HOLOGIC INC
Form 4
January 03, 2014

FORM 4

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

STATEMENT OF CHANGES IN BENEFICIAL OWNERSHIP OF SECURITIES

Filed pursuant to Section 16(a) of the Securities Exchange Act of 1934, Section 17(a) of the Public Utility Holding Company Act of 1935 or Section 30(h) of the Investment Company Act of 1940

OMB APPROVAL

OMB Number:	3235-0287
Expires:	January 31, 2005
Estimated average burden hours per response...	0.5

Check this box if no longer subject to Section 16. Form 4 or Form 5 obligations may continue. *See* Instruction 1(b).

(Print or Type Responses)

1. Name and Address of Reporting Person *
LAVANCE DAVID R JR

(Last) (First) (Middle)

35 CROSBY DRIVE

(Street)

BEDFORD, MA 01730

(City) (State) (Zip)

2. Issuer Name **and** Ticker or Trading Symbol
HOLOGIC INC [HOLX]

3. Date of Earliest Transaction (Month/Day/Year)
01/01/2014

4. If Amendment, Date Original Filed(Month/Day/Year)

5. Relationship of Reporting Person(s) to Issuer

(Check all applicable)

__X__ Director _____ 10% Owner
_____ Officer (give title below) _____ Other (specify below)

6. Individual or Joint/Group Filing(Check Applicable Line)
_X_ Form filed by One Reporting Person
___ Form filed by More than One Reporting Person

Table I - Non-Derivative Securities Acquired, Disposed of, or Beneficially Owned

1.Title of Security (Instr. 3)	2. Transaction Date (Month/Day/Year)	2A. Deemed Execution Date, if any (Month/Day/Year)	3. Transaction Code (Instr. 8)		4. Securities Acquired (A) or Disposed of (D) (Instr. 3, 4 and 5)			5. Amount of Securities Beneficially Owned Following Reported Transaction(s) (Instr. 3 and 4)	6. Ownership Form: Direct (D) or Indirect (I) (Instr. 4)	7. Nature of Indirect Beneficial Ownership (Instr. 4)
			Code	V	Amount	(A) or (D)	Price			

Reminder: Report on a separate line for each class of securities beneficially owned directly or indirectly.

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SEC 1474 (9-02)

Table II - Derivative Securities Acquired, Disposed of, or Beneficially Owned
(*e.g.*, puts, calls, warrants, options, convertible securities)

1. Title of Derivative Security (Instr. 3)	2. Conversion or Exercise Price of	3. Transaction Date (Month/Day/Year)	3A. Deemed Execution Date, if any (Month/Day/Year)	4. Transaction Code (Instr. 8)	5. Number of Derivative Securities Acquired (A)	6. Date Exercisable and Expiration Date (Month/Day/Year)	7. Title and Amou Underlying Securi (Instr. 3 and 4)

	Derivative Security			or Disposed of (D) (Instr. 3, 4, and 5)							
				Code	V	(A)	(D)	Date Exercisable	Expiration Date	Title	Amo or Num of S
Restricted Stock Unit Award (Right To Receive)	$ 0	01/01/2014		A		5,033		(1)	01/01/2018	Common Stock	5,0
Non-qualified Stock Option (Right to Buy)	$ 22.35	01/01/2014		A		14,331		01/01/2015	01/01/2021	Common Stock	14,

Reporting Owners

Reporting Owner Name / Address	Relationships			
	Director	10% Owner	Officer	Other
LAVANCE DAVID R JR 35 CROSBY DRIVE BEDFORD, MA 01730	X			

Signatures

/s/ Mark J. Casey, Attorney-In-Fact for David R. LaVance Jr.	01/03/2014
**Signature of Reporting Person	Date

Explanation of Responses:

***** If the form is filed by more than one reporting person, *see* Instruction 4(b)(v).

****** Intentional misstatements or omissions of facts constitute Federal Criminal Violations. *See* 18 U.S.C. 1001 and 15 U.S.C. 78ff(a).

(1) These shares represent restricted stock units (RSUs) awarded to the Reporting Person pursuant to the 2008 Equity Incentive Plan and are subject to vesting as provided in the agreement evidencing the award.

Note: File three copies of this Form, one of which must be manually signed. If space is insufficient, *see* Instruction 6 for procedure.
Potential persons who are to respond to the collection of information contained in this form are not required to respond unless the form displays a currently valid OMB number. ejudice, after the District Court partially dismissed the related claims on August 23, 2018 and the parties entered a stipulation of dismissal with prejudice.

Pending District Court Case

The remaining District Court case has been partially dismissed. For more information, see Note 6 - Commitments and Contingent Liabilities - Legal Claims.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operation should be read in conjunction

with the unaudited condensed consolidated financial statements and the related notes included elsewhere in this quarterly report and with our audited consolidated financial statements included in our 2017 Form 10-K as filed with the SEC. In addition to historical condensed financial information, the following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. For a discussion of factors that could cause or contribute to these differences, see "Special Note Regarding Forward-Looking Statements" below.

Special Note Regarding Forward-Looking Statements

In addition to historical information, this quarterly report on Form 10-Q (this "quarterly report") contains forward-looking statements within the meaning of Section 27A of the Securities Act, Section 21E of the Exchange Act, and the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, that are based on our management's beliefs and assumptions and on information currently available to our management. Forward-looking statements include information concerning our possible or assumed future results of operations, business strategies, financing plans, competitive position, industry environment, potential growth opportunities, potential market opportunities and the effects of competition. Forward-looking statements may include projections regarding our future performance and, in some cases, can be identified by words like "anticipate," "assume," "believe," "could," "seek," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "future," "should," "will," "would" or similar expressions uncertainty of future events or outcomes and the negatives of those terms. These statements may be found in this section of this quarterly report titled "Part I, Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this quarterly report. These statements include, but are not limited to, statements regarding:

- our expectations regarding future growth, including our ability to increase sales in our existing geographic markets, expand to new markets and achieve our planned expense reductions;
- our management's conclusion, and our independent registered public accounting firm's statement in its opinion relating to our accompanying consolidated financial statements, that there is a substantial doubt as to our ability to continue as a going concern;
- our ability to regain 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;
- 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 expectations as to our clinical research program and clinical results;

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- our expectations as to the results of the Food and Drug Administration's ("FDA"), potential regulatory developments with respect to our mandatory 522 postmarket surveillance study;
- the outcome of ongoing shareholder class action litigation relating to our initial public offering ("IPO");
- our ability to repay our secured indebtedness;
- our ability to improve our products and develop new products;
- our ability to close periodic issuances of our ordinary shares to, and to form a joint venture in China with, Timwell and the resulting effect on our liquidity and financial condition;
- the risk of substantial dilution resulting from the periodic issuances, if any, of our ordinary shares to Timwell;
- the significant voting power and de facto voting control Timwell may acquire upon additional issuances, if any, of our ordinary shares to Timwell;
- our ability to maintain adequate protection of our intellectual property and to avoid violation of the intellectual property rights of others;
- our ability to gain and maintain regulatory approvals;
- our ability to secure capital from equity and debt financings in light of limitations under our effective registration statement on Form S-3, the price range of our ordinary shares and conditions in the financial markets, and the risk that such financings may dilute our shareholders or restrict our business;
- our ability to use effectively the proceeds of our offerings of securities;
- the impact of the market price of our ordinary shares on the determination of whether we are a passive foreign investment company;
- our ability to maintain relationships with existing customers and develop relationships with new customers; and
- our compliance with medical device reporting regulations to report adverse events involving our products and the potential impact of such adverse events on ReWalk's ability to market and sell its products.

