ReWalk Robotics Ltd.
Form 8-K
July 23, 2018

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): July 23, 2018

ReWalk Robotics Ltd.

(Exact name of registrant as specified in its charter)

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

3 Hatnufa St., Floor 6, Yokneam Ilit, Israel (Address of principal executive offices)	2069203 (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—Second Quarter 2018 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

Reimbursement Updates

VA Policy

In June 2018, the U.S. Department of Veterans Affairs (the "***VA***") issued a revision to its national policy, initially released in December 2015, on exoskeleton medical device evaluation, training and procurement for qualifying veterans with spinal cord injury across the United States. The updated policy includes further guidance on the evaluation process and expands access to training program locations among the VA network and private rehabilitation centers, where veterans can be trained to use the ReWalk device.

Under the VA's revised policy, the exoskeleton evaluation process will have all veterans flow through one of 24 designated spinal cord injury VA centers ("***SCI/D***"). Once a veteran is determined to be qualified for training and

procurement of his/her own exoskeleton system, the individual may be allowed to pursue training on exoskeleton use, such as use of the ReWalk, in one of three ways: (i) at the applicable SCI/D hub center; (ii) on a case-by-case basis, at a qualified VA hospital designated by the VA's "hub & spoke" program; or (iii) on a case-by-case basis, at a qualified private rehabilitation center via the VA's Veterans Choice Program, through which veterans can receive care from a community provider paid for by the VA.

As a result of the revised policy, there are now 142 ReWalk certified private and VA SCI/D training centers across the United States and Canada potentially available to train veterans to use ReWalk. Furthermore, the network of VA SCI/D spoke sites may now be eligible to conduct training and provide additional opportunities.

German Medical Aid

As of June 2018, the Company's ReWalk Personal device has been included in the official list of medical aids (*Hilfsmittelverzeichnis*) by the German National Association of Statutory Health Insurance Funds (*GKV-Spitzenverband*). The list provides comprehensive information on the obligation of the health insurance funds to pay, as well as on the nature and quality of the products that are available on the market, for statutory health insurance beneficiaries in Germany. These beneficiaries may now apply for coverage of the ReWalk Personal device by using the medical aid code number assigned to ReWalk.

Timwell Investment Update

As previously announced, on March 6, 2018, the Company entered into an investment agreement (the "***Investment Agreement***") with Timwell Corporation Limited, a Hong Kong corporation ("***Timwell***"), pursuant to which we agreed to issue to Timwell an aggregate of 16,000,000 ordinary shares for $20.0 million. The first tranche, consisting of $5.0 million for 4,000,000 shares, closed on May 15, 2018. The remaining investment is to occur in two tranches, including $10.0 million for 8,000,000 shares (the "***Second Tranche***") and $5.0 million for 4,000,000 shares. Pursuant to the Investment Agreement, the Second Tranche will close if, by July 1, 2018, (i) the Company and an affiliate of Timwell have formed a joint venture in China, and (ii) by no later than 20 days after the establishment of the joint venture (or as soon thereafter as possible), the joint venture and the Company have executed a license agreement and supply agreement. For more information, see the Company's annual report on Form 10-K for the fiscal year ended December 31, 2017, filed with the SEC on March 8, 2018 (the ***"2017 Form 10-K***").

Due to the different jurisdictions involved and certain technical and administrative delays, the Company and Timwell continue to work toward the closing of the Second Tranche following July 1, 2018, and the Company expects to be able to move forward with the closing. For more information, see "Part I, Item 1A. Risk Factors—Risks Related to the Timwell Investment Agreement and Related Transactions—The closings of the three tranches of ordinary shares under the Investment Agreement are subject to various conditions, many of which are outside our control" in the 2017 Form 10-K.

1

Second Quarter 2018 Preliminary Results: Cash, Revenue and Unit Information

Our unaudited consolidated condensed financial statements for the three and six months ended June 30, 2018 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 revenues were approximately $1.8 million and $3.4 million for the three and six months ended June 30, 2018, respectively, compared to revenues of $2.0 million and $4.5 million for the three and six months ended June 30, 2017, respectively. We derived approximately 68% of our revenues from the United States for the six months ended June 30, 2018, compared to 76% for the six months ended June 30, 2017. We derived approximately 30% of our revenues from Europe for the six months ended June 30, 2018, compared to 24% for the six months ended June 30, 2017. The remaining 2% in revenues originated in Latin America and Asia Pacific for the six months ended June 30, 2018. We placed 21 and 44 units during the three and six months ended June 30, 2018, respectively, compared to 31 and 68 units during the three and six months ended June 30, 2017, respectively. As of June 30, 2018, there were 250 pending insurance claims relating to coverage for ReWalk, compared to 217 as of June 30, 2017.

Our cash and cash equivalents were approximately $9.1 million as of June 30, 2018, compared to $16.3 million as of June 30, 2017 and $14.6 million as of December 31, 2017.

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 six months ended June 30, 2018 when they are completed.

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 annual report on Form 10-K for the fiscal year ended December 31, 2017 filed with the SEC, as updated by other filings we make with the SEC.

Risk Related to Government Regulation

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 U.S. Food and Drug Administration (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. Between 2013 and 2017, we submitted a number of MDRs 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 fractures and submitted a report to the FDA under 21 CFR Part 806 ("***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. We recently made labeling and design modifications to the ReWalk to mitigate the risk of fractures. We believe the implementation of the revised use instructions and/or additional labeling or design modifications will trigger the need for a new 510(k), which we plan to submit to the FDA. In 2018, we submitted additional MDRs for fractures that occurred in foreign countries between 2015 and 2018, and for fractures that occurred in the United States. We received a letter in June 2018 from the FDA agreeing with ReWalk actions and formally classifying our decision to change the training instructions and labeling for the ReWalk and requesting that we make regular status reports to the FDA regarding our progress.

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, 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. Moreover, the FDA could find that the already implemented use instructions should have been reviewed by the FDA through the 510(k) premarket notification process, and such a finding could also result in an FDA enforcement action. 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.

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 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, in some cases, may be identified by words like "anticipate," "assume," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "futu "would," "seek" and similar terms or phrases. The forward-looking statements contained in this current report 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, and to expand to new markets and achieve its planned expense reductions; the conclusion of ReWalk's management and the previous opinion of ReWalk's auditors in 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 offerings of securities; 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 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; the risk of substantial dilution resulting from the issuance to Timwell; the significant voting power and de facto voting control Timwell may acquire; the risk that the remaining Timwell issuances will fail to close and the China joint venture will not form; and other factors discussed under the heading "Risk Factors" in ReWalk's Annual Report on Form 10-K for the fiscal year

ended December 31, 2017 filed with the SEC and other documents subsequently filed with or furnished to the SEC. Any forward-looking statement made in this current report 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/ Ori Gon
Name: Ori Gon
Title: Chief Financial Officer

Dated: July 23, 2018

4