UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

Qian Deng, David Hershlikovitz, Jackie888, Inc., Michael C. Kemmerling, Narbeh Nathan, and Paul Sislin, Individually and on Behalf of All Others Similarly Situated, Plaintiffs, v. REWALK ROBOTICS LTD.; LARRY JASINSKI; AMI KRAFT; AMIT GOFFER; JEFF DYKAN; HADAR RON; ASAF SHINAR; WAYNE B. WEISMAN; YASUSHI ICHIKI; ARYEH DAN; GLENN MUIR; BARCLAYS CAPITAL INC.; JEFFRIES LLC; and CANACCORD GENUITY INC., Defendants.	No.: **CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **JURY TRIAL DEMANDED**

Plaintiffs Qian Deng, David Hershlikovitz, Jackie888, Inc., Michael C. Kemmerling, Narbeh Nathan, and Paul Sislin, individually and on behalf of all others similarly situated, make the following allegations against ReWalk Robotics Ltd. ("**ReWalk**" or the "**Company**") and the other defendants based upon personal knowledge as to himself and his own acts, and information and belief as to all other matters. Plaintiffs' information and belief is based upon, among other things, the investigation of his attorneys, which included, among other things: (i) a review of the defendants' public filings; (ii) defendants' public statements; (iii) the United Sates Securities and Exchange Commission ("SEC") filings; (iv) press releases and news articles published by and regarding ReWalk. Plaintiffs believe that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a securities class action brought on behalf of Plaintiffs and all other persons who purchased ReWalk common stock in or traceable to ReWalk's September 12, 2014 initial public stock offering (the "**IPO**"), asserting violations of the Securities Act of 1933.

2. ReWalk is a medical device company that designs develops and markets wearable robotic exoskeletons for people with spinal cord injuries. ReWalk became a public company on September 12, 2014 when it completed its IPO and issued 3,450,000 ordinary shares and raised $41.4 million. The registration statement and prospectus relating to the IPO purported to describe, among other things, ReWalk's exoskeleton product, the anticipated market for the Company's products, the regulatory requirements mandated by the FDA and other regulatory agencies, and ReWalk's efforts to obtain regulatory approval for its exoskeleton product.

3. ReWalk filed with the SEC a Form S-1 registration statement relating to the IPO on July 10, 2014, which along with the amendments, became effective on September 11, 2014 ("**Registration Statement**"). On September 15, 2014, the Company filed with the SEC the final prospectus relating to the IPO, dated September 11, 2014, which forms part of the Registration Statement ("**Prospectus**"). The Registration Statement and the Prospectus contained untrue statements of material fact or omitted to state facts necessary to make the statements made not misleading. Those documents failed to disclose that the Company was wholly unprepared or unable to comply with the extensive postmarket regulatory requirements set forth by the United States Food and Drug Administration ("**FDA**"). It was crucial to ReWalk's business to comply with FDA regulations so that the Company could continue to market and sell its prized exoskeleton device. Thus, the Company's ability to market and sell its medical device is material information that goes to the heart of ReWalk's business and financial success.

4. On February 25, 2016, when the public became aware that ReWalk had not been able to comply with FDA postmarket surveillance requirements and the Company had failed to disclose that material information from the Registration Statement, ReWalk's stock dropped over 22%, thereby causing Plaintiffs and other members of the Class substantial damages in connection with their purchases of ReWalk ordinary shares.

JURISDICTION AND VENUE

5. The claims asserted herein arise under and pursuant to Sections 11, 12(a)(2) and 15 of the Securities Act of 1933 (the "**Securities Act**""), §§ 15 U.S.C. §§ 77k, 77l(a)(2) and 77o.

6. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §1331 and Section 22 of the Securities Act.

7. Venue is proper in this District under 28 U.S.C. § 1391(b) because Defendants' acts giving rise to Plaintiff's claims arose in and emanated from this judicial district.

8. ReWalk's United States headquarters is located in this District, ReWalk conducts substantial business in this District and many of the Defendants' acts and practices complained of herein occurred in substantial part in this District.

9. In connection with the acts, conduct and other wrongs alleged herein, the Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to the United States mails, interstate telephone communications and the facilities of the national securities markets.

PARTIES

10. Plaintiffs acquired ReWalk ordinary shares in, or traceable to, ReWalk's September 12, 2014 IPO, as set forth in the attached certifications, and have been damaged thereby.

11. Defendant ReWalk is a medical device company founded in 2001, organized under the laws of the State of Israel and located in Yokneam, Isreal. Rewalk's United States headquarters are located in Marlborough, Massachusetts. The Company's shares trade on the NASDAQ Global Market under the symbol "RWLK."

12. Defendant Larry Jasinski ("**Jasinski**") signed the Registration Statement as the Company's Chief Executive Officer and a member of the board of directors. Jasinki has served as a ReWalk director and its Chief Executive Officer since 2012.

13. Defendant Ami Kraft ("**Kraft**") signed the Registration Statement as ReWalk's Chief Financial Officer. Kraft has served as Senior Vice President and General Manager for ReWalk since 2015.