The preceding list is not intended to be an exhaustive list of all of our statements. The statements are based on our beliefs, assumptions and expectations of future performance, taking into account the information currently available to us. These statements are only predictions based upon our current expectations and projections about future events. There are important factors that could cause our actual results, levels of activity, performance or achievements to differ materially from the results, levels of activity, performance or achievements expressed or implied by the statements. In particular, you should consider the risks provided under "Part 1, Item 1A. Risk Factors" of our 2017 Form 10-K, and in other reports filed by us with the SEC.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that future results, levels of activity, performance and events and circumstances reflected in the forward-looking statements will be achieved or will occur.

Any forward-looking statement in this quarterly report speaks only as of the date hereof. Except as required by law, we undertake no obligation to update publicly any forward-looking statements, whether as a result of new information, future developments or otherwise.

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Overview

We are an innovative medical device company that is designing, developing and commercializing 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 ReWalk, an exoskeleton that uses our patented tilt-sensor technology and an onboard computer and motion sensors to drive motorized legs that power movement. Additionally, we are developing and intend to commercialize a lightweight soft suit exoskeleton, designed to support mobility for individuals suffering from other lower limb disabilities such as stroke, multiple sclerosis, cerebral palsy, Parkinson's disease and elderly assistance.

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

In June 2018, the VA updated its national policy to provide expanded access to ReWalk exoskeletons for veterans in private rehabilitation clinics through the Veterans Choice Program. 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 (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 Veteran’s Choice Program, through which veterans can receive care from a community provider paid for by the VA. Additionally, to date several private insurers in the United States and Europe have provided reimbursement for ReWalk in certain cases, and in September 2017, each of German insurer BARMER GEK ("Barmer") and national social accident insurance provider Deutsche Gesetzliche Unfallversicherung (“DGUV”), signed a confirmation and letter of agreement, respectively, regarding the provision of ReWalk systems for all qualifying beneficiaries. In February 2018, the head office of German statutory health insurance ("SHI"), Spitzenverband (“GKV”) confirmed their decision to list the ReWalk Personal 6.0 Exoskeleton System in the German Medical Device Directory and in June 2018 the ReWalk Personal 6.0 exoskeleton was added to the official German list of medical aids, becoming the first exoskeleton device to be included in the list. This decision means that ReWalk will be listed among all medical devices for compensation, which SHI providers can procure for any approved beneficiary on a case-by-case basis.

We have incurred net losses and negative cash flow from operations since inception and anticipate this to continue in the near term. During the remainder of 2018, we will continue to evaluate means of reducing spending where possible, while continuing to focus resources on achieving commercial reimbursement coverage decisions, furthering commercialization activities, and advancing our clinical studies including the FDA 522 postmarket study and the Restore clinical studies to support regulatory clearance and commercializing the Restore device for stroke patients in the third quarter of 2019.

Third Quarter 2018 and subsequent Business Highlights

- 37 patients fully enrolled and five patients completing medical assessment out of 40 participants for the clinical study of the ReStore soft exo-suit for stroke patients.
- Applied for CE mark clearance for the ReStore.
- Placed 500th ReWalk Personal and Rehabilitation system.

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Results of Operations for the Three and Nine Months Ended September 30, 2018 and September 30, 2017

Our operating results for the three and nine months ended September 30, 2018, as compared to the same periods in 2017, are presented below. The results set forth below are not necessarily indicative of the results to be expected in future periods.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues	$1,617	$ 1,732	$4,966	$ 6,238
Cost of revenues	855	1,024	2,755	3,740
Gross profit	762	708	2,211	2,498
Operating expenses:				
Research and development, net	1,597	1,618	5,645	4,433
Sales and marketing	1,926	2,637	6,187	8,643
General and administrative	1,362	1,805	5,620	5,796
Total operating expenses	4,885	6,060	17,452	18,872
Operating loss	(4,123)	(5,352)	(15,241)	(16,374)
Loss on extinguishment of debt	—	—	—	313
Financial expenses, net	405	479	1,412	1,843
Loss before income taxes	(4,528)	(5,831)	(16,653)	(18,530)
Income taxes	5	15	4	25
Net loss	$(4,533)	$ (5,846)	$(16,657)	$ (18,555)
Net loss per ordinary share, basic and diluted	$(0.13)	$ (0.27)	$(0.51)	$ (1.00)
Weighted average number of shares used in computing net loss per ordinary share, basic and diluted	35,541,762	21,660,757	32,809,424	18,463,444

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Three and Nine Months Ended September 30, 2018 Compared to Three and Nine Months Ended September 30, 2017
Revenues
Our revenues for the three and nine months ended September 30, 2018 and 2017 were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(in thousands, except unit amounts)		(in thousands, except unit amounts)	
Personal units placed	21	15	64	81
Rehabilitation units placed	1	1	2	3
Total units placed	22	16	66	84
Personal unit revenues	$1,504	$1,707	$4,773	$6,033
Rehabilitation unit revenues	$113	$25	$193	$205
Revenues	$1,617	$1,732	$4,966	$6,238

Revenues decreased by $115 thousand, or 7%, for the three months ended September 30, 2018 compared to the three months ended September 30, 2017. Revenues decreased by approximately $1.3 million, or 20%, for the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017. The decrease in revenue for the three months ended September 30, 2018 compared to the three months ended September 30, 2017 was driven primarily by lower number of units converted from rentals into purchase during the quarter. The decrease in revenue for the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017 was mainly due to a lower number of units placed in the United States.
In the future, we expect our growth to be driven by sales of our ReWalk Personal device to third-party payors as we continue to focus our resources on broader commercial coverage policies with third-party payors as well as sales of the Restore device to rehabilitation institutes.

Gross Profit
Our gross profit for the three and nine months ended September 30, 2018 and 2017 were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Gross profit	$762	$708	$2,211	$2,498

Gross profit was 47% of revenue for the three months ended September 30, 2018, compared to 41% of revenue for the three months ended September 30, 2017. Gross profit was 45% of revenue for the nine months ended September 30, 2018, compared to 40% of revenue for the nine months ended September 30, 2017. The increase in gross profit for both three and nine months ended September 30, 2018 was driven by sales mix and lower product cost.
We expect our gross profit to gradually improve as we increase our sales volumes and decrease the product manufacturing costs, which may be partially offset by potential price increases.

Research and Development Expenses
Our research and development expenses, net, for the three and nine months ended September 30, 2018 and 2017 were as follows (in thousands):

	Three Months Ended	Nine Months Ended

	September 30, 2018	2017	September 30, 2018	2017
Research and development, net	$1,597	$1,618	$5,645	$4,433

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Research and development expenses, net, decreased by $21 thousand, or 1%, for the three months ended September 30, 2018 compared to the three months ended September 30, 2017. The decrease is attributable to reduction in our research and development subcontracting costs in the three months ended September 30, 2018, offset with increased costs related to the ReStore clinical study and IIA grants received in the three months ended September 30, 2017.
Research and development expenses, net, increased by approximately $1.2 million, or 27%, for the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017. The increase for nine months ended September 30, 2018 is attributable to increased costs associated with the development and clinical study of our ReStore soft suit exoskeleton and fewer IIA grants received in the period.
We intend to focus our research and development expenses in the near term primarily on the Restore system for stroke patients and in the longer term on a “soft suit” exoskeleton 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.

