii) the maximum number of ordinary shares issuable upon exercise of the December 2020 Warrants, determined as if the outstanding warrants were exercised in full as of December 8, 2020, without regard to any limitations on the exercise of the December 2020 Warrants. The fifth column assumes the sale of all of the December 2020 Shares and shares underlying the December 2020 Warrants offered by the selling shareholders pursuant to this prospectus.

Under the terms of the December 2020 Warrants, a selling shareholder may not exercise such warrants to the extent such exercise would cause such selling shareholder, together with its affiliates and attribution parties, to beneficially own a number of ordinary shares which would exceed 4.99% or 9.99%, as applicable, of our then-outstanding ordinary shares following such exercise, excluding for purposes of such determination ordinary shares issuable upon exercise of the warrants which have not been exercised. The number of shares in the second column does not reflect this limitation. The selling shareholders may sell all, some or none of their shares in this offering. See "Plan of Distribution."

Certain of the selling shareholders are representatives of H.C. Wainwright. We and/or our affiliates have from to time to time in the past engaged and may in the future engage in investment banking and other commercial dealings in the ordinary course of business with H.C. Wainwright or its affiliates, for which they have received or may receive customary fees and expenses. H.C. Wainwright acted as lead book-running manager of our underwritten follow-on public offering in November 2018 of units consisting of ordinary shares and common warrants and pre-funded units consisting common warrants and pre-funded warrants, as placement agent in our best-efforts follow-on public offering of ordinary shares in February 2019, as placement agent in our registered direct offerings of ordinary shares and concurrent private placement of warrants in April 2019, June 2019 and July 2020, as placement agent in our June 2019 and July 2020 private placement of warrants, as placement agent in our best-efforts public offering of units in February 2020 and as placement agent in our December 2020 Private Placement. Otherwise, except for the ownership of the December 2020 Shares, December 2020 Warrants and other ordinary shares and the warrants discussed in the footnotes to the table below, the selling shareholders have not had any material relationship with us within the past three years.

	Number of Shares Beneficially		Maximum Number	Shares Beneficially Owned After	
	Owned Prior to the		Offered by Selling	Completion of	
Selling Shareholders	Offering(12)	Percent(13)	Shareholder(14)	Offering(15)	Percent(16)
Armistice Capital Master Fund, Ltd.	5,647,965(1)	5.63%	2,441,152	3,206,813	4.99%
Anson Investments Master Fund LP	3,468,413(2)	4.99%	1,830,864	1,637,549	4.99%
Sabby Volatility Warrant Master Fund, Ltd.	3,262,737(3)	4.99%	1,525,720	1,737,017	4.99%
Intracoastal Capital, LLC	2,843,962(4)	9.99%	1,525,720	1,318,242	4.31%
Cavalry Fund I LP	915,432(5)	3.64%	915,432	_	_
Bigger Capital Fund, LP	915,432(6)	3.64%	915,432	_	_
Lind Global Macro Fund, LP	610,288(7)	2.44%	610,288	_	_
Noam Rubinstein	403,076(8)	1.60%	105,458	297,618	1.01%
Craig Schwabe	32,639(9)	*	11,299	21,340	*
Michael Vasinkevich	821,719(10)	3.21%	214,682	607,037	2.73%
Charles Worthman	12,796(11)	*	3,348	9,448	*

Number of

* Less than 1%

- (1) Holds (i) 1,394,944 ordinary shares, all of which are December 2020 Shares and (ii) ordinary shares underlying currently exercisable warrants to purchase up to an aggregate of 4,253,021 ordinary shares, including 1,046,208 ordinary shares underlying the December 2020 Warrants, with the remaining ordinary shares underlying the June 2019 Institutional Warrants, February 2020 Common Warrants and July 2020 Institutional Warrants. Armistice Capital, LLC, the investment manager of Armistice, and Steven Boyd, the managing member of Armistice Capital, LLC, hold shared voting and dispositive power over the shares held by Armistice. The principal business address of Armistice is c/o Armistice Capital, LLC 510 Madison Avenue, 7th Floor New York, NY 10022.
- Holds (i) 1,046,208 ordinary shares, all of which are December 2020 Shares and (ii) ordinary shares underlying currently exercisable warrants to purchase up to an aggregate of 2,422,205 ordinary shares, including 784,656 ordinary shares underlying the December 2020 Warrants, with the remaining ordinary shares underlying the November 2016 Oppenheimer Warrants, April 2019 Institutional Warrants, June 2019 Institutional Warrants, February 2020 Common Warrants and July 2020 Institutional Warrants. Anson Advisors Inc and Anson Funds Management LP, the Co-Investment Advisers of Anson Investments Master Fund LP ("Anson"), hold voting and dispositive power over the securities held by Anson. Bruce Winson is the managing member of Anson Management GP LLC, which is the general partner of Anson Funds Management LP. Moez Kassam and Amin Nathoo are directors of Anson Advisors Inc. Mr. Winson, Mr. Kassam and Mr. Nathoo each disclaim beneficial ownership of these securities except to the extent of their pecuniary interest therein. The principal business address of Anson is Walkers Corporate Limited, Cayman Corporate Centre, 27 Hospital Road, George Town, Grand Cayman KY1-9008, Cayman Islands.
- Holds (i) 1,131,039 ordinary shares, including 871,840 December 2020 Shares and (ii) ordinary shares underlying currently exercisable warrants to purchase up to an aggregate of 2,131,698 ordinary shares, including 653,880 ordinary shares underlying the December 2020 Warrants, with the remaining ordinary shares underlying the April 2019 Institutional Warrants, June 2019 Institutional Warrants and February 2020 Common Warrants. Sabby Management, LLC, the investment manager of Sabby Volatility Warrant Master Fund, Ltd., and Hal Mintz, manager of Sabby Management, LLC, may be deemed to share voting and dispositive power with respect to these securities. Each of Sabby Management, LLC and Hal Mintz disclaims beneficial ownership over the securities listed except to the extent of their pecuniary interest therein. The principal business address of Sabby Volatility Warrant Master Fund, Ltd. is c/o Ogier Fiduciary Services (Cayman) Limited, 89 Nexus Way, Camana Bay, Grand Cayman KY1-9007, Cayman Islands. The principal business address of Sabby Management, LLC and Hal Mintz is 10 Mountainview Road, Suite 205, Upper Saddle River, New Jersey 07458.