14. Defendant Amit Goffer ("**Goffer**") signed the Registration Statement as the Company's President, Chief Technical Officer and a member of the board. Goffer is the Company's founder and previously served as the Company's Chief Executive Officer and Chief Technology Officer. Defendant Goffer resigned from the Company effective November 18, 2015.

15. Defendant Jeff Dykan ("**Dykan**") signed the Registration Statement as Chairman of the Board. Dykan has served as a ReWalk director since 2006 and has been its Chairperson since 2009.

16. Defendant Hadar Ron ("**Ron**") signed the Registration Statement as a director of ReWalk.

17. Defendant Asaf Shinar ("**Shinar**") signed the Registration Statement as a director of ReWalk.

18. Defendant Wayne B. Weisman ("**Weisman**") signed the Registration Statement as a director of ReWalk.

19. Defendant Yasushi Ichiki ("**Ichiki**") signed the Registration Statement as a director of ReWalk.

20. Defendant Aryeh Dan ("**Dan**") signed the Registration Statement as a director of ReWalk.

21. Defendant Glenn Muir ("**Muir**") signed the Registration Statement as a director of ReWalk.

22. Defendants Jasinski, Kraft, Goffer, Dykan, Ron, Shinar, Weisman, Ichiki, Dan and Muir are collectively referred to as the "**Individual Defendants**."

23. Defendant Barclays Capital Inc. ("**Barclays**") is a financial services company that served as an underwriter and book running manager for ReWalk's IPO. Barclays drafted and disseminated the Prospectus and sold the Company's stock to the investing public in the IPO.

24. Defendant Jeffries LLC ("**Jeffries**") is a financial services company that served as an underwriter and book running manager for ReWalk's IPO. Jeffries drafted and disseminated the Prospectus and sold the Company's stock to the investing public in the IPO.

25. Defendant Canaccord Genuity Inc. ("**Canaccord**") is a financial services company that served as an underwriter for ReWalk's IPO. Canaccord drafted and disseminated the Prospectus and sold the Company's stock to the investing public in the IPO.

26. Defendants Barclays, Jeffries and Canaccord are collectively referred to as the "**Underwriter Defendants**."

SUBSTANTIVE ALLEGATIONS

Company Background Prior to the IPO

27. ReWalk is a medical device company that designs, develops and markets wearable robotic exoskeletons for individuals with spinal cord injury. ReWalk was founded in 2001 by Goffer, who served as the Company's Chief Executive Officer and Chief Technical Officer until 2012, and who resigned from the Company in November 2015.

28. Rewalk offered two products at the time of its IPO: ReWalk Personal (designed for everyday use by individuals at home and in their communities, and custom-fit for each user) and ReWalk Rehabilitation (designed for the clinical rehabilitation environment, it enables individuals to evaluate their capacity for using ReWalk Personal in the future). At the time of the IPO, ReWalk stated that the ReWalk Personal "is the first exoskeleton cleared by the FDA for personal use." Registration Statement at 59.

29. ReWalk's medical products and manufacturing operations are subject to regulation by the FDA, the European Union, the Ministry of Health in Israel, 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.

30. On or about July 10, 2014, ReWalk filed with the SEC its Registration Statement on Form F-1, which included several amendments the last of which was filed with the SEC on August 26, 2014, effective September 11, 2014, and was which issued to the public in connection with the IPO.

31. On or about September 12, 2014, ReWalk and the Underwriter Defendants priced the IPO at $12 per share.

32. On or about September 15, 2014, ReWalk filed with the SEC the final Prospectus relating to the IPO.

33. ReWalk described itself in its Registration Statement as an "innovative medical device company," that had developed a breakthrough product:

> ReWalk is a breakthrough product that can fundamentally change the health and life experiences of users. ReWalk is currently the only commercialized exoskeleton using a tilt sensor to restore self-initiated walking. Designed for all-day use, ReWalk is battery-powered and consists of a light, wearable exoskeleton with integrated motors at the joints, an array of sensors and a computer-based control system to power knee and hip movement.

Registration Statement at 1.

34. ReWalk disclosed that it expected sales of ReWalk Personal to make up a substantial majority of its future revenues:

> Our commercialization strategy is to penetrate rehabilitation centers, hospitals and similar facilities that treat patients with spinal cord injuries to become an integral part of their rehabilitation programs and to develop a broad based training network with these facilities to prepare users for home and community use. According to the National Spinal Cord Injury Statistical Center, 87.1% of persons with spinal cord injuries are sent to private, non-institutional residences (in most cases, their homes) after hospital discharge. As a result, while the majority of our sales to date have been ReWalk Rehabilitation units, the primary focus of our commercialization efforts going forward will be marketing ReWalk Personal for routine use at home, work or in the community, and we expect sales of ReWalk Personal to account for the substantial majority of our revenues in the future.

Registration Statement at 1.

35. In June 2014, the FDA granted ReWalk's petition for "*de novo*" classification, and approved ReWalk to market its exoskeleton device (the "**June 2014 Letter**").

