

ReWalk Robotics Ltd.
Form 8-K
October 23, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

**PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934**

Date of Report (Date of earliest event reported): October 17, 2017

ReWalk Robotics Ltd.

(Exact name of registrant as specified in its charter)

Israel	001-36612	N/A
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

3 Hatnufa St., Floor 6, Yokneam Ilit, Israel	2069203
(Address of principal executive offices)	(Zip Code)

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

Not applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

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

Item 2.02 Results of Operations and Financial Condition.

The information in Item 8.01 under “Business—Recent Developments—Third Quarter 2017 Preliminary Results: Cash, Revenue and Unit Information” is incorporated herein by reference.

Item 8.01 Other Events.

ReWalk Robotics Ltd. (“**ReWalk**,” the “**Company**,” “**we**” or “**us**”) is providing the following information as an update to the business and risk factor disclosure contained in our universal shelf registration statement on Form S-3 (File No. 333-209833) (the “**Form S-3**”) and our periodic reports filed with the Securities and Exchange Commission (the “**SEC**”) under the Securities Exchange Act of 1934, as amended (the “**Exchange Act**”), which are incorporated by reference into the Form S-3.

BUSINESS

Recent Developments

Third Quarter 2017 Preliminary Results: Cash, Revenue and Unit Information

Our unaudited consolidated condensed financial statements for the three and nine months ended September 30, 2017 are not yet available. The financial and operational results we present below are therefore preliminary and subject to the completion of our financial closing procedures and any adjustments that may result from the completion of the quarterly review of our unaudited consolidated condensed financial statements. Our independent registered public accounting firm has not audited, reviewed or performed any procedures with respect to these preliminary results and, accordingly, does not express an opinion or any other form of assurance about them. These preliminary results may differ materially from the actual results that will be reflected in our unaudited consolidated condensed financial statements for the three and nine months ended September 30, 2017 when they are completed.

Our revenues were approximately \$1.7 million and \$6.2 million for the three and nine months ended September 30, 2017, respectively, compared to revenues of \$1.4 million and \$4.3 million for the three and nine months ended September 30, 2016, respectively. We derived approximately 68% of our revenues from the United States for the nine

months ended September 30, 2017, compared to 70% for the nine months ended September 30, 2016. The remaining 32% in revenues originated in Europe for the nine months ended September 30, 2017, compared to 21% originating in Europe and 9% originating in Asia-Pacific for the nine months ended September 30, 2016. This increase in revenue for the three and nine months ended September 30, 2017, compared to the same periods in 2016, was primarily due to sales mix, including higher sales to the Veterans' Administration (the "VA") for use in an ongoing clinical study (reaching, as of September 30, 2017, 60 units placed as part of the study since its inception in the fourth quarter of 2015) and an increase in the conversion of rental units into purchases. We placed 16 and 84 units during the three and nine months ended September 30, 2017, respectively, compared to 23 and 80 units during the three and nine months ended September 30, 2016, respectively. During the three and nine months ended September 30, 2017, seven and 34 unit placements were covered by insurance, respectively, compared to 13 and 41 unit placements covered by insurance, respectively, during the three and nine months ended September 30, 2016. As of September 30, 2017, there were 218 pending insurance claims relating to coverage for ReWalk, compared to 149 as of September 30, 2016. In July 2017, we also signed an exclusive distribution agreement in France with Harmonie Médical Service ("HMS"), through which HMS will serve as the sole distributor of ReWalk exoskeleton systems to qualifying candidates with spinal cord injury across France.

Our cash and cash equivalents were approximately \$12.9 million as of September 30, 2017, compared to \$12.4 million as of September 30, 2016 and \$23.7 million as of December 31, 2016.