Sales and Marketing Expenses
Our sales and marketing expenses for the three and nine months ended September 30, 2018 and 2017 were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Sales and marketing	$1,926	$2,637	$6,187	$8,643

Sales and marketing expenses decreased $711 thousand, or 27%, for the three months ended September 30, 2018 compared to the three months ended September 30, 2017. Sales and marketing expenses decreased approximately by $2.5 million, or 28%, for the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017. The decrease for both three and nine months ended September 30, 2018 is driven by personnel and personnel-related costs and consulting expenses as result of our cost reduction efforts.

In the near term our sales and marketing expenses are expected to be driven by our commercialization efforts and reimbursement for the ReWalk Personal device as we continue to pursue insurance claims on a case by case basis and invest in efforts to expand coverage.

General and Administrative Expenses
Our general and administrative expenses for the three and nine months ended September 30, 2018 and 2017 were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
General and administrative	$1,362	$1,805	$5,620	$5,796

General and administrative expenses decreased by $443 thousand, or 25%, for the three months ended September 30, 2018 compared to the three months ended September 30, 2017. The decrease in expenses is primarily attributable to personnel and personnel-related costs.
General and administrative expenses decreased by $176 thousand, or 3%, for the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017. The decrease in expenses is primarily attributable to personnel and personnel-related costs and of legal cost reduction, offset by an increase in our insurance related expenses and market development efforts in China.
Loss on Extinguishment of Debt

There was no loss on extinguishment of debt during the three and nine months ended September 30, 2018. Loss on extinguishment of debt of $313 thousand for the nine months ended September 30, 2017 is due to amending of our debt under the Loan Agreement with Kreos, such that $3 million in principal is now subject to the Kreos Convertible Note. The entry into the

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Kreos Convertible Note, which decreased the outstanding principal amount under the Loan Agreement from $17.2 million to $14.2 million, resulted in extinguishment of debt accounting treatment.

Financial Expenses, Net

Our financial expenses, net, for the three and nine months ended September 30, 2018 and 2017 were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Financial expenses, net	$405	$479	$1,412	$1,843

Financial expenses, net, decreased by $74 thousand, or 15% for the three months ended September 30, 2018 compared to the three months ended September 30, 2017. Financial expenses, net, decreased by $431 thousand, or 23% for the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017. The decrease for both three and nine months ended September 30, 2018 is attributable mainly to interest expenses related to our Loan Agreement with Kreos.

Income Tax

Our income tax for the three and nine months ended September 30, 2018 and 2017 was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Income tax (tax benefit)	$ 5	$ 15	$ 4	$ 25

Income taxes increased by $10 thousand for the three months ended September 30, 2018 compared to the three months ended September 30, 2017. Income taxes decreased by $21 thousand for the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017.

Critical Accounting Policies and Estimates

Our consolidated financial statements are prepared in accordance with United States generally accepted accounting principles. The preparation of our financial statements requires us to make estimates, judgments and assumptions that can affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. We base our estimates, judgments and assumptions on historical experience and other factors that we believe to be reasonable under the circumstances. Materially different results can occur as circumstances change and additional information becomes known. Besides the estimates identified above that are considered critical, we make many other accounting estimates in preparing our financial statements and related disclosures. See Note 2 to our audited consolidated financial statements included in our 2017 Form 10-K for a description of the significant accounting policies that we used to prepare our consolidated financial statements.

There have been no material changes to our critical accounting policies or our critical judgments from the information provided in “Part II, Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations - Critical Accounting Policies” of our 2017 Form 10-K except for the updates provided in note 3b of our unaudited

condensed consolidated financial statements set forth in “Part I, Item 1. Financial Statements” of this quarterly report.

Recent Accounting Pronouncements

See Note 3b to our unaudited condensed consolidated financial statements set forth in “Part I, Item 1. Financial Statements” of this quarterly report for information regarding new accounting pronouncements.

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Liquidity and Capital Resources

Sources of Liquidity and Outlook

Since inception, we have funded our operations primarily through the sale of certain of our equity securities and convertible notes to investors in private placements, the sale of our ordinary shares in public offerings and the incurrence of bank debt. As of September 30, 2018, the Company had cash and cash equivalents of $5.2 million. The Company had an accumulated deficit in the total amount of approximately $147.9 million as of September 30, 2018 and further losses are anticipated in the development of its business. Those factors raise substantial doubt about the Company’s ability to continue as a going concern. The ability to continue as a going concern is dependent upon the Company obtaining the necessary financing to meet its obligations and repay its liabilities arising from normal business operations when they become due.

The Company intends to finance operating costs over the next 12 months with existing cash on hand, reducing operating spend, issuances under the Company's ATM Offering Program, or other future public or private issuances of equity and debt securities , or through a combination of the foregoing. However, the Company will need to seek additional sources of financing if the Company require more funds than anticipated during the next 12 months or in later periods.

The accompanying condensed consolidated financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and liabilities and commitments in the normal course of business. The consolidated financial statements for the three and nine months ended September 30, 2018 do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from uncertainty related to the Company’s ability to continue as a going concern.

Our anticipated primary uses of cash are (i) sales, marketing and reimbursement expenses related to market development activities and broadening third-party payor coverage, and (ii) research and development costs related to, in the shorter term, our Restore device that will assist patients who had stroke, and, in the longer term, developing our next generation of ReWalk with design improvements and building upon our technological platform to address new medical indications that affect the ability to walk including multiple sclerosis, cerebral palsy, Parkinson’s disease and elderly assistance. Our future cash requirements will depend on many factors, including our rate of revenue growth, the expansion of our sales and marketing activities, the timing and extent of our spending on research and development efforts and international expansion. If our current estimates of revenue, expenses or capital or liquidity requirements change or are inaccurate, we may seek to sell additional equity or debt securities, arrange for additional bank debt financing or refinance our indebtedness. There can be no assurance that we will be able to raise such funds on acceptable terms. For more information, see “Part I, Item 1A. Risk Factors-We have concluded that there are substantial doubts as to our ability to continue as a going concern" in our 2017 Form 10-K.

Loan Agreement with Kreos and Related Warrant to Purchase Ordinary Shares

On December 30, 2015, we entered into a loan agreement with Kreos (the “Loan Agreement”) pursuant to which Kreos extended a line of credit to us in the amount of $20 million. On January 4, 2016, we drew down $12 million under the Loan Agreement. Under the terms of the Loan Agreement we were entitled to draw down up to an additional $8 million until December 31, 2016, if we raised $10 million or more in the issuance of shares of our capital stock (including debt convertible into shares of our capital stock) by December 31, 2016. On December 28, 2016, we drew down the remaining $8 million available under the Loan Agreement. Interest is payable monthly in arrears on any

amounts drawn down at a rate of 10.75% per year from the applicable drawdown date through the date on which all principal is repaid. As of June 30, 2017, the Company raised more than $20 million in connection with the issuance of its share capital and therefore, in accordance with the terms of the Loan Agreement, the repayment period was extended from 24 months to 36 months. The principal was also reduced in connection with the issuance of the Kreos Convertible Note on June 9, 2017. Pursuant to the Loan Agreement, we paid Kreos a transaction fee equal to 1.0% of the total available amount of the line of credit upon the execution of the agreement and we will be required to pay Kreos an end of loan payment equal to 1.0% of the amount of each tranche drawn down upon the expiration of each such tranche. During both the three and nine months ended September 30, 2018 and the three months ended September 30, 2017 the Company did not pay fees in connection with the Loan Agreement, compared to $23 thousand during the nine months ended September 30, 2017. Pursuant to the Loan Agreement, we granted Kreos a first priority security interest over all of our assets, including intellectual property and equity interests in its subsidiaries, subject to certain permitted security interests.