36. At the same time the FDA approved the ReWalk Personal, the FDA also ordered Rewalk to conduct "postmarket surveillance" studies in order to determine the products' risks and

safety. Postmarket surveillance includes monitoring the safety of a pharmaceutical drug or medical device after it has been released on the market. According to the FDA:

> Postmarket surveillance is a collection of processes and activities the FDA uses to monitor the safety and effectiveness of medical devices once they are on the market. These activities are designed to generate information to quickly identify poorly performing devices and other safety problems, accurately characterize real-world device performance and clinical outcomes, and facilitate the development of new devices, or new uses for existing devices.

See U.S. Food & Drug Administration, Device Postmarket Surveillance, available at http://www.fda.gov/MedicalDevices/Safety/CDRHPostmarketSurveillance/default.htm (last visited Nov. 2, 2016).

37. The FDA regulation relating to surveillance plans, 24 C.F.R. § 822.10, requires providers to report:

> (a) The plan objective(s) addressing the surveillance question(s) identified in our order;
>
> (b) The subject of the study, e.g., patients, the device, animals;
>
> (c) The variables and endpoints that will be used to answer the surveillance question, e.g., clinical parameters or outcomes;
>
> (d) The surveillance approach or methodology to be used;
>
> (e) Sample size and units of observation;
>
> (f) The investigator agreement, if applicable;
>
> (g) Sources of data, e.g., hospital records;
>
> (h) The data collection plan and forms;
>
> (i) The consent document, if applicable;
>
> (j) Institutional Review Board information, if applicable;
>
> (k) The patient followup plan, if applicable;
>
> (l) The procedures for monitoring conduct and progress of the surveillance;

(m) An estimate of the duration of surveillance;

(n) All data analyses and statistical tests planned;

(o) The content and timing of reports.

38. The FDA's postmarket surveillance regulations are mandatory, and a company's failure to comply with the FDA's requirements could lead to enforcement actions, including seizure of the product, injunction, prosecution and/or civil money penalties.

39. In granting sales and marketing approval for the ReWalk Personal, the FDA identified specific risks in the June 2014 Letter that called for further "clinical testing." These "Identified Risks" included: "Instability, Falls and Associated Injuries," "Bruising, Skin Abrasion, Pressure Sores, Soft Tissue Injury"; "Diastolic hypertension and changes in blood pressure, and heart rate"; "Device Malfunction resulting in Unanticipated Operation (e.g., Device Stoppage, Unintended Movement)"; and "User Error."

40. In the June 2014 Letter, the FDA required ReWalk to comply with the following "special controls," found in 21 C.F.R. § 890.3480 ("Powered lower extremity exoskeleton"), in connection with the ReWalk product:

- Elements of the device materials that may contact the patient must be demonstrated to be biocompatible.
- Appropriate analysis/testing must validate electronic compatibility/interference (EMC/EMI), electrical safety, thermal safety, mechanical safety, battery performance and safety, and wireless performance, if applicable.
- Appropriate software verification, validation, and hazard analysis must be performed.
- Design characteristics must ensure geometry and materials composition are consistent with intended use.
- Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Performance testing must include:

- Mechanical bench testing (including durability testing) to demonstrate that the device will withstand forces, conditions and environments encountered during use.

- Simulated use testing (i.e. cyclic loading testing) to demonstrate performance of device commands and safeguard under worst case conditions and after durability testing.

- Verification and validation of manual override controls are necessary, if present.
- The accuracy of device features and safeguards.

- Device functionality in terms of flame retardant materials, liquid/particle ingress prevention, sensor and actuator performance, and motor performance.

- Clinical testing must demonstrate safe and effective use and capture any adverse events observed during clinical use when used under the proposed conditions of use, which must include considerations for:

    - Level of supervision necessary

    - Environment of use (e.g., indoors and/or outdoors) including obstacles and terrain representative of the intended use environment

- A training program must be included with sufficient educational elements so that upon completion of training program, the clinician, user and companion can:

    - Identify the safe environments for device use

    - Use all safety features of device

    - Operate the device in simulated or actual use environments representative of indicated environments and use

- Labeling for the Physician and User must include the following:

    - appropriate instructions, warning, cautions, limitations, and information related to the necessary safeguards of the device, including warning against activities and environments that may put the user at greater risk.

    - specific instructions and the clinical training needed for the safe use of the device, which includes:

        - instructions on assembling the device in all available configurations,
        - instructions on fitting the patient,

- instructions and explanations of all available programs and how to program the device,
- instructions and explanation of all controls, input, and outputs,
- instructions on all available modes or states of the device,
- instructions on all safety features of the device, and
- instructions for properly maintaining the device.

- information on the patient population for which the device has been demonstrated to have a reasonable assurance of safety and effectiveness.