Insurance Coverage Updates

In September 2017, BARMER GEK ("**Barmer**") confirmed it will provide ReWalk systems to all qualifying beneficiaries. Barmer provides insurance coverage for nearly ten million people in Germany, as a member of the German Statutory Health Insurance network and one of the most significant national insurers in the country. Exoskeletons will be provided to users that meet certain inclusion criteria and assessment by the German Health Insurance Medical Service (*Medizinischer Dienst der Krankenversicherungen*) before and after training. Barmer has already begun processing claims with users entering training for in-home use of an exoskeleton.

We continue to engage with U.S. and European national and regional insurance providers, including European workers' compensation groups, to secure potential coverage policies based on supportive data and appeal rulings that have deemed exoskeleton devices a "medically necessary" standard of care for individuals with SCI. As part of this ongoing initiative, a large national insurance provider has requested additional information from us in order to continue to evaluate a change from its current non-coverage policy. We are also submitting data to two additional U.S. commercial groups for policy reviews.

In the future, we intend to pursue reimbursement coverage through the Centers for Medicare and Medicaid Services (the "**CMS**"). While we believe that a positive response from CMS may broaden coverage by private insurers, we cannot currently predict how long it would take for us to receive a decision from CMS. For more information, see "Part I. Item 1A. Risk Factors—Risks Related to Our Business and Our Industry—We may fail to secure or maintain adequate insurance coverage or reimbursement for ReWalk by third-party payors, including the VA, which risk may be heightened if insurers find ReWalk 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" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016 (the "**2016 Form 10-K**").

As previously disclosed, we regularly assist in litigation efforts by individuals bringing claims against national and regional insurers for reimbursement of the ReWalk device, and have received and expect to receive revenues from settlements or judgments paid to the insured users. We have in the past generated and expect to generate in the future revenues from a combination of third-party payors, self-payors, including private and government employers, and institutions.

Equity Exchange Program

On September 6, 2017, we commenced a one-time equity award exchange program (the "**Equity Exchange Program**"), offering to certain of our eligible employees, executive officers and consultants the opportunity to cancel certain outstanding "underwater" stock options issued under the ReWalk Robotics Ltd. 2014 Incentive Compensation Plan (the "**2014 Plan**"), in exchange for the grant under such plan of a lesser number of restricted share units ("**RSUs**"). We conducted the Equity Exchange Program as a "value-for-value" exchange, in accordance with the terms approved by our shareholders at the annual meeting of shareholders held on June 27, 2017. The primary purpose of the Equity Exchange Program was to restore the intended retention and incentive value of certain of our employee and consultant equity awards, which we believe will promote long-term shareholder value. We do not expect that the Equity Exchange Program will create additional material compensation expense, other than immaterial expense resulting from fluctuations in our share price after the exchange ratios were set and before the Equity Exchange Program began and due to exchange ratio rounding. On the Equity Exchange Program's expiration date of October 4, 2017, 46 holders tendered options to purchase an aggregate of 945,416 ordinary shares, representing 96.4% of all options eligible for exchange, and on October 5, 2017, we granted to these holders an aggregate of 251,872 new RSUs. 180,167 of these new RSUs were granted to our executive officers and "named executive officers" (as defined in Item 402 of Regulation

S-K of the SEC). Unless our compensation committee accelerates their vesting, the new RSUs will vest over a three-year period, with one-third vesting on the first anniversary of the date of grant and one-third vesting on each of the next two successive anniversaries. Additionally, the forfeiture terms of the new RSUs will be substantially the same as those that apply generally to previously-granted RSUs granted under the 2014 Plan.

Restore System and R&D Updates

In June 2017, we unveiled our lightweight “soft suit” exoskeleton prototype, and in October 2017, we announced the start of pre-clinical testing on our Restore system to study its safety and use in the rehabilitation setting for the mobility needs of stroke patients. A prospective clinical trial with the Restore system is targeted to begin in early 2018, and we aim to commercialize the system for use by stroke patients in Europe in late 2018, followed by the United States in late 2018 or early 2019, subject to the timing and receipt of CE mark and United States Food and Drug Administration (“**FDA**”) clearance, respectively.