- (4) Holds (i) 871,840 ordinary shares, all of which are December 2020 Shares and (ii) ordinary shares underlying currently exercisable warrants to purchase up to an aggregate of 1,972,122 ordinary shares, including 653,880 ordinary shares underlying the December 2020 Warrants, with the remaining ordinary shares underlying the February 2020 Institutional Warrants, the November 2016 Oppenheimer Warrants, April 2019 Institutional Warrants, June 2019 Institutional Warrants and July 2020 Institutional Warrants. Mitchell P. Kopin and Daniel B. Asher, each of whom are managers of Intracoastal, have shared voting control and investment discretion over the securities held by Intracoastal. As a result, each of Mr. Kopin and Mr. Asher may be deemed to have beneficial ownership over such shares of Intracoastal. The principal business address of Intracoastal is 245 Palm Trail, Delray Beach, FL 33482.
- (5) Holds (i) 523,104 ordinary shares, all of which are December 2020 Shares and (ii) ordinary shares underlying currently exercisable warrants to purchase up to an aggregate of 392,328 ordinary shares, all of which are ordinary shares underlying the December 2020 Warrants. Thomas Walsh, General Partner and Chief Information Officer of Calvary Fund I LP, has sole voting control and investment discretion over the securities held by Calvary. As a result, Mr. Walsh may be deemed to have beneficial ownership over such shares of Calvary. The principal business address of Cavalry is 61 Kinderkamack Rd., Woodcliff Lake, NJ 07677.
- (6) Holds (i) 523,104 ordinary shares, all of which are December 2020 Shares and (ii) ordinary shares underlying currently exercisable warrants to purchase up to an aggregate of 392,328 ordinary shares, all of which are ordinary shares underlying the December 2020 Warrants. Bigger Capital, LLC is the investment manager of Bigger Capital Fund, LP. Mr. Michael Bigger is a managing partner of Bigger Capital GP, LLC and has sole voting and investment power over the shares being offered under this prospectus. Bigger Capital GP, LLC and Mr. Bigger may deemed to beneficially own the shares of the Company beneficially held by Bigger Capital Fund, LP. The principal business address of Bigger Capital Fund, LP is 11434 Glowing Sunset, Las Vegas, NV 89135.
- (7) Holds (i) 348,736 ordinary shares, all of which are December 2020 Shares and (ii) ordinary shares underlying currently exercisable warrants to purchase up to an aggregate of 261,552 ordinary shares, all of which are ordinary shares underlying the December 2020 Warrants. Jeff Easton is the managing member of The Lind Partners, LLC which is the manager of Lind Global Macro Fund, LP and has sole voting control and investment discretion over the securities held by Lind Global Macro Fund, LP. Mr. Easton disclaims beneficial ownership over the securities listed except to the extent of his pecuniary interest therein. The principal business address of Lind is 444 Madison Ave, 41st Floor, New York, NY 10022.
- (8) Holds other outstanding warrants to purchase 297,618 ordinary shares and December 2020 HCW Warrants to purchase 105,458 ordinary shares issued to the selling shareholder as a representative of H.C. Wainwright. The business address is c/o H.C. Wainwright & Co., LLC, 430 Park Avenue, 3rd Floor, New York, New York 10128.
- (9) Holds other outstanding warrants to purchase 21,340 ordinary shares and December 2020 HCW Warrants to purchase 11,299 ordinary shares issued to the selling shareholder as a representative of H.C. Wainwright. The business address is c/o H.C. Wainwright & Co., LLC, 430 Park Avenue, 3rd Floor, New York, New York 10128.
- (10) Holds other outstanding warrants to purchase 607,037 ordinary shares and December 2020 HCW Warrants to purchase 214,682 ordinary shares issued to the selling shareholder as a representative of H.C. Wainwright. The business address is c/o H.C. Wainwright & Co., LLC, 430 Park Avenue, 3rd Floor, New York, New York 10128.

- (11) Holds other outstanding warrants to purchase 9,448 ordinary shares and December 2020 HCW Warrants to purchase 3,348 ordinary shares issued to the selling shareholder as a representative of H.C. Wainwright. The business address is c/o H.C. Wainwright & Co., LLC, 430 Park Avenue, 3rd Floor, New York, New York 10128.
- (12) Includes all ordinary shares held outright and ordinary shares underlying all warrants, whether or not registered hereby, and whether or not they may be exercised due to beneficial ownership limitations on exercise discussed in footnote 13 below.
- Under the terms of the December 2020 Warrants, a selling shareholder may not exercise Warrants to the extent that such selling shareholder, together with its affiliates, would beneficially own, after such exercise, more than 4.99% or 9.99%, as applicable, of the ordinary shares then outstanding (subject to the right of a selling shareholder with a 4.99% ownership limitation to increase or decrease such beneficial ownership limitation upon notice to us, provided that such limitation cannot exceed 9.99%) and provided that any increase in the beneficial ownership limitation shall not be effective until 61 days after such notice is delivered. Substantially similar beneficial ownership limitations of 4.99% or 9.99% are found in other outstanding warrants held by the selling shareholders.
- (14) Represents the maximum number of ordinary shares that may be offered based on the assumption that all of the outstanding December 2020 Warrants held by the selling shareholder will be exercised for cash, irrespective of limitations on exercise discussed in footnote 13 above.
- (15) Represents the number of ordinary shares that will be beneficially owned, irrespective of limitations on exercise discussed in footnote 9 above, by each selling shareholder after completion of this offering. Each number is based on the assumptions that (i) all of the ordinary shares registered for resale by the registration statement of which this prospectus is a part will be sold (following exercise of the December 2020 Warrants), (ii) no other ordinary shares will be sold (including ordinary shares held outright or underlying other outstanding warrants owned as of December 8, 2020) or acquired by the selling shareholder before completion of this offering and (iii) no exercise or vesting of any other warrants or outstanding convertible securities issued by the Company.
- (16) Each applicable percentage ownership following the offering is based on 29,276,844 shares outstanding as of December 8, 2020, assuming the exercise of all the outstanding December 2020 Warrants and the resale of all December 2020 Shares and ordinary shares underlying the December 2002 Warrants by the selling shareholders in offerings under this prospectus.