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In connection with the $12 million drawdown under the Loan Agreement, we issued to Kreos the warrant to purchase up to 119,295 of our ordinary shares at an exercise price of $9.64 per share, which represented the average of the closing prices of our ordinary shares for the 30-day calendar period prior to the date of the issuance of the warrant, subject to adjustment as set forth in the warrant. In connection with the $8 million drawdown under the Loan Agreement on December 28, 2016, we increased the amount of the warrant from $1.15 million to $1.61 million, or by $460 thousand, such that the warrant represents the right to purchase up to 167,012 of our ordinary shares. The increase was based on the terms of the warrant, which provide that the amount of the warrant will be increased by 5.75% of any additional drawdowns. Subject to the terms of the warrant, the warrant is exercisable, in whole or in part, at any time prior to the earlier of (i) December 30, 2025, or (ii) immediately prior to the consummation of a merger, consolidation, or reorganization of us with or into, or the sale or license of all or substantially all our assets or shares to, any other entity or person, other than a wholly- owned subsidiary of us, excluding any transaction in which our shareholders prior to the transaction will hold more than 50% of the voting and economic rights of the surviving entity after the transaction.

On June 9, 2017, the Company and Kreos entered into the First Amendment. As of that date the outstanding principal amount under the Loan Agreement was $17.2 million. Under the First Amendment, $3 million of the outstanding principal under the Loan Agreement is subject to repayment pursuant to the senior secured Kreos Convertible Note issued on June 9, 2017, thus reducing the outstanding principal amount under the Loan Agreement to $14.2 million as of June 9, 2017. This amended outstanding principal amount remains subject to repayment in accordance with the terms and conditions of the Loan Agreement and an amended repayment schedule. Interest on the Kreos Convertible Note is payable monthly in arrears at a rate of 10.75% per year. On September 3, 2018, Kreos agreed to defer $0.5 million in principal and interest payments under the Kreos Loan Agreement and Kreos Convertible Note until October 2, 2018. We are in discussions with Kreos regarding deferral of up to $1.0 million in additional payments under the Kreos Loan Agreement until early 2019.

Kreos may convert the then-outstanding principal and “end of loan payments” under the Kreos Convertible Note, in whole or in part, on one or more occasions, into up to 2,523,660 ordinary shares, at a conversion price per share equal to $1.268 per share (subject to customary anti-dilution adjustments) at any time until the earlier of (i) the maturity date of June 9, 2020 or (ii) a “Change of Control,” as defined in the Loan Agreement.

As of September 30, 2018, there was $12.4 million in outstanding principal and interest under the Loan Agreement, compared to $15.4 million as of December 31, 2017, including, in each case, $3.0 million in outstanding principal and interest under the Kreos Convertible Note, as of September 30, 2018 and December 31, 2017.

We may in the future seek to refinance up to a substantial portion of our indebtedness under our Kreos Loan Agreement, which we have considered with Kreos from time to time, including by exchanging our indebtedness with Kreos for new convertible debt from third-party investor, or to borrow additional funds.

Equity Raises

Our initial public offering in September 2014 generated $36.3 million in net proceeds. Additionally, on May 9, 2016, the SEC declared effective our Form S-3, pursuant to which we registered up to $100 million of ordinary shares, warrants and/or debt securities and up to 4,388,143 ordinary shares offered by selling shareholders named therein. On May 10, 2016, we entered into our Equity Distribution Agreement with Piper Jaffray, pursuant to which we may offer and sell, from time to time, ordinary shares having an aggregate offering price of up to $25 million through Piper Jaffray acting as our agent. The ordinary shares issued under the Equity Distribution Agreement may be registered under the Securities Act using our Form S-3.

Additionally, on November 1, 2016, we closed our follow-on public offering of 3,250,000 units, each consisting of one ordinary share and 0.75 of a warrant to purchase one ordinary share. The ordinary shares and the warrants underlying the units and the ordinary shares issuable upon exercise of the warrants are registered under the Securities Act on our Form S-3. The warrants became exercisable during the period commencing from the date of original issuance and ending on November 1, 2021, the expiration date of the warrants, at an initial exercise price of $4.75 per ordinary share. Our net aggregate proceeds, after deducting underwriting discounts and commissions and estimated expenses, were $11.1 million. We also granted Oppenheimer & Co. (“Oppenheimer”), as underwriter under the underwriting agreement, an option to purchase up to 487,500 additional units at the public offering price, less the underwriting discount, for 30 days after October 27, 2016, which Oppenheimer did not exercise.

On November 21, 2017, we closed the base portion of our follow-on offering of 6,857,000 ordinary shares. Each ordinary share was sold to the public at a price of $1.05. On November 22, 2017, National Securities Corporation, as underwriter, exercised in full its option to purchase 1,028,550 additional ordinary shares at the public offering price of $1.05 per unit, less the underwriting discount. The Company's net aggregate proceeds of the base offering and over-allotment exercise, after deducting underwriting discounts and commissions and expenses, were $7.2 million.

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Since we filed our Form 10-K on February 17, 2017, we have been subject to limitations under the applicable rules of Form S-3, which constrain our ability to secure capital pursuant to our ATM Offering Program or other public offerings pursuant to our effective Form S-3. These rules limit the size of primary securities offerings conducted by issuers with a public float of less than $75 million to no more than one-third of their public float in any 12-month period. Pursuant to these rules, we may not sell in primary offerings under our Form S-3 more than approximately $13.7 million in any 12 month period, unless and until we are no longer subject to these limitations. We will cease to be subject to these limitations once our public float exceeds $75 million. As of the date of this quarterly report, we have sold approximately $4.6 million in securities under our Form S-3 during the last 12 months, when we were subject to these restrictions. We will also recalculate the amount of this limitation if we terminate our ongoing takedown and conduct another takedown under our Form S-3. Additionally, these limitations do not apply to secondary offerings for the resale of our ordinary shares or other securities by selling shareholders or to the issuance of ordinary shares upon conversion by holders of convertible securities, such as warrants.

With respect to our ATM Offering Program, because we have sold $15.7 million in the program since its inception, we could only raise up to a remaining $9.3 million using the program, subject to the $13.7 million limitation. Because of these limitations, to raise additional capital in securities offerings above that limitation, we may be required to seek other methods of completing primary offerings, including, for example, under a registration statement on Form S-1 (which has no such size limitations), the preparation of which would be more time-consuming and costly, including due to potential SEC review. We may also conduct such offerings 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"). Any such transactions could result in substantial dilution of shareholders’ interests.