ReWalk “soft suit” exoskeleton

The Restore transmits power to key joints of the legs with motor-driven cable technologies, applying software and mechanics similar to the technologies employed in the currently-marketed ReWalk structural exoskeleton systems. The system is designed to allow a user’s unimpaired leg to adjust and assist the leg with mobility impairments affected by stroke. The exoskeletal suit consists of a lightweight fabric-based structure that wraps around the waist and supports an actuator with a motor, computer and cable, along with sensors attached to a stable point on the user’s calf and footplate in the user’s shoe. This design transfers force in a controlled manner, enabling both powered plantarflexion, or bending to decrease the angle between the sole of the foot and the back of the leg, and powered dorsiflexion, or bending to decrease the angle between the upper surface of the foot and the front of the leg. We believe that the Restore system’s soft, lightweight material will facilitate a natural walking pattern for patients using the device, and provide advantages to stroke rehabilitation clinics as compared with other traditional therapies and devices, by minimizing setup time, maximizing session productivity and reducing staffing requirements, staff fatigue and the risk for potential staff injuries. The prospective clinical trial on the Restore system, targeted for early 2018, is intended to assess the safety of the Restore system during gait training in stroke patients in a rehabilitation setting. Based on the proposed study design, we anticipate that the study will involve 40 patients each partaking in seven training sessions at designated stroke research centers, with first patient enrollments occurring in early 2018.

We intend to commercialize use of the Restore system by stroke patients in Europe and the United States after receiving CE mark and FDA clearance, respectively, to market the device. We have not yet applied for these clearances and intend to apply in mid-2018. Obtaining clearance could involve an extensive and time-consuming process and delay commercialization beyond our planned timetable, and we cannot make any assurances regarding the ultimate timing of FDA or CE mark clearance or commercialization of the products. For more information on the clearance processes, see “Part I, Item 1. Business—Government Regulation” in our 2016 Form 10-K.

We plan to focus our research and development efforts in the near term primarily on the Restore system for stroke patients and in the longer term on “soft suit” exoskeletons for additional indications affecting the ability to walk, including multiple sclerosis, cerebral palsy, Parkinson’s disease and elderly assistance, and the next generation of our current ReWalk device. We anticipate that the next generation of the ReWalk will be a structural exoskeleton similar to our existing ReWalk devices, but with a slimmer profile, lighter body and improved drive mechanism. For more information, see “Part I, Item 1. Business—Research and Development” in our 2016 Form 10-K.

RISK FACTORS

An investment in our ordinary shares involves a high degree of risk. Our business, financial condition and results of operations could be materially and adversely affected by any of these risks. If any of these risks occurs, the value of our ordinary shares may decline and you may lose all or part of your investment. Before investing in our ordinary shares, you should consider carefully the risk factors set forth below, along with the risk factors described in “Item 1A. Risk Factors” in our 2016 Form 10-K, as updated by other filings we make with the SEC.

Risks Related to Our Business and Our Industry

We may not have sufficient funds to meet certain future capital requirements or grow our business, and may need to take advantage of various forms of capital-raising transactions. Future equity or debt financings or strategic transactions may dilute our shareholders, disrupt our business or place us under restrictive covenants, while limitations under our registration statement on Form S-3 may make it more difficult for us to raise money in the public markets.

As of June 30, 2017, we had an accumulated deficit in the total amount of \$119 million, and further losses are anticipated 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.