PLAN OF DISTRIBUTION

Each selling shareholder of the resale securities and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their securities covered hereby on the Nasdaq Capital Market or any other stock exchange, market or trading facility on which the securities are traded or in private transactions. These sales may be at fixed or negotiated prices. A selling shareholder may use any one or more of the following methods when selling securities:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;

- privately negotiated transactions;
- · settlement of short sales;
- in transactions through broker-dealers that agree with the Selling Shareholders to sell a specified number of such securities at a stipulated price per security;
- · through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or any other method permitted pursuant to applicable law.

The selling shareholders may also sell securities under Rule 144 or any other exemption from registration under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the selling shareholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling shareholders (or, if any broker-dealer acts as agent for the purchaser of securities, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with FINRA IM-2440.

In connection with the sale of the securities or interests therein, the selling shareholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the securities in the course of hedging the positions they assume. The selling shareholders may also sell securities short and deliver these securities to close out their short positions, or loan or pledge the securities to broker-dealers that in turn may sell these securities. The selling shareholders may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities which require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The selling shareholders and any broker-dealers or agents that are involved in selling the securities may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the securities purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each selling shareholder has informed the Company that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities. If any selling shareholder notifies us that a material arrangement has been entered into with a broker-dealer or other agent for the sale of shares through a block trade or certain other methods, we may be required to file an amendment or supplement to this prospectus pursuant to applicable SEC rules promulgated under the Securities Act.

The Company is required to pay certain fees and expenses incurred by the Company incident to the registration of the resale securities. Other than in connection with indemnification, we will bear only the costs, expenses and fees in connection with the registration of the resale securities (which do not include the fees and expenses of any selling shareholder counsel). The Company has also agreed to indemnify the selling shareholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act. The selling shareholders will pay any commissions, discounts and transfer taxes attributable to the sales of the resale securities.

We agreed to keep this prospectus effective until the earlier of (i) the date on which the securities may be resold by the selling shareholders without registration and without regard to any volume or manner-of-sale limitations by reason of Rule 144, without the requirement for the Company to be in compliance with the current public information under Rule 144 under the Securities Act or any other rule of similar effect or (ii) all of the securities have been sold pursuant to this prospectus or Rule 144 under the Securities Act or any other rule of similar effect. The resale securities will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale securities covered hereby may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale securities may not simultaneously engage in market making activities with respect to the ordinary shares for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the selling shareholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of the ordinary shares by the selling shareholders or any other person. We will make copies of this prospectus available to the selling shareholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

LEGAL MATTERS

Certain legal matters with respect to Israeli law and with respect to the validity of the offered securities under Israeli law will be passed upon for us by Goldfarb Seligman & Co., Tel Aviv, Israel. Certain legal matters with respect to U.S. federal securities laws and New York law will be passed upon for us by White & Case LLP, New York, New York.

EXPERTS

The consolidated financial statements as of December 31, 2019 and 2018 and for each of the years in the three-year period ended December 31, 2019 incorporated by reference into this prospectus have been audited by Kost Forer Gabbay & Kasierer, a member of Ernst & Young Global, an independent registered public accounting firm, as set forth in its report thereon and appearing therein (which report contains an explanatory paragraph regarding the Company's ability to continue as a going concern as described in Note 1e to the consolidated financial statements), and are included in reliance upon such report given on the authority of such firm as an expert in accounting and auditing. The offices of Kost, Forer Gabbay & Kasierer are located at 144 Menachem Begin Road, Tel Aviv, 6492102.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the securities offered by this prospectus. This prospectus, which is part of our registration statement on Form S-1, omits certain non-material information, exhibits, schedules and undertakings set forth in the registration statement. For further information about us and the securities offered by this prospectus, please refer to the registration statement. You may access copies at the SEC's website (www.sec.gov).

We are subject to the information reporting requirements of the Exchange Act applicable to U.S. domestic issuers and, as such, file annual, quarterly and current reports, proxy statements and other information with the SEC. The SEC's website (www.sec.gov) also contains reports, proxy statements and other information regarding issuers, such as us, that file electronically with the SEC. We also maintain a website (www.rewalk.com), from which you can access such reports and other information free of charge as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. Information contained on, or that can be accessed through, our website does not constitute a part of this prospectus.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to "incorporate by reference" information into this prospectus, which means that we can disclose important information to you by referring you to other documents which we have filed or will file with the SEC. We are incorporating by reference in this prospectus the documents listed below and all amendments or supplements we may file to such documents after the effective date of the registration statement to which this prospectus relates and prior to the termination of the offering under this prospectus:

- our Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on February 20, 2020, as amended by Amendment No. 1 thereto filed with the SEC on December 18, 2020;
- our Definitive Proxy Statement on Schedule 14A filed with the SEC on May 12, 2020;
- our Quarterly Reports on Form 10-Q for the quarter ended March 31, 2020 filed with the SEC on November 10, 2020, for the quarter ended June 30, 2020 filed with the SEC on August 12, 2020 and for the quarter ended September 30, 2020 filed with the SEC on November 10, 2020;
- our current reports on Form 8-K filed with the SEC on February 10, 2020, March 6, 2020, March 19, 2020, March 27, 2020, April 9, 2020, May 5, 2020, May 11, 2020, June 18, 2020, July 6, 2020, August 27, 2020, October 19, 2020, December 1, 2020 and December 8, 2020; and
- the description of our ordinary shares contained in Item 1 of the Registration Statement on Form 8-A (File No. 001-36612) filed with the SEC on September 2, 2014, as updated by Exhibit 4.2 to the 2019 Form 10-K (description of the Company's securities registered pursuant to Section 12 of the Exchange Act) and any other amendment or report filed for the purpose of updating that description.