ATM Offering Program

On May 10, 2016, we entered into the Equity Distribution Agreement with Piper Jaffray, pursuant to which we may offer and sell, from time to time, ordinary shares having an aggregate offering price of up to $25 million through Piper Jaffray acting as our agent. The $13.7 million limitation on sales under our Form S-3 also applies to this ATM Offering Program. Subject to the terms and conditions of the Equity Distribution Agreement, Piper Jaffray will use its commercially reasonable efforts to sell on our behalf all of the ordinary shares requested to be sold by us, consistent with its normal trading and sales practices. Piper Jaffray may also act as principal in the sale of ordinary shares under the Equity Distribution Agreement. Such sales may be made under our Form S-3 in what may be deemed “at-the-market” equity offerings as defined in Rule 415 promulgated under the Securities Act, directly on or through the Nasdaq Capital Market, to or through a market maker other than on an exchange or otherwise, in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices, and/or any other method permitted by law, including in privately negotiated transactions.

Piper Jaffray is entitled to compensation at a fixed commission rate of 3.0% of the gross sales price per share sold through it as agent under the Equity Distribution Agreement. Where Piper Jaffray acts as principal in the sale of ordinary shares under the Equity Distribution Agreement, such rate of compensation will not apply, but in no event will the total compensation of Piper Jaffray, when combined with the reimbursement of Piper Jaffray for the out-of-pocket fees and disbursements of its legal counsel, exceed 8.0% of the gross proceeds received from the sale of the ordinary shares.

We may instruct Piper Jaffray not to sell ordinary shares if the sales cannot be effected at or above the price designated by us in any instruction. We or Piper Jaffray may suspend an offering of ordinary shares under the ATM Offering Program upon proper notice and subject to other conditions, as further described in the Equity Distribution Agreement. Additionally, the ATM Offering Program will terminate on the earlier of (i) the sale of all ordinary shares subject to the Equity Distribution Agreement or (ii) the termination of the Equity Distribution Agreement. The Equity

Distribution Agreement may be terminated by Piper Jaffray or us at any time on the close of business on the date of receipt of written notice, and by Piper Jaffray at any time in certain circumstances, including any suspension or limitation on the trading of our ordinary shares on the Nasdaq Capital Market, as further described in the Equity Distribution Agreement. During the nine months ended September 30, 2018, the Company issued and sold 1,247,172 ordinary shares at an average price of $1.08 per share under its ATM Offering Program (as defined in Note 8e to our unaudited condensed consolidated financial statements set forth in “Part I, Item 1. Financial Statements” of this quarterly report). The gross proceeds to the Company were approximately $1.4 million, and the net aggregate proceeds after deducting commissions, fees and offering expenses in the amount of approximately $237 thousand were approximately $1.1 million. As a result, from the inception of the ATM Offering Program in May 2016 until September 30, 2018, we had sold 7,552,318 ordinary shares under the ATM Offering Program for net proceeds to us of approximately $14.6 million (after commissions, fees and expenses). Additionally, as of that date, we had paid Piper Jaffray compensation of approximately $471 thousand and had incurred total expenses of approximately $1.1 million in connection with the ATM Offering Program. We intend to continue using this program opportunistically to raise additional funds. Because we registered up to $25 million in sales under our Form S-3 in our ATM Offering Program, we could raise up to a remaining $9.3 million under the program, subject to a limitation on sales under the Form S-3 limiting sales to $13.7 million during any 12-month period.

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Timwell investment agreement

On March 6, 2018, we entered into the Investment Agreement with Timwell, pursuant to which we agreed, in return for aggregate gross proceeds to us of $20 million, to issue to Timwell an aggregate of 16,000,000 of our ordinary shares, at a price per share of $1.25. Timwell is to make the investment in three tranches, including $5 million for 4,000,000 shares in the First Tranche, $10 million for 8,000,000 shares in the Second Tranche and $5 million for 4,000,000 shares in the Third Tranche. We intend to use the net proceeds from this agreement primarily for (i) sales, marketing activities related to market development in our existing markets as well as expanding into China and reimbursement expenses related to broadening third-party payor coverage and (ii) research and development costs related to developing our lightweight “soft suit” exoskeleton technology for various lower limb disabilities, including stroke and other indications affecting the ability to walk, while using the remainder for general corporate purposes. We will have broad discretion in the way that we use the net proceeds of this agreement.

The First Tranche, consisting of $5 million for 4,000,000 shares, closed on May 15, 2018. In connection with the closing, the parties signed the registration rights agreement in the form attached to the Investment Agreement and Ning Cong was appointed to the board of directors as Timwell's designee. The net aggregate proceeds after deducting commissions, fees and offering expenses in the amount of approximately $705 thousand were approximately $4.3 million.

The closing of the Second and Third Tranches is 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, among others, with the Third Tranche Closing expected to occur by December 31, 2018 and no later than April 1, 2019. While we are still in discussions with Timwell, due to the different jurisdictions involved, new positions taken by the counterparty on certain key commercial points, and certain technical and administrative delays relating to governmental approvals in China, there is a significant risk that we and Timwell will not reach the required milestones in order to complete the closings of the second and third tranches and receive the gross proceeds of $10.0 million and $5.0 million, respectively. We continue to view China as a market with key opportunities for products designed for stroke patients. Thus, although we remain in dialogue with RealCan, Timwell’s affiliate, and have discussed with RealCan various alternatives to the original investment agreement, we are also evaluating alternative paths with different groups to penetrate the Chinese market.

Additional information about the Investment Agreement is available in the 2017 Form 10-K and elsewhere in this report. See "Part I. Item 1. Business-Timwell Investment Agreement and Related Transactions" in our 2017 Form 10-K for information generally about the Investment Agreement and "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 for information about the delays in the Second Tranche Closing.

Cash Flows for the Nine Months Ended September 30, 2018 and September 30, 2017

	Nine Months Ended September 30,	
	2018	2017
Net cash used in operating activities	$(12,174)	$(17,042)
Net cash used in investing activities	(3)	(19)
Net cash provided by financing activities	2,823	6,341
Net cash flow	$(9,354)	$(10,720)

Net Cash Used in Operating Activities

Net cash used in operating activities decreased to $12.2 million for the nine months ended September 30, 2018 compared to $17.0 million for the nine months ended September 30, 2017, primarily as a result of lower working capital as well as reduction in operating costs .

Net Cash Used in Investing Activities

Net cash used in investing activities decreased to $3 thousand for the nine months ended September 30, 2018 compared to $19 thousand for the nine months ended September 30, 2017, primarily as a result of decreased use of cash for the purchase of property and equipment.

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Net Cash Provided by Financing Activities

Net cash provided by financing activities was $2.8 million for the nine months ended September 30, 2018, compared to $6.3 million in the nine months ended September 30, 2017. The decrease is related primarily to the receipt of proceeds from private placement and ATM offering , which were lower than the proceeds we received from issuance of ordinary shares in the ATM Offering Program in the nine months ended September 30, 2018, offset with proceeds from an investment agreement in the nine months ended September 30, 2018.

Obligations and Commercial Commitments

Set forth below is a summary of our contractual obligations as of September 30, 2018.

	Payments due by period (in dollars, in thousands)				
Contractual obligations	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Purchase obligations (1)	$936	$936	$—	$—	$—
Collaboration Agreement and License Agreement obligations (2)	3,000	800	1,600	600	—
Operating lease obligations (3)	3,617	635	1,166	1,184	632
Long-term debt obligations (4)	14,162	6,978	7,184	—	—
Total	$21,715	$9,349	$9,950	$1,784	$632

(1) The Company depends on one contract manufacturer, Sanmina. We place our manufacturing orders with Sanmina pursuant to purchase orders or by providing forecasts for future requirements.