- pertinent non-clinical testing information (e.g., EMC, battery longevity)

- a detailed summary of the clinical testing including:

  - Adverse events encountered under use conditions.
  - Summary of study outcomes and endpoints.
  - Information pertinent to use of the device including the conditions under which the device was studied [e.g., level of supervision or assistance, and environment of use (e.g., indoors and/or outdoors) including obstacles and terrain].

Letter dated June 26, 2014 from Jonette Foy of the FDA to John Hamilton, ReWalk, Vice President of Regulatory, Clinical Reimbursement and Service, available at http://www.accessdata.fda.gov/cdrh_docs/pdf13/DEN130034.pdf (last visited Nov. 3, 2016).

41. The FDA said it issued the order for the postmarket surveillance study, pursuant to § 522 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §3601, and 21 C.F.R. §822, upon *de novo* approval in June 2014 because "the device's failure to prevent a fall would be reasonably likely to cause serious user injury and/or death through fall related sequelae, such as traumatic brain injury (TBI), spinal cord injury (SCI), and fractures to the user."

ReWalk's IPO

42. The Company launched its IPO on or about September 12, 2014, and on or about September 17, 2014, announced the closing of its offering of 3,450,000 ordinary shares to the public (including 450,000 shares pursuant to the full exercise of the underwriter's option to purchase additional shares). The Company raised roughly $41.4 million in the IPO, of

which $5.1 million included expenses, underwriting discounts and commissions, resulting in net proceeds to the Company of approximately $36.3 million.

43. The Underwriter Defendants shared approximately $2.7 million in fees collectively for their work on the IPO.

The Registration Statement Contained Untrue Statements of Material Facts and Omitted From Disclosure Facts Necessary To Make the Statements Made Not Misleading

44. The Registration Statement and Prospectus relating to the Company's IPO contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading and was not prepared in accordance with the rules and regulations governing its preparation.

45. The Registration Statement discussed that ReWalk's medical products and manufacturing operations would be subject to government regulation. The Registration Statement also explained the premarket registration that governed ReWalk's devices, ReWalk's disagreement with the FDA of the classification of its ReWalk device, and the special controls established by the FDA in its *de novo* order for the ReWalk device:

> Unless an exemption applies, each medical device commercially distributed in the United States requires either a substantial equivalence determination under a 510(k) premarket notification submission, or an approval of a premarket approval application (PMA). 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 each medical device and the extent of control needed to provide reasonable assurance of safety and effectiveness. Classification of a device is important because the class to which a device is assigned determines, among other things, the necessity and type of FDA review required prior to marketing the device. Class I devices are those for which reasonable assurance of safety and effectiveness can be assured by adherence to general controls that include compliance with the applicable portions of the FDA's Quality System Regulation, or QSR, facility registration and product listing, reporting of adverse medical events, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials. Class I also includes devices for which there is insufficient information to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide

such assurance, but that are not life-supporting or life-sustaining or for a use which is of substantial importance in preventing impairment of human health, and that do not present a potential unreasonable risk of illness of injury.

Class II devices are those for which general controls alone are insufficient to provide reasonable assurance of safety and effectiveness and there is sufficient information to establish "special controls." These special controls can include performance standards, postmarket surveillance, patient registries and FDA guidance documents. While most Class I devices are exempt from the 510(k) premarket notification requirement, only about 60 types of Class II devices are exempt from premarket notification. As a result, manufacturers of most Class II devices are required to submit to the FDA premarket notifications under Section 510(k) of the FFDCA requesting classification of their devices in order to market or commercially distribute those devices. To obtain a 510(k), a substantial equivalence determination for their devices, manufacturers must submit to the FDA premarket notifications demonstrating that the proposed device is "substantially equivalent" to a predicate device already on the market. A predicate device is a legally marketed device that is not subject to premarket approval, *i.e.*, a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was found substantially equivalent through the 510(k) process. If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If the device is not "substantially equivalent" to a previously cleared device, the device is automatically a Class III device. The device sponsor must then fulfill more rigorous premarket approval requirements, or can request a risk-based classification determination for the device in accordance with the "de novo" process, which is a route to market for medical devices that are low to moderate risk, but are not substantially equivalent to a predicate device.

***

We currently distribute ReWalk product to medical/rehabilitation institutions and take the position that the ReWalk for this use qualifies as powered exercise equipment, which is a Class I device and does not require a 510(k). Although the FDA disagrees with this position, the agency is exercising enforcement discretion, *i.e.*, it is permitting us to continue to distribute the ReWalk to institutions for therapeutic use. This exercise of enforcement discretion is in the context of our working with the FDA through the *de novo* classification process to obtain a classification determination for the ReWalk for uses that go beyond the institutional/rehabilitation setting, potentially leading to a limited community ambulation use. We submitted a *de novo* petition to the FDA in June 2013 and have had ongoing communications with the agency, including an in-person meeting in October 2013.

In June 2014, the FDA granted our petition for "*de novo*" classification, which is 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 special controls. The special controls established in the *de novo* order include compliance with medical device consensus standards; performance of a postmarket surveillance clinical study demonstrating a reasonable assurance of safety and effectiveness in urban terrain; non-clinical performance testing of the system's function and durability; a training program; and labeling related to device use and user training. The special controls of this *de novo* order will also apply to competing products seeking FDA clearance.