In addition, we incorporate by reference into this prospectus any filings we make with the SEC pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act on or after the effective date of the registration statement to which this prospectus relates and until the termination or completion of the offering hereunder (in each case, except for the information furnished under Item 2.02 or Item 7.01 in any current report on Form 8-K). Notwithstanding the foregoing, no information is incorporated by reference in this prospectus or any prospectus supplement hereto where such information under applicable forms and regulations of the SEC is not deemed to be "filed" under Section 18 of the Exchange Act or otherwise subject to the liabilities of that section, unless we indicate in this prospectus or the report or filing containing such information that the information is to be considered "filed" under the Exchange Act or is to be incorporated by reference in this prospectus or any prospectus supplement hereto.

Certain statements in and portions of this prospectus update and replace information in the above-listed documents incorporated by reference. Likewise, statements in or portions of a future document incorporated by reference in this prospectus may update and replace statements in and portions of this prospectus or the above-listed documents.

ENFORCEABILITY OF CIVIL LIABILITIES

We are incorporated under the laws of the State of Israel. It may be difficult to obtain service of process within the United States upon us, upon our directors and executive officers, a majority of whom reside outside of the United States, and upon those Israeli experts named in this prospectus who reside outside of the United States. Furthermore, because a majority of our assets and a majority of our directors and executive officers are located outside of the United States, any judgment obtained in the United States against us, certain of our directors and executive officers or the Israeli experts named herein may be difficult to collect within the United States.

We have been informed by our legal counsel in Israel, Goldfarb Seligman & Co., Tel Aviv, that it may be difficult to assert U.S. securities laws claims in original actions instituted in Israel. Israeli courts may refuse to hear a claim based on a violation of U.S. securities laws because 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 which can be a time-consuming and costly process. Matters of procedure will also be governed by Israeli law.

We have irrevocably appointed our subsidiary, ReWalk Robotics Inc., which is incorporated in Delaware, as our agent to receive service of process in any action against us in any United States federal or state court arising out of offerings or sales pursuant to this prospectus or any purchase or sale of securities in connection with this prospectus. Subject to specified time limitations and legal procedures, Israeli courts may enforce a non-appealable foreign judgment in a civil matter, provided that, among other things:

- the judgment is obtained after due process before a court of competent jurisdiction, according to the laws of the foreign state in which the judgment is given and the rules of private international law currently prevailing in Israel;
- · the prevailing law of the foreign state in which the judgment is rendered allows for the enforcement of judgments of Israeli courts;
- adequate service of process has been effected and the defendant has had a reasonable opportunity to be heard and to present his or her evidence;
- the judgment is not contrary to the public policy of Israel, and the enforcement of the civil liabilities set forth in the judgment is not likely to impair the security or sovereignty of Israel;
- the judgment was not obtained by fraud and does not conflict with any other valid judgment in the same matter between the same parties;
- an action between the same parties in the same matter was not pending in any Israeli court at the time the lawsuit was instituted in the foreign court; and
- the judgment is enforceable according to the laws of Israel and according to the law of the foreign state in which the relief was granted.

If a foreign judgment is enforced by an Israeli court, it generally will be payable in Israeli currency, which can then be converted into non-Israeli currency and transferred out of Israel. Traditionally, in an action before an Israeli court to recover an amount in a non-Israeli currency, the Israeli court issues a judgment for the equivalent amount in Israeli currency at the rate of exchange in force on the date of the judgment, but the judgment debtor may make payment in foreign currency. Pending collection, the amount of the judgment of an Israeli court stated in Israeli currency ordinarily will be linked to the Israeli consumer price index plus a per-annum statutory rate of interest set on a quarterly basis by Israeli regulations. Judgment creditors must bear the risk of unfavorable exchange rates. The trend in recent years has increasingly been for Israeli courts to enforce a foreign judgment in the foreign currency specified in the judgment, in which case there are also applicable rules regarding the payment of interest.



ReWalk Robotics Ltd.

5,579,776 Ordinary Shares

4,519,619 Ordinary Shares Issuable upon Exercise of Outstanding Warrants

To Be Sold by Selling Shareholders

PRELIMINARY PROSPECTUS

PART II INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth all expenses paid or payable by the registrant in connection with the filing of this registration statement. All amounts shown are estimates except for the SEC registration fee.

SEC registration fee	\$ 1,476.47
Legal fees and expenses ⁽¹⁾	35,000
Accountants' fees and expenses	15,000
Printing fees	5,000
Miscellaneous	523.23
TOTAL	\$ 57,000

(1) Represents estimated fees of the registrant's Israeli and U.S. securities counsel.

Item 14. Indemnification of Directors and Officers.

Under the Israeli Companies Law, a company may not exculpate an office holder from liability for a breach of the duty of loyalty. An Israeli company may exculpate an office holder in advance from liability to the company, in whole or in part, for damages caused to the company as a result of a breach of duty of care but only if a provision authorizing such exculpation is included in its articles of association. Our Articles of Association include such a provision. An Israeli company also may not exculpate in advance a director from liability arising out of a prohibited dividend or distribution to shareholders.