(2) As of September 30, 2018, our Collaboration Agreement is for a period of six years from the date of signing and requires us to pay in quarterly installments for the funding of our joint research collaboration with Harvard, subject to a minimum funding commitment under applicable circumstances. Our License Agreement consists of patent reimbursement expenses payments and of license upfront fee payment. There are also several milestone payments contingent upon the achievement of certain product development and commercialization milestones and royalty payments on net sales from certain patents licensed to Harvard. These product development and commercialization milestones depend on favorable clinical developments, sales and regulatory actions, some or all of which may not occur. Since the achievement and timing of these milestones is neither determinable nor reasonably estimable, these milestone payments are not included in this “Contractual Obligations” table or recorded on our consolidated condensed balance sheet as of September 30, 2018. Moreover, since such royalties are dependent on future product sales which are neither determinable nor reasonably estimable, these royalty payments are not included in this “Contractual Obligations” table or recorded on our consolidated consolidated balance sheet as of September 30, 2018. For more information, see Note 7 to our condensed consolidated financial statements included in “Part I, Item 1” of this quarterly report.

(3) Our operating leases consist of leases for our facilities and motor vehicles.

(4) Our long-term debt obligations consist of payments of principal and interest under our Loan Agreement with Kreos. For more information, see “-Liquidity and Capital Resources -Loan Agreement with Kreos and Related Warrant to Purchase Ordinary Shares” above.

We calculated the payments due under our operating lease obligation for our Israeli office that are to be paid in NIS at a rate of exchange of NIS 3.650:$1.00, and the payments due under our operating lease obligation for our German subsidiary that are to be paid in Euro at a rate of exchange of 1.166 Euro:$1:00, both of which were the applicable exchange rates as of September 30, 2018. We calculated the payments due under our Loan Agreement with Kreos according to the current schedule of repayment of principal and interest.

Off-Balance Sheet Arrangements

We had no off-balance sheet arrangements or guarantees of third-party obligations as of September 30, 2018.

Explanation of Responses: 23

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There have been no material changes to our market risk during the third quarter of 2018. For a discussion of our exposure to market risk, please see Part II, Item 7A, “Quantitative and Qualitative Disclosures About Market Risk” of our 2017 Form 10-K.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

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

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

Changes in Internal Control over Financial Reporting

During the third quarter of 2018 there were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

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PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

There have been no material changes to our legal proceedings as described in “Part I, Item 3. Legal Proceedings” of our 2017 Form 10-K except as described in Note 6 in our condensed consolidated financial statements included in “Part I, Item 1” of this quarterly report.

ITEM 1A. RISK FACTORS

There have been no material changes to our risk factors from those disclosed in “Part I, Item 1A. Risk Factors” of our 2017 Form 10-K except as noted below:

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.

We have incurred accumulated losses in the amount of $147.9 million as of September 30, 2018 and further losses are anticipated in the development of our business. Those factors raise substantial doubt about the Company’s ability to continue as a going concern. The ability to continue as a going concern is dependent upon the Company obtaining the necessary financing to meet its obligations and repay its liabilities arising from normal business operations when they come due. 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, 2017 regarding the substantial doubts about the Company’s ability to continue as a going concern.

The Company intends to finance operating costs over the next twelve months with existing cash on hand, reducing operating spend, issuances under our ATM Offering Program, or other future public or private issuances of equity and debt securities, or through a combination of the foregoing. Additionally, regarding our Investment Agreement with Timwell relating to the issuance of an additional 12,000,000 ordinary shares in exchange for gross proceeds of $15.0 million, while we are still in discussions in Timwell, due to various delays in the process and other barriers to closing, there is a significant risk that we and Timwell will not reach the required milestones in order to close the remaining issuances. We will also 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 our loan repayments under our Kreos Loan Agreement, or if we cannot raise sufficient funds from equity issuances, such as the ATM Offering Program. If we cannot raise the required funds on acceptable terms, we may be forced to substantially curtail 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.

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.

As of September 30, 2018, we had an accumulated deficit in the total amount of $147.9 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.

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 ATM Offering Program, other future public or private issuances of securities, or through a combination of the foregoing. Additionally, with respect to our Investment Agreement with Timwell relating to the issuance of an additional 12,000,000 ordinary shares in exchange for gross proceeds of $15.0 million, while we are still in discussions in Timwell, due to various delays in the process and other barriers to closing, there is a significant risk that we and Timwell will not reach the required milestones in order to close the remaining issuances. See Part I, Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations-Liquidity and Capital Resources-Timwell investment agreement. We will also 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 our loan repayments under our Kreos Loan Agreement, or if we cannot raise sufficient funds from equity issuances, such as the ATM Offering Program.

In addition, although we registered up to $25.0 million in sales under our effective registration statement on Form S-3 (the Form S-3) for our ATM Offering Program, due to limitations under the rules of Form S-3, which have applied to us since we filed our 2017 Form 10-K, we may only sell up to approximately $13.7 million in primary offerings under the Form S-3 during any 12-month period while we remain subject to these limitations. We will recalculate the amount of this limitation if we terminate our ongoing takedown and conduct another takedown under our Form S-3. Additionally, because we have already sold $15.7 million in the ATM Offering Program since its inception, we may only raise up to a remaining $9.3 million using the program, subject to the $13.7 million cap during any rolling 12-month period. As of September 30, 2018, we had sold approximately $1.6 million in securities under our Form S-3 during the last 12 months, when we were subject to these restrictions. For more information, see Part I, Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources - Equity Raises.

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 offerings on 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 Nasdaq, or other equity raise transactions such as equity lines of credit. We have in the past been, and may in the future be, required to pay advisory fees to investment banks assisting us with financing transactions. 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. 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. We are in discussions routinely with such possible sources of additional funding. As another alternative, we may seek to refinance up to a substantial portion of our indebtedness under our Kreos Loan Agreement, which we have considered with Kreos from time to time, including by exchanging our indebtedness with Kreos for new convertible debt from a third-party investor, or to borrow additional funds. Agreements governing any borrowing arrangement may contain covenants that could restrict our operations.

If we cannot raise the required funds on acceptable terms, we may be forced to substantially curtail 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.

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The closings of the remaining two tranches of ordinary shares under the Investment Agreement are subject to various conditions, some of which are outside our control. There is a significant risk that we will not achieve the required milestones to close the remaining tranches and form the China JV, which could significantly and adversely impact our liquidity and our financial condition.

The prospective issuance of 12,000,000 remaining ordinary shares to Timwell in exchange for proceeds of $15 million, under the Investment Agreement, represents a significant source of liquidity for the Company. Additionally, to the extent formed, the minimum payments owed by the China JV to us would be expected to provide us with a source of ongoing income to supplement our other then-available capital resources. The remaining issuances under the Investment Agreement, which will occur in two tranches, are subject to specified closing conditions, including the formation of a joint venture, the signing of a license agreement and a supply agreement, in the case of the second tranche closing, and the successful production of certain ReWalk products, among others, in the case of the third tranche closing. While we have pursued actively the steps necessary to fulfill all closing conditions to the remaining two tranches under the Investment Agreement, some of the conditions are outside of our control. We have also experienced significant delays and difficulties working to form the China JV and to negotiate the required joint venture, license and supply agreement, as required for the second tranche closing for proceeds of $10 million. Additionally, even after the second tranche closing, to the extent it occurs, regulatory, competitive and marketing factors may hinder the ability of a China-based manufacturer or agent to successfully produce our ReStore product to certain quality requirements, as required for the third tranche closing for proceeds of $5.0 million.