Registration Statement at 68-70.

46. These statements in the Registration Statement failed to disclose the material fact that despite the FDA's order that Rewalk comply with "special controls" and provide the FDA with a postmarket surveillance study for the ReWalk exoskeleton device, the Company was unprepared or unable to comply with the FDA June 24, 2014 directive that the Company perform a premarket surveillance clinical study.

47. While the Registration Statement included a section entitled "Postmarket Regulation Requirements" that disclosed certain postmarket regulation requirements in connection with its exoskeleton device, it failed to disclose in that section of the Registration Statement that one of its regulation requirements included the postmarket surveillance study. Failure to disclose the Company's postmarket surveillance obligations in Registration Statement's recitation of its postmarket regulation requirements is materially misleading.

48. At the time of the IPO – when the above statements were made in the Registration Statement – Defendants knew, but did not disclose, that the Company was unable to, or unprepared to, comply with its regulatory obligations.

ReWalk Fails to or is Unable to Comply with FDA Requirements

49. More than one year after the FDA's June 2014 mandate that Rewalk perfom a postmarket surveillance clinical study (known as a 522 Order), the Company was still not able to provide an adequate postmarket surveillance plan to the FDA.

50. ReWalk previously attempted to comply with the FDA's postmarket surveillance study requirement, but failed. The Company provided the FDA with a postmarket surveillance study plan synopsis in late July 2014. But, on September 29, 2014, the FDA informed the Company that the submission lacked the information needed to complete the review. The FDA listed the deficiencies in the Company's submission and required a complete response within 30 days. The Company did not timely respond.

51. On November 5, 2014, the FDA informed the Company that its response was overdue. ReWalk then sent a letter to the FDA on November 6, 2014, enclosing a postmarket surveillance study plan. On February 13, 2015, the FDA again informed the Company that the November 5, 2014, submission also lacked the information needed to complete the review. The FDA identified the deficiencies in the Company's second submission and required a complete response within 30 days. Again, the Company did not timely respond.

52. On March 16, 2015, the FDA informed the Company that a response to the FDA's February 13, 2015 letter was overdue. While the Company informed the FDA on March 20, 2015, that a response letter would be submitted by April 15, 2015, the Company did not submit a letter to the FDA on that date. The following day, the FDA asked he Company for a response to its February 2015 letter.

53. On May 22, 2015, the Company replied stating that it was in a position to respond on most issues, but wanted to discuss one issue with the FDA staff before submitting the formal response. The Company failed to respond to the FDA's numerous attempts to discuss the issue with the Company.

54. Finally, on August 10, 2015, the Company notified the FDA for the first time that it was proposing substantial changes to the methods and study plan and requested an in-person meeting regarding the proposed changes to the plan.

55. On September 2, 2015, the FDA provided feedback on the Company's August 10, 2015 letter and recommended that the Company submit a revised postmarket surveillance study plan based on the feedback and deficiencies identified in the FDA's February 13, 2015 letter as soon as possible. The Company did not timely respond.

The Truth Emerges

56. On September 30, 2015, the FDA issued a warning letter (the "**Warning Letter**") to Argo Medical Technologies, Inc. (ReWalk's former name) outlining ReWalk's substantial failures to outline and commence an adequate postmarket surveillance plan. The Warning Letter informed ReWalk of its failure to comply with FDA regulations, identifying the specific failures as follows:

> To date, FDA has received no response to this communication from your firm, [ReWalk] has not submitted a revised study plan, and there has been a substantial lack of progress towards commencement of the 522 PS study required under the 522 Order.
>
> Further, as stated within the 522 Order, a manufacturer must commence surveillance under section 522 of the Act not later than 15 months after the day on which an order is issued under section 522 (see section 522(b) of the Act). The 15-month time frame within which Argo's PS study plan must be approved and its study must be commenced closed on September 28, 2015.
>
> Failure or refusal of a manufacturer to comply with requirements under section 522 of the Act, which includes requirements specified under 21 CFR Part 822, is a prohibited act under section 301(q)(1)(C) of the Act, 21 U.S.C. § 331(q)(1)(C). Further, failure or refusal to comply with a requirement under section 522 of the Act renders a device misbranded under section 502(t)(3) of the Act, 21 U.S.C. § 352(t)(3).
>
> Argo Medical Technologies, Inc. has:

> - failed to submit a revised PS study plan that adequately addresses the deficiencies described in FDA's September 29, 2014 letter, as well as those deficiencies described in FDA's February 13, 2015 letter (see 21 CFR 822.19);
> - failed to design a PS study plan that answers the questions identified in the 522 Order (see 21 CFR 822.11);
> - failed to have an approved PS study plan (see 21 CFR 822.20); and
> - failed to commence surveillance under section 522 of the Act not later than 15 months after the day on which the 522 Order was issued (see section 522(b) of the Act).
>
> Therefore, [ReWalk] has committed a prohibited act under section 301(q)(1)(C) of the Act by failing to comply with requirements under section 522 of the Act. Your firm's ReWalk device, authorized for marketing under de novo classification (K131798/DEN130034), is currently misbranded under section 502(t)(3) of the Act.
>
> You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Please note that Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.
>
> Within fifteen (15) calendar days from the date you receive this letter, please submit your firm's section 522 post-market surveillance study plan that addresses the deficiencies identified in the FDA letters dated September 29, 2014 and February 13, 2015. In addition, please notify this office in writing of the specific steps you have taken to correct the noted violations, as well as those actions performed to prevent recurrence for this order and future studies. Include documentation of the corrective actions you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. If corrective actions cannot be completed within 15 calendar days, state the reason for the delay and the time within which the corrections will be completed.

57. Despite the fact that the Warning Letter was issued to the Company in September 2015, the letter was not disclosed to the public until February 25, 2016. And it was disclosed to the public by the FDA, not by ReWalk.

58. On May 10, 2016, ReWalk ultimately admitted that it had been unprepared or unable at the time of the IPO to timely and adequately comply with the FDA's "special controls"

due to inadequate staffing. As disclosed in the Company's 10-Q filed with the SEC on May 10, 2016:

> ***The FDA has sent us letters suggesting a potential need for us to seek new pre-market clearance for our ReWalk Personal 6.0 and stating that it may take regulatory action for deficiencies in our mandatory post-market surveillance study on the device.***
>
> On September 30, 2015, we received a warning letter (the "September 2015 Letter") from the Food and Drug Administration (the "FDA") citing deficiencies in our protocol for a post-market surveillance study of our ReWalk Personal and our failure to initiate a post-market study by the September 28, 2015 deadline. Between June 2014 and our receipt of the September 2015 Letter, we submitted our post-market study protocol to the FDA, amended the protocol in response to the FDA's subsequent request and proposed additional amendments to enhance the protocol after the FDA notified us that our subsequently-amended protocol was still deficient. While we responded to the FDA's requests throughout this period, we did not submit all of our responses on a timely basis. The September 2015 Letter warned that the FDA could take regulatory action against us for violations of Section 522 of the Federal Food, Drug and Cosmetic Act ("Section 522") based on the late post-market study and allegedly deficient protocol for that study. In February 2016, the FDA sent us an additional information request (the "February 2016 Letter") requesting additional changes to our post-market surveillance study protocol and asking that we comply within 30 days. In the February 2016 Letter, the FDA also expressed its belief that we should submit a new pre-market notification for our ReWalk device stemming from the FDA's review of what it considered to be changes to the device.
>
> We held several discussions with the FDA, including an in-person meeting in March 2016, which based on our understanding of the conclusions reached by the FDA, resulted in the FDA narrowing its request for a new pre-market notification to an abbreviated, special application (the "special 510(k)"). This special 510(k) relates only to a computer included with the ReWalk device and is subject to an approximate 30-day review period, rather than the standard 90-day review period for pre-market applications. In late March 2016, the FDA confirmed that, based on these resolutions, we could continue to market our ReWalk device as long as we submit the special 510(k) and initiate the post-market study by June 1, 2016. Our special 510(k) submission was received by the FDA on April 11, 2016, at which time the FDA commenced its review of the special 510(k). Additionally, we have submitted a protocol for the post-market surveillance study that was approved by the FDA on May 5, 2016 and that we are required to commence within 30 days after that date. We expect to initiate our post-market surveillance study by the end of May 2016. The FDA also confirmed that, based on the public health significance of the ReWalk device, it did not view regulatory action against us for the late start in or deficient protocol for the post-market study as a priority for the agency, and

> that it expected to reassess the issues surrounding the pre-market notification and post-market study in June 2016. We have met all deadlines for submission of responses and have communicated regularly with the FDA after receiving each of the September 2015 Letter and the February 2016 Letter.
>
> We expect we will be able to adhere fully to the FDA's timeline and to respond promptly to the FDA's requests based on significant additions in staffing aimed at addressing a need for greater internal clinical and regulatory resources. However, if we are unable to satisfy this timing or if the results of our post-market clinical study are not as favorable as we expect, the FDA may issue additional warning letters to us, may impose limitations on the labelling of our device or may limit us to marketing a previous version of the ReWalk device in the United States. We derived 65% of our revenues in 2015 from sales of the ReWalk device in the United States and, if we are required to market a previous version of 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.

ReWalk Form 10-Q for the quarter ended March 31, 2016, filed May 10, 2016, at 38 (emphasis added).

59. Acknowledging its previous unpreparedness and inability to comply with the FDA postmarket surveillance study protocol, the Company disclosed that it will finally attempt to comply with the FDA requirements due to "significant additions in staffing aimed at … internal clinical and regulatory resources."

60. The foregoing demonstrates that at the time of its IPO, ReWalk was: (i) not prepared or not able to comply with the FDA's 522 Order that the Company conduct postmarket surveillance; (ii) not prepared or not able to provide adequate details to the FDA concerning the Company's postmarket surveillance study; and (iii) not prepared or not able to undertake an adequate postmarket surveillance study.