Under the Israeli Companies Law, a company may indemnify an office holder in respect of the following liabilities and expenses incurred for acts performed by him or her as an office holder, either pursuant to an undertaking made in advance of an event or following an event, provided its articles of association include a provision authorizing such indemnification:

- financial liability imposed on him or her in favor of another person pursuant to a judgment, including a settlement or arbitrator's award approved by a court. However, if an undertaking to indemnify an office holder with respect to such liability is provided in advance, then such an undertaking must be limited to events which, in the opinion of the board of directors, can be foreseen based on the company's activities when the undertaking to indemnify is given, and to an amount or according to criteria determined by the board of directors as reasonable under the circumstances, and such undertaking shall detail the abovementioned foreseen events and amount or criteria;
- reasonable litigation expenses, including attorneys' fees, incurred by the office holder (1) as a result of an investigation or proceeding instituted against him or her by an authority authorized to conduct such investigation or proceeding, provided that (i) no indictment was filed against such office holder as a result of such investigation or proceeding; and (ii) no financial liability was imposed upon him or her as a substitute for the criminal proceeding as a result of such investigation or proceeding or, if such financial liability was imposed, it was imposed with respect to an offense that does not require proof of criminal intent; and (2) in connection with a monetary sanction; and
- reasonable litigation expenses, including attorneys' fees, incurred by the office holder or imposed by a court in proceedings instituted against him or her by the company, on its behalf, or by a third party, or in connection with criminal proceedings in which the office holder was acquitted, or as a result of a conviction for an offense that does not require proof of criminal intent.

Under the Israeli Companies Law, a company may insure an office holder against the following liabilities incurred for acts performed by him or her as an office holder if and to the extent provided in the company's articles of association:

- a breach of the duty of loyalty to the company, provided that the office holder acted in good faith and had a reasonable basis to believe that the act would not harm the company;
- a breach of duty of care to the company or to a third party, to the extent such a breach arises out of the negligent conduct of the office holder; and
- a financial liability imposed on the office holder in favor of a third party.

Under the Israeli Companies Law, a company may not indemnify, exculpate or insure an office holder against any of the following:

- a breach of the duty of loyalty, except for indemnification and insurance for a breach of the duty of loyalty to the company to the extent that the office holder acted in good faith and had a reasonable basis to believe that the act would not prejudice the company;
- · a breach of duty of care committed intentionally or recklessly, excluding a breach arising out of the negligent conduct of the office holder;
- an act or omission committed with intent to derive illegal personal benefit; or
- a civil or criminal fine or forfeit levied against the office holder.

Under the Israeli Companies Law, exculpation, indemnification and insurance of office holders in a public company must be approved by the compensation committee and the board of directors and, with respect to certain office holders or under certain circumstances, also by the shareholders.

We have entered into indemnification agreements with our office holders to exculpate, indemnify and insure our office holders to the fullest extent permitted by our Articles of Association, the Israeli Companies Law and the Israeli Securities Law, 5728-1968.

We have obtained directors' and officers' liability insurance for the benefit of our office holders and intend to continue to maintain such coverage and pay all premiums thereunder to the fullest extent permitted by the Israeli Companies Law.

Item 15. Recent Sales of Unregistered Equity Securities.

Since December 1, 2017, we issued securities that were not registered under the Securities Act of 1933, as amended, or the Securities Act, as set forth below. We believe that each of such sales or issuances was exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act, Regulation D thereunder and/or Regulation S thereunder.

The following is a summary of transactions during the preceding three years involving sales of our securities that were not registered under the Securities Act:

• On March 6, 2018, we entered into an investment agreement (as amended, the "Investment Agreement") for a private placement of 640,000 of our ordinary shares to Timwell Corporation Limited ("Timwell") in exchange for total aggregate proceeds of \$20 million at a price of \$31.25 per share. Timwell agreed to make the investment in three separate tranches, consisting of \$5.0 million for 160,000 shares in the first tranche \$10 million for 320,000 shares in the second tranche and \$5.0 million for 160,000 shares in the third tranche. We issued the first tranche of 160,000 shares pursuant to the investment agreement on May 15, 2018. The closings of the remaining tranches were subject to various specified closing conditions, including the formation of a joint venture, the signing of a license agreement and a supply agreement, and the successful production of certain ReWalk products. We believe that Timwell committed various material breaches of the Investment Agreement, including failure to consummate its second and third investment tranches in the Company for a total of \$15 million, failure to enter into a detailed joint venture with the Company, and failure to make payments for product-related commitments. In late March 2020, Timwell notified us that it would not invest the second and third tranches under the Investment Agreement. In response, in early April 2020, our Board of Directors also removed Timwell's designee, who was appointed pursuant to the Investment Agreement, from the Board of Directors, due to this breach pursuant to the terms of the Investment Agreement.