The second tranche closing was initially expected to occur by July 1, 2018 and the third tranche closing was initially expected to occur by December 31, 2018 and no later than April 1, 2019. While we are still in discussions with Timwell, due to the different jurisdictions involved, new positions taken by the counterparty on certain key commercial points, and certain technical and administrative delays relating to governmental approvals in China, there is a significant risk that we and Timwell will not reach the required milestones in order to complete the closings of the second and third tranches and receive the gross proceeds of $10.0 million and $5.0 million, respectively. The failure to close any or all of the remaining two tranches could significantly and adversely impact our liquidity and financial condition, requiring us to find additional sources of liquidity on reasonable terms as a replacement. Additionally, if the China JV (to the extent it is formed, if at all) were to fail to incorporate or to operate at a level necessary to make the minimum payments owed to us, we would also lose an additional source of income, which could adversely affect our business and financial condition. We continue to view China as a market with key opportunities for products designed for stroke patients. Thus, although we remain in dialogue with RealCan, Timwell’s affiliate, and have discussed with RealCan various alternatives to the original investment agreement, we are also evaluating alternatives with different groups to penetrate the Chinese market.

To the extent that the non-completion of the second and third tranches causes us to modify or terminate any arrangements 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. Additionally, because Timwell is our largest shareholder with representation on our board of directors, it may have significant influence over our affairs, which may adversely affect us in the event of a dispute. For more information, see Risks Related to an Investment in our Ordinary Shares-Timwell, along with a small number of shareholders, currently has significant influence over matters requiring shareholder approval. Additionally, as a result of the potential issuances of additional ordinary shares to it, Timwell may on its own have increasing influence and ultimately possible de facto control over such matters. This could discourage takeover or merger attempts or other actions shareholders may consider favorable.

We rely on sales of our ReWalk 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 systems or, once approved and commercialized, our ReStore lightweight soft suit exoskeleton, or to generate sufficient revenues from these current and future products.

We currently rely, and in the future will rely, on sales of our ReWalk systems and related service contracts and extended warranties for our revenue. Additionally, we are developing and intend to commercialize the ReStore lightweight soft suit exoskeleton, designed to support mobility for individuals suffering from other lower limb disabilities, and aim to begin marketing an initial indication for stroke patients in the third quarter of 2019 after the receipt of mandatory CE mark (for which we applied in the fourth quarter of 2018) and FDA clearance (for which we have not yet applied). Several factors could negatively affect our ability to achieve and maintain market acceptance of our ReWalk system or, once commercialized, 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 of the device depends on educating people with limited upright mobility and healthcare 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 the disadvantages of using the ReWalk, including the time it takes for a user to put on ReWalk, the slower pace of the device 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 the current ReWalk system 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 products 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. Although 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 Barmer and DGUV have issued broad coverage decisions for the ReWalk device, no broad uniform policy of coverage and reimbursement for electronic exoskeleton medical technology exists among third-party payors in the United States. 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, Barmer or DGUV may cancel or materially curtail their current policy of providing coverage for ReWalk devices in the United States and Germany for qualifying individuals who have suffered spinal cord injury, or we may not place enough ReWalk units through to make our sales profitable under their policies. For more information, see Part I, Item 1A. Risk Factors-Risks Relating to our Business and our Industry-We may fail to secure or maintain adequate insurance coverage or reimbursement for ReWalk by third-party payors, 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 2017 Form 10-K.

- ReStore. We are currently undertaking a prospective clinical trial on the ReStore system to assess its safety during gait training in stroke patients in a rehabilitation setting. 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, supplying real-time analytics to optimize session productivity and generating on-going 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 will first be used 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, the functionality of the device for the variety of 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: 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 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.

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 multiple sclerosis, and, in the future, we plan to address these needs in cerebral palsy, Parkinson’s disease and elderly assistance. In addition to other research and development projects, we 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 new soft suit exoskeleton products we create for use by individuals suffering from a stroke or multiple sclerosis, and, in later years, from other new products of ours aimed at addressing other medical indications which affect the ability to walk, including 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. For instance, while we recently applied for CE mark for our ReStore product for stroke patients, we have not yet submitted a 510(k) premarket notification to the FDA for the product and intend to do so by the first quarter 2019, following only after the completion of clinical trials. We aim to commercialize the system for use by stroke patients in Europe and the United States during the third quarter of 2019. Obtaining clearance for the ReStore product or other soft suit exoskeleton products could involve an extensive, costly and time-consuming process, and could be prolonged significantly beyond our expectations based on unexpected inquiries from regulators, thus delaying commercialization beyond our planned timetable. As a result, we cannot make any assurances regarding the ultimate timing of FDA clearance or CE mark or commercialization of the ReStore product or any future products. For more information on the clearance processes, see Part I, Item 1. Business-Government Regulation in our 2017 Form 10-K.

Harvard may also terminate its license agreement with us if we fail to obtain the requisite insurance, become insolvent or do not meet certain developmental milestones with respect to the products we develop using the patents licensed to us. 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 do not yet have any clinical data demonstrating the benefits of our products for indications other than paraplegia and we might not be able

to support the economic benefits the new product has for the customer.

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-spinal cord injury markets such as the stroke and multiple sclerosis communities, and, in the longer term, 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 systems and related service contracts and extended warranties for our revenue, and we may not be able to achieve or maintain market acceptance or to 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.

Risks Related to Government Regulation

We have submitted medical device report (MDRs), to the FDA for numerous serious injuries relating to use of the ReWalk Personal system, and have initiated 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, which could result in voluntary corrective actions or FDA 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 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. 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 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.

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. We submitted to the FDA revised labeling that incorporates the revised use instructions intended to prevent fractures as a special 510(k) in September of 2018, and the 510(k) is currently undergoing acceptance review. While 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.

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. 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.

While we addressed the observations that the FDA cited in a 2015 warning letter related to our mandatory postmarket 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.

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, or 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 (the FFDCA), 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 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, and we intend to continue providing the FDA with periodic reports as required. Through these reports, we have made the FDA aware that due to enrollment issues, we are currently unable to satisfy the target enrollment specified in the study protocol.

As of November 2018, we had four active centers participating in the study (with a fifth site set to complete the process by the end of 2018), but only two sites have successfully enrolled patients. Ten subjects have enrolled in the study, one has completed the study and three are using the device in the community. This is substantially below the required number of patients included in our study protocol, currently leading the FDA to label our progress as inadequate. We are in ongoing communications with the FDA regarding options to address the inadequate progress. However, there can be no assurance that we will be able to satisfy the postmarket study requirements. If we cannot meet FDA requirements for the postmarket 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 59.3% of our revenues in the fiscal year ended December 31, 2017 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.

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 above.