61. Because compliance with FDA regulations and mandates was required for the Company to continue to market and sell its ReWork device, the facts regarding the Company's ability to comply with the FDA's "special controls" was of the utmost importance should have been disclosed in the Registration Statement and Prospectus. Failure to disclose ReWalk's inability to

comply with government regulations was a material omission that rendered the Registration Statement and Prospectus false and misleading.

62. At the very least, ReWalk should have disclosed in the Registration Statement and Prospectus that its own internal clinical and regulatory resources were insufficient or inadequate to allow the Company to comply with the FDA's postmarket surveillance requirements. The Company should have disclosed in the Registration Statement that it intended to employ or retain a skilled staff to enable ReWalk to plan, undertake and timely complete an adequate postmarket surveillance study. This was a material omission that went to the heart of ReWalk's business and financial wellbeing. The FDA had warned ReWalk that failure to complete a postmarket surveillance study on time would result in ReWalk misbranding its product. ReWalk's continued failure to comply with the postmarket surveillance requirements affected ReWalk's ability to increase revenues, and impeded ReWalk's ability to persuade third-party payors, like Medicare and private pay insurers, that the ReWalk Personal model improved patient health and strength, thus meriting insurance coverage or reimbursement.

63. The Company's failure to comply with the FDA postmarket surveillance obligations compromised its ability to ensure that third parties would pay or provide reimbursements for the ReWalk products because a lack of clinical data puts insurance reimbursements in question. The absence of such data jeopardizes insurance coverage. This additional risk-created solely by ReWalk's failure to comply with the 522 Order-was also not disclosed. Because federal agencies – through CMS, Medicare, Medicaid, Veterans Affairs, etc. – represent a substantial number of third parties that would pay or reimburse the Company for ReWalk's products, the failure of ReWalk to comply with the FDA 522 Order directly jeopardizes those agencies' willingness to compensate users for ReWalk's products.

64. Once the FDA publicly disclosed the Warning Letter on or about February 25, 2016, the market price of ReWalk stock fell from $11.65 (the closing price on February 24, 2016) to $9.07 (the closing price on March 1, 2016), a difference of $2.58 per share or a drop of over 22%. Between March 1, 2016 and September 1, 2016, the price of ReWalk stock continued to spiral downward, eventually reaching as low as $5.70 on September 1, 2016, a drop of approximately $5.90 per share, or over 50% since late February 2016.

CLASS ACTION ALLEGATIONS

65. Plaintiffs bring this action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class of persons or entities who purchased or acquired ReWalk common stock pursuant to, or traceable to, the Registration Statement and Prospectus issued in connection with the Company's September 12, 2014 IPO (the "**Class**"). Excluded from the Class are Defendants, its/his/their directors, officers, employees, parents, affiliates and subsidiaries, successors, agents, legal representatives, heirs and assigns, and any persons controlled by any excluded person.

66. The members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown at this time and can only be ascertained through appropriate discovery, Plaintiffs believe that there are hundreds of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by ReWalk or its transfer agent or and may be notified of the pendency of this action by mail, using the form of notice customarily used in securities class action.

67. Plaintiffs' claims are typical of the claims of the Class because Plaintiffs and the Class members' damages arise from and were by the same omissions and misleading statements made by Defendants.

68. Plaintiffs will adequately protect the interest of the members of the Class and have retained counsel competent and experienced in class and securities litigation.

69. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the lass are:

a) Whether the Defendants violated the Securities Act of 1933;

b) Whether the Registration Statement and Prospectus omitted or misrepresented material facts about the business, operation and prospects of ReWalk; and

c) The extent of the damages sustained by Plaintiffs and the members of the Class and the appropriate measure of damages.

70. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy. Because of the size of the individual Class members' claims few, if any, Class members could afford to seek legal redress individually for the wrongs complained of herein.

THE INAPPLICABILITY OF THE STATUTORY SAFE HARBOR AND BESPEAKS CAUTION DOCTRINE

71. The statutory safe harbor and/or bespeaks caution doctrine applicable to forward-looking statements under certain do not apply to any of the false or misleading statements or material omissions pleaded with respect to the Securities Act.

72. Section 27(A) of the Securities Act of 1933 provides that the statutory safe harbor "shall not apply to a forward-looking statement that is made in connection with an initial public offering." 15 U.S.C. §77z-2(b)(2)(D).

73. None of the misstatements complained of herein were forward-looking statements, but were misstatements concerning current facts and conditions existing at the time the statements were made.

74. To the extent any statements may be construed as forward-looking, those statements were not accompanied by meaningful cautionary language identifying important facts that could cause actual results to differ materially from those in the statements.