We intend to finance operating costs over the next 12 months with existing cash on hand, issuances of equity and/or debt securities, including issuances under our at-the-market equity offering program (the “**ATM Offering Program**”), or through a combination of the foregoing. However, we will need to seek additional sources of financing to the extent that we require more funds than anticipated during the next 12 months or in later periods, including if we cannot make our loan repayments under our loan agreement, as amended (the “**Kreos V Loan Agreement**”), with Kreos Capital V (Expert Fund) Limited (“**Kreos V**”), or if we cannot raise sufficient funds from equity issuances, such as the ATM Offering Program. Due to limitations under the rules of Form S-3, which have applied to us since we filed our 2016 Form 10-K, and taking into account ordinary shares issued and settled under our ATM Offering Program, as of September 30, 2017, we could only issue up to \$4.3 million in primary offerings under our effective Form S-3, including our ATM Offering Program, during the 12 months following February 17, 2017, until and unless we cease to be subject to these limitations. For more information on these limitations, see “Part I, Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Equity Raises” in our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2017 (the “**Q2 2017 Form 10-Q**”). This limitation makes it more difficult for us to raise money in the public markets.

To raise additional capital in the public markets, including taking into account the limitation above, we may be required to seek other more costly or time-consuming methods, such as registration statements on Form S-1. We may also conduct fundraising transactions in the form of private placements, potentially with registration rights or priced at a discount to the market value of our ordinary shares, which could require shareholder approval under the rules of The NASDAQ Stock Market LLC (“**NASDAQ**”), or other equity raise transactions. In addition to 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. These private financings and strategic transactions could require significant management attention, disrupt our business, adversely affect our financial results, be unsuccessful or fail to achieve the desired results. We are in discussions routinely with such possible sources of additional funding, including during the pendency of sales under our ATM Offering Program. We have not entered into any agreement or understanding regarding any such transaction.

As another alternative, we may in the future choose to refinance up to a substantial portion of our remaining indebtedness under the Kreos V Loan Agreement, including by tying our repayment obligations and amortization schedule to the achievement of certain business milestones, which we have considered with Kreos V from time to time. Agreements governing any borrowing arrangement may contain covenants that could restrict our operations. In sum, if we are unable to obtain additional funds on reasonable terms, it could impair our efforts to develop and commercialize existing and new products and to repay our liabilities as they become due, materially harming our results of operations and financial condition.

If we are unable to leverage and expand our sales, marketing, training and reimbursement infrastructure, including in light of our announced plan to reduce corporate spending, we may fail to increase our revenues.

A key element of our long-term business strategy is the continued enhancement 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 and other factors in various geographies. Managing and maintaining this 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 ReWalk into both existing and new markets. In addition, as discussed above under “Summary—Overview,” we have set a goal to reduce total operating expenses in 2017 by up to 30% compared to 2016, in part through a realignment of and reduction in staffing to match our 2017 business goals. As we move forward with these plans, we intend to continue funding field sales, service and training efforts for our ReWalk products. However, certain decisions we make regarding staffing in these areas, in our efforts to decrease expenses, 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. For instance, the number of our staff focused on reimbursement has decreased, and we recently consolidated the functions of two employees that previously focused on reimbursement into the roles of certain executive officers and employees in other departments. Additionally, our Chief Commercial Officer recently passed away.

We also 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, which could inhibit new sales and harm our reputation. If we are unable to expand our sales, marketing and training capabilities, we may not be able to effectively commercialize ReWalk, or enhance the strength of our brand, which could have a material adverse effect on our operating results.

We are subject to securities class action lawsuits against us that may result in an adverse outcome.

Between September 2016 and January 2017, eight putative class actions on behalf of alleged shareholders that purchased or acquired our ordinary shares pursuant and/or traceable to our registration statement on Form F-1 (File No. 333-197344) used in connection with our initial public offering (the “**IPO**”), were commenced in the following courts: (i) the Superior Court of the State of California, County of San Mateo; (ii) the Superior Court of the Commonwealth of Massachusetts, Suffolk County; (iii) the United States District Court for the Northern District of California; and (iv) the United States District Court for the District of Massachusetts. The actions involve claims under various sections of the Securities Act of 1933, as amended (the “**Securities Act**”), against us, certain of our current and former directors and officers, the underwriters of our IPO and certain other defendants. The four actions commenced in the Superior Court of the State of California, County of San Mateo have been dismissed for lack of personal jurisdiction, and the action commenced in the United States District Court for the Northern District of California has been voluntarily dismissed.