- In May 2018, we entered into a fee and release agreement with Canaccord Genuity LLC ("Canaccord Genuity"), requiring us to pay to Canaccord Genuity, in connection with a settlement, in addition to certain cash amounts, (i) \$125,000 in our ordinary shares after the closing of the first tranche of the Timwell transaction, and (ii) \$225,000 in our ordinary shares after the closing of the second tranche of the Timwell transaction (or such lower amount if the second tranche closing is less than \$10,000,000). The price per share used for calculation of the number of ordinary shares issued by the Company to Canaccord Genuity is based on the volume weighted average price of the Company's ordinary shares as reported on the Nasdaq Capital Market for the five consecutive trading days prior to the date of issuance. Following the closing of the first tranche of the Timwell transaction on May 15, 2018, we issued 4,715 ordinary shares to Canaccord Genuity.
- On February 25, 2019, we issued to representatives of H.C. Wainwright warrants to purchase up to 45,600 ordinary shares with an exercise price of \$7.1875 per share, exercisable from February 25, 2019 until February 21, 2024, as compensation for H.C. Wainwright's role as the placement agent in our "best efforts" public offering of ordinary shares in February 2019.
- On April 3, 2019, we entered into securities purchase agreements with certain institutional purchasers whereby we issued warrants to purchase up to 408,457 ordinary shares with an exercise price of \$5.14 per share, exercisable from April 5, 2019 until October 7, 2024, in a private placement that took place concurrently with our registered direct offering of ordinary shares in April 2019. In connection therewith, we issued warrants to purchase up to 49,015 ordinary shares, with an exercise price of \$6.503125 per share, exercisable from April 5, 2019 until April 3, 2024, to representatives of H.C. Wainwright as compensation for H.C. Wainwright's role as the placement agent in our April 2019 registered direct offering and concurrent private placement of warrants.
- On June 5, 2019 and June 6, 2019, we entered into warrant exercise agreements with certain institutional investors whereby we issued warrants to purchase up to 1,464,665 ordinary shares with an exercise price of \$7.50 per share, exercisable from June 5, 2019 or June 6, 2019 until June 5, 2024 or June 6, 2024, respectively. In connection therewith, we issued warrants to purchase up to 87,880 ordinary shares, with an exercise price of \$9.375 per share, exercisable from June 5, 2019 until June 5, 2024, to certain representatives of H.C. Wainwright as compensation for H.C. Wainwright's role as the placement agent in our June 2019 warrant exercise agreement and concurrent private placement of warrants.
- On June 12, 2019, we entered into securities purchase agreements with certain institutional investors whereby we issued warrants to purchase up to 416,667 ordinary shares with an exercise price of \$6.00 per share, exercisable from June 12, 2019 until December 12, 2024, in a private placement that took place concurrently with our registered direct offering of ordinary shares in June 2019. In connection therewith, we issued warrants to purchase up to 50,000 ordinary shares, with an exercise price of \$7.50 per share, exercisable from June 12, 2019 until June 10, 2024, to certain representatives of H.C. Wainwright as compensation for H.C. Wainwright's role as the placement agent in our June 2019 registered direct offering and concurrent private placement of warrants.
- On July 1, 2020, we entered into securities purchase agreements with certain institutional investors whereby we issued warrants to purchase up to 2,765,436 ordinary shares with an exercise price of \$1.76 per share, exercisable from July 1, 2020 until February 1, 2025, in a private placement that took place concurrently with our registered direct offering of ordinary shares in July 2020. In connection therewith, we 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 1, 2025, to certain representatives of H.C. Wainwright as compensation for H.C. Wainwright's role as the placement agent in our July 2020 registered direct offering and concurrent private placement of warrants.

• On December 3, 2020, we entered into a securities purchase agreements with certain institutional investors whereby we issued 5,579,776 ordinary shares and 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. In connection therewith, we 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 H.C. Wainwright's role as the placement agent in such December 2020 private placement of ordinary shares and warrants.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits

No. <u>Description</u>

- 3.1 Third 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 April 1, 2019).
- 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 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).
- 4.3 Form of warrant issued in connection with the Company's follow-on offering in November 2016 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on October 31, 2016).
- 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 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 July 6, 2020).
- 4.17 Form of placement agent warrant from July 2020 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 July 6, 2020).
- 4.18 Form of purchaser warrant from the December 2020 private placement (incorporated by reference to Exhibit 4.1 to 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 the December 2020 private placement (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on December 8, 2020).
- 4.20 Form of Registration Rights Agreement, dated December 3, 2020, by and among the Company and the investors party thereto (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on December 8, 2020).
- 5.1 Opinion of Goldfarb Seligman & Co., Israeli counsel to the Company (including consent).†
- 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 registration statement on Form F-1 (File No. 333-197344), filed with the SEC on July 10, 2014).*
- 10.2 Strategic Alliance Agreement, dated September 24, 2013, between the Company and Yaskawa Electric Corporation (incorporated by reference to Exhibit 10.2 to the Company's registration statement on Form F-1 (File No. 333-197344), filed with the SEC on July 10, 2014).
- 10.3 Confidentiality and Non-Disclosure Agreement, dated September 24, 2013, between the Company and Yaskawa Electric Corporation (incorporated by reference to Exhibit 10.4 to the Company's registration statement on Form F-1 (File No. 333-197344), filed with the SEC on July 10, 2014).
- 10.4 Side Letter, dated September 30, 2013, between the Company and Yaskawa Electric Corporation (incorporated by reference to Exhibit 10.5 to the Company's registration statement on Form F-1 (File No. 333-197344), filed with the SEC on July 10, 2014).
- 10.5 Loan Agreement, dated December 30, 2015, between the Company and Kreos Capital V (Expert Fund) Limited (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on January 4, 2016).#
- 10.6 First Amendment, dated June 9, 2017, to the Loan Agreement, dated December 30, 2015, between ReWalk Robotics, Ltd. and Kreos Capital V (Expert Fund) Limited (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 3, 2017).#
- 10.7 Research Collaboration Agreement, dated May 16, 2016, between the Company and the President and Fellows of Harvard College (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on May 17, 2016).*
- 10.8 License Agreement, dated May 16, 2016, 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 May 17, 2016).*
- 10.9 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).**
- 10.10 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).**
- 10.11 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).**

- 10.12 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).**
- 10.13 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).**
- Amended and Restated 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).**
- 10.15 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).**
- 10.16 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).**
- 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).**
- 10.18 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).**
- 10.19 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).**
- 10.20 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).**
- 10.21 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).**
- 10.22 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)**
- 10.23 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).**
- 10.24 ReWalk Robotics Ltd. Compensation Policy for Executive Officers and Non-Executive Directors, as amended (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on June 18, 2020).**
- 10.25 Equity Distribution Agreement, dated May 10, 2016, between the Company and Piper Jaffray & Co., as Agent (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed with the SEC on May 10, 2016).
- 10.26 Amendment No. 1 to Equity Distribution Agreement, dated May 9, 2019, between the Company and Piper Jaffray & Co., as Agent (incorporated by reference to Exhibit 10.1 to the Company's current report on Form 8-K filed with the SEC on May 9, 2019).
- 10.27 Amendment to Employment Agreement, dated March 1, 2018, between the Company and Ori Gon (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on March 7, 2018).**
- 10.28 Employment Agreement, dated May 25, 2015, between the Company and Ori Gon (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on March 7, 2018).**#
- 10.29 Investment Agreement, dated March 6, 2018, by and between the Company and Timwell Corporation Limited (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on March 23, 2018).*