In June 2014, the FDA granted our petition for de novo classification, which provides a route to market for medical devices that are low to moderate risk, but are not substantially equivalent to a predicate device, and classified ReWalk as Class II subject to certain special controls. The ReWalk is intended to enable individuals with spinal cord injuries to perform ambulatory functions under supervision of a specially trained companion, and inside rehabilitation institutions. The special controls established in the de novo order include the following: compliance with medical device consensus standards; clinical testing to demonstrate safe and effective use considering the level of supervision necessary and the use environment; non-clinical performance testing, including durability testing to demonstrate that the device performs as intended under anticipated conditions of use; a training program; and labeling related to device use and user training. In order for us to market ReWalk, we must comply with both general controls, including controls related to quality, facility registration, reporting of adverse events and labeling, and the special controls established for the device. Failure to comply with the general and special controls could lead to removal of ReWalk from the market, 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 product performance, 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 the ReWalk. 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. Recent changes in enforcement practice by the FDA, European Union and other agencies have resulted in increased enforcement activity, which increases the compliance risk that we and other companies in our industry are facing. 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 -While we addressed the observations that FDA cited in a 2015 warning letter related to our mandatory postmarket surveillance study and initiated the study, we are currently experiencing enrollment issues that make our study progress inadequate.

In addition, governmental agencies may impose new requirements regarding registration, labeling or prohibited materials that may require us to modify or re-register ReWalk once it is already on the market or otherwise impact our ability to market ReWalk 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 ReWalk. In the European Union, for example, a new Medical Device Regulation was published in 2017, which, when it enters into full force in 2020, will include additional premarket and post-market requirements, as well as potential product reclassifications or more stringent commercialization requirements that could adversely affect our clearances and approvals. 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 or suppliers fail to comply with the FDA’s Quality System Regulation, or QSR, our manufacturing operations could be interrupted.

We, our manufacturer Sanmina Corporation, or Sanmina, and some of our suppliers 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 for repair, replacement or refunds;
- operating restrictions, partial suspension or total shutdown of production;
- recalls, withdrawals, administrative detention or seizure of our products;
- refusing or delaying requests for 510(k) marketing clearance or 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 ReWalk 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 (the FCPA). See Item 1. Business-Government Regulation in our 2017 Form 10-K. U.S. federal and state laws, including the federal Physician Payments Sunshine Act (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. 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.

Explanation of Responses: 39

Risks Related to an Investment in our Ordinary Shares

We may not be able to maintain the listing of our ordinary shares on the Nasdaq Capital Market, which could adversely affect our liquidity and the trading volume and market price of our ordinary shares, and decrease or eliminate your investment.

We recently received a notification letter (the Bid Price Letter), from Nasdaq indicating that we did not satisfy the requirement for continued listing on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(a) (Rule 5550(a)), to maintain a minimum bid price of $1 per share. Separately, we received a notification letter (the MVLS Letter), from Nasdaq stating that, under Nasdaq Listing Rule 5550(b) (Rule 5550(b)), we failed to comply with the minimum $35 million market value of listed securities, or MVLS, 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 became deficient as of October 26, 2018 with Rule 5550(a) as our closing bid price was less than $1 per share for 30 consecutive business days, and with Rule 5550(b) because, in addition to not meeting the alternative shareholders' equity and net income requirements, our MVLS was below $35 million for 30 consecutive business days. The MVLS Letter addresses the same continued listing deficiency raised by NASDAQ in letters from November 2017 and May 2018, which we cured temporarily in June 2018 when our MVLS exceeded $35 million for the required period after the closing of a private placement. As in the past, the Bid Price Letter and the MVLS Letter are notices of deficiency, not delisting, and do not currently affect the listing or trading of ReWalk ordinary shares on The Nasdaq Capital Market.

We have 180 days, or until April 24, 2019, to comply with (i) Rule 5550(a) by maintaining a closing bid price of at least $1 per share for 10 consecutive business days, and (ii) Rule 5550(b) by (1) maintaining a MVLS (the product of total shares outstanding and the daily closing bid price) of $35 million or (2) having shareholders' equity of at least $2.5 million. Additionally, we may be eligible for a second 180-day period to satisfy Rule 5550(a)'s minimum bid price requirement, if, as of April 24, 2019, we continue to have a market value of publicly held shares of at least $1 million and meets all other initial listing standards of The Nasdaq Capital Market (with the exception of the bid price requirement). As of September 30, 2018, our shareholders' deficiency was $5.2 million, and for the nine months ended September 30, 2018, and our net loss was $16.6 million, both below the alternative standards for compliance under Rule 5550(b). We intend to monitor closely the closing bid price of our ordinary shares and our MVLS and to consider plans for regaining compliance with Rules 5550(a) and 5550(b), which may include implementing additional capital raises. While we plan to review all available options, there can be no assurance that we will be able to regain compliance with the applicable rules.

If we do not regain compliance with Rule 5550(b) by April 24, 2019, or if we regain compliance with Rule 5550(b) by April 24, 2019 but fail to regain compliance with Rule 5550(a) during that rule's applicable cure period, Nasdaq will notify us that our ordinary shares are subject to delisting. We would then be permitted to appeal any delisting determination to a Nasdaq Hearings Panel. 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, we may list our ordinary shares on an over-the-counter exchange. Any such 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 a 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 and decreased trading prices of 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 for our Company, 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.

Explanation of Responses:

Following the dismissal of several securities class lawsuits against us, we are currently subject to one securities class action lawsuit against us, which 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 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. As of November 7, 2018, the California state and federal cases and the case in Massachusetts Superior Court have been dismissed with no further right to appeal, and the case in the United States District Court for the District of Massachusetts has been partially dismissed. The actions involved or involve claims under various sections of the Securities Act, against us, certain of our current and former directors and officers, the underwriters of our IPO and certain other defendants.

The remaining action, which was commenced in the United States District Court for the District of Massachusetts, or the District Court, and alleges violations of Sections 11 and 15 of the Securities Act and Sections 10(b) and 20(a) of the Exchange Act, was partially dismissed on August 23, 2018. The District Court granted the motion to dismiss the claims under Sections 11 and 15 of the Securities Act, finding that the plaintiff failed to plead a false or misleading statement in the IPO registration statement. The District Court did not address the claims under Sections 10(b) and 20(a) of the Exchange Act because, as a result of the dismissal of the claims under the Securities Act, the lead plaintiff lacked standing to pursue those claims. Because the action in the District Court was styled as a class action, the District Court permitted the plaintiff to file a supplemental memorandum concerning standing or a motion to appoint a substitute or supplemental plaintiff. For more information, see Recent Developments-Securities Litigation Update.

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 the remaining lawsuit; therefore, no litigation reserve has been recorded in our consolidated balance sheets. Although we plan to defend against the remaining lawsuit vigorously, there can be no assurances that a favorable final outcome will be obtained. This lawsuit 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.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHER INFORMATION

Not applicable.

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ITEM 6. EXHIBIT INDEX

Exhibit Number	Description
10.1	Waiver, dated September 3, 2018, between the Company and Kreos Capital V (Expert Fund) Limited (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).
10.2	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).**
10.3	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).**
10.4	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).**
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act 2002.
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act 2002.
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document

* Furnished herewith.

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

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 thereunto duly authorized.

ReWalk Robotics Ltd.

Date: November 8, 2018 By: /s/ Larry Jasinski
Larry Jasinski
Chief Executive Officer

Date: November 8, 2018 By: /s/ Ori Gon
Ori Gon
Chief Financial Officer
(Principal Financial and Principal Accounting Officer)

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