As of October 13, 2017, three actions remain pending, including (i) the two actions commenced in the Superior Court of the Commonwealth of Massachusetts (“**Massachusetts State Court**”), which have been consolidated, and (ii) the action commenced in the United States District Court for the District of Massachusetts (“**Massachusetts Federal Court**”), which was brought in part by certain of the plaintiffs whose actions were dismissed in the Superior Court of the State of California, County of San Mateo. The parties in the consolidated Massachusetts State Court actions have completed briefing on the Company’s motion to dismiss. The plaintiffs in the Massachusetts Federal Court action filed a consolidated amended complaint in August 2017 adding claims that certain statements we made after our IPO were materially misleading. For more information, see Notes 5d and 11 to our unaudited condensed consolidated financial statements included in “Part I, Item 1” of our Q2 2017 Form 10-Q.

We are generally required, to the extent permitted by Israeli law, to indemnify our current and former directors and officers who are named as defendants in these types of lawsuits. We also have certain contractual indemnification obligations to the underwriters of our IPO regarding the securities class action lawsuits. While a certain amount of insurance coverage is available for expenses or losses associated with these lawsuits, this coverage may not be sufficient. Based on information currently available, we are unable to reasonably estimate a possible loss or range of

possible losses, if any, with regard to these lawsuits; therefore, no litigation reserve has been recorded in our consolidated balance sheets. Although we plan to defend against these lawsuits vigorously, there can be no assurance that a favorable final outcome will be obtained. These lawsuits or future litigation may require significant attention from management and could result in significant legal expenses, settlement costs or damage awards that could have a materially adverse impact on our financial position, results of operations and cash flows.

Risks Related to Government Regulation

We have initiated a mandatory postmarket surveillance study on our ReWalk Personal 6.0 with a revised FDA-approved protocol, addressing certain violations and deficiencies cited by the FDA that had previously led the FDA to warn us of potential regulatory action. Going forward, if we cannot meet certain FDA requirements 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 labeling or marketing efforts.

We are currently 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 letter on September 30, 2015 (the “**September 2015 Letter**”), warning of potential regulatory action against us for violations of Section 522 of the Federal Food, Drug, and Cosmetic Act, based on our failure to initiate a postmarket surveillance study by the September 28, 2015 deadline and our allegedly deficient protocol for that study. Between June 2014 and our receipt of the September 2015 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 (the “**February 2016 Letter**”), requesting additional changes to our study protocol and asking that we comply within 30 days. This letter also discussed the FDA’s request, as modified in our later discussions with the FDA, for a new premarket notification for our ReWalk device (a “**special 510(k)**”), linked to what the FDA viewed as changes 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 apply enforcement discretion to 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 Letter, we had adequately addressed the violations cited in the September 2015 Letter. As part of our study, we have provided the FDA with the required periodic reports on the study’s progress, in a few cases with delay. We intend to continue providing the FDA with such reports on a timely basis going forward.

We expect we will be able to respond promptly to the FDA’s further requests associated with the postmarket surveillance study with the assistance of our outside clinical and regulatory services provider. However, we may ultimately be unable to timely satisfy the FDA’s requests with respect to the study. Additionally, as of October 13, 2017, we had three active centers enrolling patients in the study, with a total of seven enrolled patients and four active patients, and two others were completing the process to enroll patients by the second half of 2017. This is substantially below the estimated number of patients included in our study protocol, currently leading the FDA to label our progress as “inadequate.” We may seek to modify our study protocol to expand the pool of patients and/or decrease the total number of patients, which change will require approval from the FDA. However, there can be no assurance that the

FDA will agree to modify our study or that we will manage to attract the required number of patients under the current requirements or with the revised requirements. If we cannot meet FDA requirements 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 approximately 64% and 68% of our revenues in the fiscal year ended December 31, 2016 and the nine months ended September 30, 2017, respectively, 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.