- 10.30 Framework Agreement Regarding a Potential Joint Venture, dated March 6, 2018, between the Company and RealCan Ambrum Healthcare Industry Investment (Shenzhen) Partnership Enterprise (Limited Partnership) (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on March 23, 2018).*
- 10.31 Amendment No. 1 to Investment Agreement, dated May 15, 2018, between the Company and Timwell Corporation Limited (incorporated by reference to Exhibit 99.3 to the Schedule 13D filed by Timwell Corporation Limited with the SEC on May 29, 2018).
- 10.32 Amendment No. 1 to the Research Collaboration Agreement, dated May 1, 2017, between the Company and the President and Fellows of Harvard College (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on June 29, 2018).*
- 10.33 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).*
- Amendment No. 3 to the Research Collaboration Agreement, dated April 30, 2020, between the Company and the President and Fellows of Harvard College (incorporated by reference to Exhibit 10.34 of the Company's registration statement on Form S-1 (File No.333-239733), filed with the SEC on July 7, 2020).△
- 10.35 Waiver, dated September 3, 2018, between the Company and Kreos Capital V (Expert Fund) L.P. (incorporated by reference to Exhibit 10.38 to the Company's registration statement on Form S-1 (File No. 333-227852), filed with the SEC on October 15, 2018).
- 10.36 Second Amendment to Loan Agreement between the Company and Kreos Capital V (Expert Fund) Limited, dated November 20, 2018 (incorporated by reference to Exhibit 10.1 to the Company's current report on Form 8-K filed with the SEC on November 21, 2018).
- 10.37 Form of securities purchase agreement from February 2019 "best efforts" public offering (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on February 25, 2019).#
- 10.38 Form of securities purchase agreement from April 2019 registered direct offering and concurrent private plcaement of warrants (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on April 5, 2019).#
- 10.39 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).
- 10.40 Form of securities purchase agreement from June 2019 registered direct offering and concurrent 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 12, 2019).#
- 10.41 Form of securities purchase agreement from February 2020 best efforts offering (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on February 10, 2020)./#
- 10.42 Engagement Letter, dated December 31, 2019 between the Company and H.C. Wainwright & Co., LLC (incorporated by reference to Exhibit 10.45 of the Company's registration statement on Form S-1 Amendment No. 1 (File No. 333-235932), filed with the SEC on January 30, 2020).^
- 10.43 Amendment No. 1 to the Engagement Letter, dated February 3, 2020, between the Company and H.C. Wainwright & Co., LLC (incorporated by reference to Exhibit 10.46 of the Company's registration statement on Form S-1 Amendment No. 2 (File No. 333-235932), filed with the SEC on February 4, 2020).
- 10.44 Amendment No. 1 to the Securities Purchase Agreement, dated February 7, 2020, by and among the Company and the purchasers party thereto (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on February 10, 2020).
- 10.45 Form of securities purchase agreement from July 2020 registered direct offering and concurrent 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 July 6, 2020)./#
- 10.46 Engagement Letter, dated June 2, 2020, between the Company and H.C. Wainwright & Co., LLC (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on July 6, 2020).

- 10.47 Form of securities purchase agreement from December 2020 private placement of ordinary shares and warrants (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on December 8, 2020).^#
- 10.48 Engagement Letter, dated December 2, 2020, between the Company and H.C. Wainwright & Co., LLC (incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K filed with the SEC on December 8, 2020).
- 21.1 <u>List of subsidiaries of the Company (incorporated by reference to Exhibit 21.1 to the Company's registration statement on Form S-1/A (File No. 333-227852), filed with the SEC on November 7, 2018).</u>
- 23.1 Consent of Kost Forer Gabbay & Kasierer, a member of Ernst & Young Global Limited.†
- 23.2 Consent of Goldfarb Seligman & Co. (included in Exhibit 5.1).†
- 24.1 Power of Attorney (included in the signature page to the registration statement).†
- * Portions of the agreement were omitted and a complete copy of the agreement has been provided separately to the SEC pursuant to the Company's application requesting confidential treatment under, as applicable, Rule 406 of the Securities Act of 1933, as amended and/or Rule 24b-2 of the Securities Exchange Act of 1934, as amended, which application was subsequently granted.
- ** Management contract or compensatory plan, contract or arrangement.
- † Filed herewith.
- # The schedules to this exhibit have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company agrees to furnish a copy of the omitted schedules to the SEC on a supplemental basis upon its request
- ^ Portions of this exhibit (indicated by asterisks) have been omitted under rules of the SEC permitting the confidential treatment of select information.
 - (b) Financial statement schedules

No financial statement schedules are provided because the information called for is not applicable or is shown in the financial statements or notes.

Item 17. Undertakings.

- (1) The undersigned registrant hereby undertakes:
- (a) to file, during any period in which offers or sales are being made, a post-effective amendment to this Registration Statement:
 - (i) to include any prospectus required by Section 10(a)(3) of the Securities Act;
 - (ii) to reflect in the prospectus any facts or events arising after the effective date of this Registration Statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in this Registration Statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and
 - (iii) to include any material information with respect to the plan of distribution not previously disclosed in the Registration Statement or any material change to such information in this Registration Statement;

provided, however, that paragraphs (i), (ii) and (iii) above do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Exchange Act that are incorporated by reference in this Registration Statement.

- (b) that, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (c) to remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
- (d) that, for the purpose of determining liability of a registrant under the Securities Act to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:
 - (i) any preliminary prospectus or prospectus of the undersigned registrant to the offering required to be filed pursuant to Rule 424;
 - (ii) any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by an undersigned registrant;
 - (iii) the portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
 - (iv) any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.
- The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in this Registration Statement shall be deemed to be a new registration statement relating to the securities offered herein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (3) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the provisions referred to in Item 15, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.
- (4) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this Registration Statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this Registration Statement as of the time it was declared effective.
- (5) The undersigned registrant hereby undertakes that, for the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Marlborough, State of Massachusetts on December 18, 2020.

REWALK ROBOTICS LTD.