CAUSES OF ACTION

COUNT ONE

For Violations of Section 11 of the Securities Act of 1933
(Against All Defendants)

75. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein. Plaintiffs, however, expressly excludes and disclaims any allegation that could be construed as alleging fraud or intentional or reckless misconduct, as this Count is based solely on claims of strict liability and/or negligence under Section 11 of the Securities Act, 15 U.S. C. § 77k, on behalf of the Class, against all Defendants.

76. The Registration Statement issued in connection with ReWalk's IPO was materially false and misleading, contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading, and omitted to state material facts required to be stated therein.

77. ReWalk is the registrant and, as such, is strictly liable to Plaintiffs and the Class for the misstatements and omissions contained or omitted from the Registration Statement.

78. None of the other Defendants named herein made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Registration Statement were true and without omissions of any material facts and were not misleading.

79. The Individual Defendants were responsible for the contents and dissemination of the Registration Statement. Each of the Individual Defendants signed or authorized the signing of the Registration Statement.

80. By reason of the conduct herein alleged, each Defendant violated, and/or controlled a person who violated, Section 11 of the Securities Act.

81. Plaintiffs acquired ReWalk pursuant to or traceable to the Registration Statement.

82. Plaintiffs and the Class have sustained damages. The value of ReWalk common stock has declined substantially subsequent to and due to Defendants' conduct.

83. At the time of Plaintiffs' purchases of ReWalk common stock, Plaintiffs and other members of the Class were without knowledge of the facts concerning the wrongful conduct alleged herein and could not have reasonably discovered those facts prior to the disclosures described herein. Less than one year has elapsed from the time that Plaintiffs commenced this action and discovered or reasonably could have discovered the facts upon which this Complaint is based. Less than three years has elapsed between the time that the securities upon which this Count is brought were offered to the public and the time Plaintiffs commenced this action.

COUNT TWO

For Violation of Section 12(a)(2) of the Securities Act of 1933
(Against All Defendants)

84. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein. For purposes of this Count, however, Plaintiffs expressly excludes and disclaims any allegation that could be construed as alleging fraud or intentional or reckless misconduct, as this Count it based solely on claims of strict liability and/or negligence under Section 12(a)(2) of the Securities Act, 15 U.S.C. §77l, on behalf of the Class, against all Defendants.

85. By means of the defective Prospectus, ReWalk, the Individual Defendants and the Underwriter Defendants promoted and sold ReWalk stock to Plaintiffs and other members of the Class.

86. The Prospectus contained untrue statements of material fact, or concealed or failed to disclose material facts, as detailed above. Defendants owed Plaintiffs and the other members of the Class who purchased ReWalk common stock pursuant to the Prospectus the duty to make a reasonable and diligent investigation of the statements contained in the Prospectus to ensure that such statements were true and that there was no omission to state a material fact required to be stated in order to make the statements contained therein not misleading. Defendants, in the exercise of reasonable care, should have known of the misstatements and omissions contained in the Prospectus as set forth above.

87. Plaintiffs did not know, nor in the exercise of reasonable diligence could have known, of the false statements and omissions contained in the Prospectus at the time Plaintiffs acquired ReWalk common stock.

88. By reason of the conduct alleged herein, Defendants violated Section 12(a)(2) of the Securities Act. As a direct and proximate result of such violations, Plaintiffs and the other members of the Class who purchased ReWalk common stock pursuant to the Prospectus sustained substantial damages in connection with their purchases of the stock. Accordingly, Plaintiffs and the other members of the Class who hold the common stock issued pursuant to the Prospectus have the right to rescind and recover the consideration paid for their shares, and hereby tender their common stock to the Defendants.

89. Class members who have sold their common stock seek damages to the extent permitted by law.

COUNT THREE
For Violation of Section 15 of the Securities Act of 1933
(Against the Individual Defendants)

90. Plaintiffs repeat and reallege each and every allegation contained above. For purposes of this Section 15 claim, however, Plaintiffs expressly excludes and disclaims any allegation that could be construed as alleging fraud or intentional or reckless misconduct, as this Count is based solely on claims of strict liability and/or negligence under Section 15 of the Securities Act of 1933, 15 U.S.C. §77k.

91. Each of the Individual Defendants was a control person of ReWalk by virtue of his position as a director and/or senior officer of ReWalk.

92. Each of the Individual Defendants was a culpable participant in the violations of Sections 11 and 12 of the Securities Act alleged in Counts One and Two above, based on his having signed or authorized the signing of the Registration Statement and filing the Prospectus, and having otherwise participated in the process that allowed the IPO to be successfully completed.

WHEREFORE, Plaintiffs pray for relief and judgment as follows:

A. Declaring that this action is a proper class action, designating Plaintiffs as Lead Plaintiffs and certifying Plaintiffs as a class representatives under Rule 23 of the Federal Rules of Civil Procedure and Plaintiffs' counsel as Lead Counsel;

B. Awarding Plaintiffs and the Class damages and other remedies as set forth in the Securities Act of 1933 in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and;

D. Granting such other and further relief in Plaintiffs' as may be just and proper.

JURY TRIAL DEMANDED

Plaintiffs demand a trial by jury.

Dated: January 31, 2017

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