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 medical device reporting regulations, which could result in voluntary corrective actions or agency enforcement actions against us.

Under the medical device reporting (MDR) regulations of the FDA, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, our product or a similar device marketed by us would be likely to cause or contribute to death or serious injury. In addition, all manufacturers placing medical devices in European Union markets 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. We recently submitted MDRs to report incidents in which ReWalk Personal users sustained falls or fractures. The FDA has sent us letters requesting additional information relating to these MDRs. Additional events may occur in the future that may require us to report to the FDA pursuant to the MDR regulations. Any adverse event involving our products could result in future voluntary corrective actions, such as recalls or customer letters, agency action, such as inspection, mandatory recall, notification to healthcare professionals and users, or other enforcement action. Any corrective 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. 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.

Risks Related to an Investment in Our Ordinary Shares

A decline in the value of our ordinary shares could result in our being characterized as a passive foreign investment company, which would cause adverse tax consequences for U.S. investors.

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 (“**PFIC**”), for U.S. federal income tax purposes. Passive income for this purpose generally includes, among other things, certain dividends, interest, royalties, rents and gains from commodities and securities transactions and from the sale or exchange of property that gives rise to passive income. Passive income also includes amounts derived by reason of the temporary investment of funds, including those raised in a public offering. In determining whether a non-U.S. corporation is a PFIC, a proportionate share of the income and assets of each corporation in which it owns, directly or indirectly, at least a 25% interest (by value) is taken into account. Based on our gross income and assets, the market price of our ordinary shares, and the nature of our business, we do not believe that we were a PFIC for the taxable year ended December 31, 2016. However, there can be no assurance that we will not be considered a PFIC for 2017 or any taxable year. PFIC status is determined as of the end of the taxable year and depends on a number of factors, including the value of a corporation’s assets and the amount and type of its gross income. Further, because the value of our gross assets is likely to be determined in large part by reference to our market capitalization, there is a significant risk that a decline in the value of our ordinary shares could result in our becoming a PFIC.

If we are characterized as a PFIC, U.S. Holders (as defined below) may suffer adverse tax consequences, including the following: (i) having gains realized on the sale of our securities treated as ordinary income, rather than as capital gains; (ii) losing the preferential rate applicable to dividends received on our ordinary shares by individuals who are U.S. Holders; and (iii) having additional taxes equal to the interest charges generally applicable to underpayments of tax apply to distributions by us and the proceeds of sales of our ordinary shares in offerings. A “U.S. Holder” is defined as follows: 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. 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). 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.

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 September 30, 2017, 3,194,556 ordinary shares remained available for issuance to our and our affiliates' respective employees, non-employee directors and consultants under our equity incentive plans, including 2,592,398 ordinary shares subject to outstanding awards (consisting of outstanding options to purchase 2,238,961 ordinary shares and 353,437 ordinary shares underlying unvested RSUs). These numbers do not reflect the ultimate results of our one-time Equity Exchange Program for the exchange of "underwater" stock options for new RSUs, which expired on October 4, 2017. For more information, see "Business—Recent Developments—Equity Exchange Program" above. Additionally, the number of ordinary shares available for issuance under 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) 972,000, (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.

We previously signed an agreement with a non-employee consultant, who agreed to assist us in commercially promoting and expanding insurance coverage of our ReWalk devices. Although this agreement terminated in May 2017 and was not extended, if we may choose to compensate this consultant for services in an amount equal to those provided for in the expired agreement, the consultant may receive up to ten percent of the increase in our market capitalization following the dates when coverage becomes active under national insurance policies that the consultant secures for us, subject to certain monetary limits. For more information, see Note 8e to our audited consolidated financial statements in our 2016 Form 10-K. If we opt to pay the consultant in ordinary shares, we may need to seek shareholder approval pursuant to the rules of NASDAQ, potentially due to the size of an issuance or an insufficient number of ordinary shares available for issuance under our 2014 Plan. Any such issuance, or the perception that we will make issuances when we solicit shareholder approval, could substantially dilute existing shareholders and materially decrease the value of an investment in our ordinary shares. 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.