By: <u>/s/Ori Gon</u> Name: Ori Gon

Title: Chief Financial Officer

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS that each person whose signature appears below hereby constitutes and appoints Larry Jasinski and Ori Gon, and each of them, his or her true and lawful attorneys-in-fact and agents, with full power to act separately and full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement and all additional registration statements pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the SEC, granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or either of them or his or her or their substitute or substitutes may lawfully do or cause to be done by virtue hereof. This Power of Attorney may be signed in counterparts.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons in the capacities and on the dates indicated:

Signature	Title of Capacities	Date
<u>/s/ Larry Jasinski</u> Larry Jasinski	Director and Chief Executive Officer (Principal Executive Officer)	December 18, 2020
<u>/s/ Ori Gon</u> Ori Gon	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	December 18, 2020
<u>/s/ Jeff Dykan</u> Jeff Dykan	Chairman of the Board	December 18, 2020
/s/ Dr. John William Poduska Dr. John William Poduska	Director	December 18, 2020
/s/ Yohanan Engelhardt Yohanan Engelhardt	Director	December 18, 2020
<u>/s/ Wayne B. Weisman</u> Wayne B. Weisman	Director	December 18, 2020
/s/ Yasushi Ichiki Yasushi Ichiki	Director	December 18, 2020
<u>/s/ Aryeh Dan</u> Aryeh Dan	Director	December 18, 2020
<u>/s/ Randel Richner</u> Randel Richner	Director	December 18, 2020
REWALK ROBOTICS, INC.	Authorized Representative in the United States	
By: <u>/s/ Larry Jasinski</u> Name: Larry Jasinski Title: Chief Executive Officer		December 18, 2020



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December 18, 2020

ReWalk Robotics Ltd. 3 Hatnufa Street, Floor 6 Yokneam Ilit 2069203 Israel

Ladies and Gentlemen:

We have acted as Israeli counsel to ReWalk Robotics Ltd., an Israeli company (the "Company"), in connection with the public offering (the "Offering") by the Company on a registration statement on Form S-1 (as amended, the "Registration Statement"), filed with the Securities and Exchange Commission (the "Commission") under the Securities Act of 1933, as amended (the "Act"), covering the resale by selling shareholders named in the Registration Statement (the "Selling Shareholders") of ordinary shares, par value NIS 0.25 per share, of the Company (the "Ordinary Shares"), (i) issued to the Selling Shareholders pursuant to that certain Securities Purchase Agreement, dated as of December 3, 2020, by and among the Company and the purchasers named therein (such Ordinary Shares, the "Outstanding Shares") and (ii) issuable upon the exercise of certain warrants to purchase Ordinary Shares (the "Warrants") held by such Selling Shareholders (including Ordinary Shares that may be issued to such Selling Shareholders in lieu of fractional shares) (such Ordinary Shares, the "Warrant Shares" and collectively with the Outstanding Shares, the "Shares").

This opinion is being furnished in connection with the requirements of Items 601(b)(5) and (b)(23) of Regulation S-K under the Act, and no opinion is expressed herein as to any matter pertaining to the contents of the Registration Statement or the prospectus that is a part of the Registration Statement, other than as expressly stated herein with respect to the issuance of the Shares.

In connection with this opinion, we have examined and relied without investigation as to matters of fact upon the Registration Statement and exhibits thereto, the prospectus that is a part of the Registration Statement, resolutions of the board of directors of the Company (such resolutions, the "Resolutions") that relate to the Registration Statement and other actions to be taken in connection with the Offering, such originals or copies, certified or otherwise identified to our satisfaction, of such other documents, corporate records, certificates and statements of public officials and officers and representatives of the Company, and instruments as we have deemed necessary or appropriate to enable us to render the opinions expressed herein. We have assumed the genuineness of all signatures on all documents examined by us, the legal competence and capacity of natural persons, the authenticity of documents submitted to us as originals, the conformity with authentic original documents of all documents submitted to us as copies and the authenticity of the originals of such copies. We have also assumed that until such time as the Warrant Shares are issued, the Resolutions will not be rescinded, cancelled, amended or modified in any way.

Based upon the foregoing, in reliance thereon and subject to the assumptions, comments, qualifications, limitations and exceptions stated herein, we are of the opinion that the Outstanding Shares are duly authorized, validly issued, fully paid and non-assessable and that the Warrant Shares to be sold by the Selling Shareholders have been duly authorized and, when issued upon exercise of the Warrants in accordance with the terms thereof, will be validly issued, fully paid and non-assessable.

We are members of the Israel Bar and we express no opinion as to any matter relating to the laws of any jurisdiction other than the laws of Israel.

The opinion set forth in this letter is effective as of the date hereof. We do not undertake to advise you of any changes in our opinion expressed herein resulting from matters that may arise after the date of this letter or that hereafter may be brought to our attention. We hereby consent to the filing of this opinion as an exhibit to the Registration Statement, and we further consent to the references to this firm in the sections entitled "Legal Matters" and "Enforceability of Civil Liabilities" in the Registration Statement and in the prospectus that forms a part thereof. This consent is not to be construed as an admission that we are a party whose consent is required to be filed as part of the Registration Statement under the provisions of the Act. We express no opinion other than as herein expressly set forth, and no opinion may be inferred or implied beyond that expressly stated herein.

Very truly yours,

/s/ Goldfarb Seligman & Co.

Goldfarb Seligman & Co.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the reference to our firm under the caption "Experts" in the registration statement on Form S-1 and the related prospectus of ReWalk Robotics Ltd. for the registration of ordinary shares, par value NIS 0.25 per share, and to the incorporation by reference therein of our report dated February 20, 2020, with respect to the consolidated financial statements of ReWalk Robotics Ltd. and its subsidiaries included in ReWalk Robotics Ltd.'s Annual Report on Form 10-K for the year ended December 31, 2019, filed with the Securities and Exchange Commission.

Haifa, Israel December 18, 2020 /s/KOST, FORER, GABBAY & KASIERER KOST, FORER, GABBAY & KASIERER A Member of EY Global