Sales of a substantial number of ordinary shares by us, our large shareholders and holders of our warrants and other derivative securities, several of whom have registration rights, or volatility or a reduction in the market price of our ordinary shares could have an adverse effect on 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, or pay for acquisitions using, our equity securities.

As of September 30, 2017, 403,804 ordinary shares were issuable pursuant to the exercise of outstanding warrants granted as part of our Series E Preferred investment round in July 2014 at an exercise price of \$10.08 and 2,437,500 ordinary shares were issuable pursuant to the exercise of warrants issued in our follow-on offering of ordinary shares and warrants in November 2016, with an exercise price of \$4.75. There were also 167,012 ordinary shares issuable pursuant to the exercise of warrants granted to Kreos V in connection with the Kreos V Loan Agreement in January and December 2016, with an exercise price of \$9.64, and 2,523,660 ordinary shares issuable pursuant to the conversion of a convertible note issued to Kreos V, dated June 9, 2017 (the “***Kreos V Convertible Note***”), at a conversion price of \$1.268 per share (subject to customary anti-dilution adjustments).

Additionally, pursuant to our Amended and Restated Shareholders’ Rights Agreement, dated July 14, 2014, with certain of our shareholders, as of September 30, 2017, the beneficial owners of approximately 4,116,143 of our ordinary shares were entitled to require that we register their shares under the Securities Act for resale into the public markets. In our Kreos V Convertible Note, we separately undertook to prepare and file with the SEC a registration statement to enable the resale by Kreos V of up to 2,523,660 ordinary shares to be issued upon conversion of the note,

unless they could otherwise be freely sold using Rule 144 under the Securities Act.

All shares sold pursuant to an offering covered by a registration statement would be freely transferable. With respect to the outstanding warrants and the Kreos V Convertible Note, 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, namely, Yaskawa Electric Corporation (“*Yaskawa*”), and certain entities and individuals affiliated with SCP Vitalife Partners II L.P (“*Vitalife*”), may also have limitations under Rule 144 under the Securities Act on the resale of certain ordinary shares they hold. 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. Any such decrease could impair the value of your investment in us.

The market price of our ordinary shares has also been highly volatile and may fluctuate substantially due to several factors. Effective May 2017, we transferred our ordinary shares from the NASDAQ Global Market to the NASDAQ Capital Market due to our failure to meet the market value of listed securities requirements and the alternative total assets and total revenue standard requirements of the NASDAQ Global Market. Additionally, since the first quarter of 2017, our ordinary shares have traded periodically between \$1.00 and \$2.00, reaching an all-time low of \$1.10 in the second quarter of 2017. To maintain our current listing on the NASDAQ Capital Market, we must meet certain requirements, including, among others, a minimum closing bid price per share. If the closing bid price of our ordinary shares for 30 consecutive business days is less than \$1.00 per share, or if we cannot meet other continued listing requirements, NASDAQ will send us a notification of deficiency and provide us a cure period of 180 days, subject to a potential subsequent cure period of an additional 180 days. After the applicable period, if we cannot show compliance with certain NASDAQ Capital Market listing requirements, we will become subject to delisting proceedings. The perception among investors that we are at heightened risk of delisting could negatively affect the market price and trading volume of our ordinary shares. Additionally, if we become subject to delisting proceedings and fail to appeal a delisting determination, our ordinary shares will be delisted from NASDAQ entirely, which could reduce the number of investors willing to hold or acquire our ordinary shares, increase the volatility of the price of such shares and significantly lower the shares' trading price and volume. Any of these events could also reduce our liquidity and impair our ability to raise capital.

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

As of September 30, 2017, the largest beneficial owners of our shares were Yaskawa, certain entities and individuals affiliated with Vitalife, and Kreos V, which is deemed a beneficial owner of our ordinary shares pursuant to its right to acquire ordinary shares upon the exercise of warrants and the conversion of the Kreos V Convertible Note, which may be converted at any time, subject to its terms. These holders beneficially owned in the aggregate 23.5% of our ordinary shares as of September 30, 2017 (taking into account Kreos V's beneficial ownership in the total number of ordinary shares outstanding). As a result, Yaskawa and Vitalife, and, if it were to convert all ordinary shares underlying its convertible note, Kreos V, would together have sufficient voting power to influence significantly the outcome of matters requiring shareholder approval. These matters may include:

- determining the composition of our board of directors, which has the authority to direct our business and to appoint and remove our officers;
- approving or rejecting a merger, consolidation or other business combination;
- raising future capital; and
-

amending our Second Amended and Restated Articles of Association, as amended by the First Amendment thereto, which govern the rights attached to our ordinary shares.

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

FORWARD-LOOKING STATEMENTS

In addition to historical information, this Current Report on Form 8-K contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act, and Section 21E of the Exchange Act. Such forward-looking statements may include projections regarding ReWalk's future performance 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 phrases. The forward-looking statements contained in this Current Report on Form 8-K are based on 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 ReWalk's control. Important factors that could cause ReWalk's actual results to differ materially from those indicated in the forward-looking statements include, among others: ReWalk's expectations regarding future growth, including its ability to increase sales in its existing geographic markets, expand to new markets and achieve its planned expense reductions; the conclusion of ReWalk's management for the financial statements for the second quarter of 2017 and for fiscal 2016, and the opinion of ReWalk's auditors in their report on the Company's financial statements for fiscal 2016, that there are substantial doubts as to ReWalk's ability to continue as a going concern; ReWalk's ability to maintain and grow its reputation and the market acceptance of its products; ReWalk's ability to achieve reimbursement from third-party payors for its products; ReWalk's expectations as to its clinical research program and clinical results; ReWalk's expectations as to the results of, and the Food and Drug Administration's potential regulatory developments with respect to, ReWalk's mandatory post-market 522 surveillance study; the outcome of ongoing shareholder class action litigation relating to ReWalk's initial public offering; ReWalk's ability to repay its secured indebtedness; ReWalk's ability to improve its products and develop new products; ReWalk's ability to maintain adequate protection of its intellectual property and to avoid violation of the intellectual property rights of others; ReWalk's ability to gain and maintain regulatory approvals; ReWalk's ability to secure capital from its equity and debt financings in light of limitations under its Form S-3, the price range of its ordinary shares and conditions in the financial markets, and the risk that such financings may dilute ReWalk's shareholders or restrict its business; ReWalk's ability to use effectively the proceeds of any offerings of its ordinary shares; ReWalk's ability to maintain relationships with existing customers and develop relationships with new customers; the impact of the market price of ReWalk's ordinary shares on the determination of whether ReWalk is a passive foreign investment company; ReWalk's ability to comply with the continued listing requirements of the NASDAQ Capital Market and the risk its ordinary shares will be delisted if it cannot do so; ReWalk's compliance with medical device reporting regulations to report adverse events involving its products and the potential impact of such adverse events on ReWalk's ability to market and sell its products; and other factors discussed under the heading "Risk Factors" in ReWalk's 2016 Form 10-K and other documents subsequently filed with or furnished to the SEC. Any forward-looking statement made in this Current Report on Form 8-K speaks only as of the date hereof. Factors or events that could cause ReWalk's actual results to differ from the statements contained herein may emerge from time to time, and it is not possible for ReWalk to predict all of them. Except as required by law, ReWalk undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ReWalk Robotics Ltd.

By: /s/ Kevin Hershberger
Name: Kevin Hershberger
Title: Chief Financial Officer

Dated: October 23, 2017