UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

WANG YAN, individually and on behalf of all other similarly situated parties, Plaintiff, v. REWALK ROBOTICS LTD., LARRY JASINSKI, KEVIN HERSHBERGER, AMI KRAFT, AMIT GOFFER, JEFF DYKAN, HADAR RON, ASAF SHINAR, WAYNE B. WEISMAN,YASUSHI ICHIKI, ARYEH DAN, GLENN MUIR, BARCLAYS CAPITAL INC., JEFFERIES, LLC, and CANACCORD GENUITY, INC., Defendants.	Civ. A. No. 1:17-cv-10169-FDS CLASS ACTION Hon. F. DENNIS SAYLOR, IV **CONSOLIDATED AMENDED COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS**

CONSOLIDATED AMENDED COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS

Lead Plaintiff Wang Yan ("Lead Plaintiff"), individually and on behalf of all other persons similarly situated, by his undersigned attorneys, for his complaint against Defendants (defined below), alleges the following based upon personal knowledge as to himself and his own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through his attorneys, which included, among other things, a review of the Defendants' public documents, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by, and regarding, ReWalk Robotics Ltd. ("ReWalk" or the "Company"), analysts' reports and advisories about the Company, interviews with confidential witnesses, and information readily obtainable on the Internet. Lead Plaintiff believes 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 class action on behalf of a "Class" consisting of all persons and entities that purchased securities of ReWalk during the period from September 12, 2014 through February 29, 2016, both dates inclusive (the "Exchange Class Period"), as well as all persons and entities that purchased ReWalk common stock pursuant or traceable to ReWalk's Initial Public Offering ("IPO") on September 12, 2014 (the "Securities Class Period"). Lead Plaintiff seeks to pursue remedies against ReWalk and certain of its officers and directors, as well as certain of the IPO underwriters, under the Securities Exchange Act of 1934 (the "Exchange Act") and/or the Securities Act of 1933 (the "Securities Act"). Excluded from the Class are Defendants herein, the officers and directors of the Company during the relevant Class periods, as well as members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

2. ReWalk is a development stage medical device company that designs and develops exoskeletons, *i.e.*, devices intended to assist individuals with spinal cord injuries, including paraplegia, to walk. The Company currently manufactures two devices: ReWalk Personal (for everyday uses) and ReWalk Rehabilitation (for use in a rehabilitation facility to provide device users with training exercise and physical therapy).[1]

3. In June 2013, the Company submitted a petition for "de novo" classification of the ReWalk device to the United States Food & Drug Administration ("FDA"), which would allow ReWalk to market its devices subject to certain conditions mandated by the FDA.

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[1] ReWalk was previously known as Argo Medical Technologies, Inc. On or about June 2014, Argo was rebranded as ReWalk Robotics Ltd. Accordingly, documents that reference Argo during the Class periods should be considered directed to ReWalk.

4. On June 26, 2014, the FDA authorized the marketing of ReWalk devices under the "de novo" classification, but further ordered the Company to conduct a post-market surveillance study of the ReWalk device. The FDA issued the June 26, 2014 order mandating the post-market surveillance "**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**. In addition, **an individual assisting the user could be placed at risk of harm from a potential fall.**" *See FDA's Warning Letter to Argo Medical Technologies Inc.*, dated September 30, 2015 (bold added) (hereinafter, the "Warning Letter").[2]

5. Less than three months after receiving the order from the FDA specifically identifying the reasonable likelihood of serious injury or death "due to the device's failure to prevent a fall," ReWalk completed its IPO on September 12, 2014, selling 3,000,000 shares of common stock pursuant to a Registration Statement. *See* Form F-1/A filed with the SEC on August 26, 2016 at 1 (the "Registration Statement").[3]

6. The Registration Statement repeatedly touted the ReWalk device as a "breakthrough product" backed by "compelling clinical data" generated in "rigorous trials," committed the Company to continue clinical studies to "demonstrate the functionality and utilization" of the ReWalk device to prove its health and economic benefits, and boasted about the Company's "robust research and development program," but omitted to disclose material

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[2] https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm487328.htm.

[3] The Form F-1/A filed on August 26, 2014 is identified as Amendment No. 3 to ReWalk's Registration Statement, and is the last full version of the Registration Statement filed with the SEC before ReWalk's IPO. As used herein, the capitalized term "Registration Statement" refers to the August 26, 2014 F-1/A.

information about the risks raised by the FDA regarding the devices' safety, as well as the risks to approval of the product. Indeed, the Registration Statement failed to disclose the reasons the FDA required the post-market surveillance study, which would have advised investors of the nature and extent of the risks the product posed for more than the limited approval of the "de novo" status. In sum, Defendants failed to disclose that the FDA specifically determined that a post-market surveillance study was required "**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, spinal cord injury, and fractures to the user**," and that "**an individual assisting the user could be placed at risk of harm from a potential fall**."

7. Within weeks of the IPO, on September 29, 2014, the FDA informed the Company in writing that its proposed plan synopsis of the post-market surveillance study was deficient and lacked the required information to complete the agency's review, and ordered a complete response within 30 days.

8. Not having received the complete response mandated in the September 29, 2014 letter, the FDA notified the Company on November 5, 2014 that its response was overdue. The Company responded the next day with another post-market surveillance plan that was subsequently rejected by the FDA in a letter dated February 13, 2015 because the plan lacked information to complete the review, as well as other deficiencies. Once again, the Company was given 30 days to file a complete response to the FDA.

9. And, once again, the Company failed to comply within the 30 day period for filing the complete response letter, and on March 16, 2015, the FDA notified the Company "via email" that its response was overdue and inquired when the Company would provide its

response. Four days later, the Company responded that it would submit a response by April 15, 2015. Once again, the Company failed to submit a response on time, as it had stated it would.

10. Not having received the response on time, the FDA again contacted the Company on April 16, 2015, requesting an update on the overdue response to the FDA's February 13, 2015 letter. Over a month later, on May 22, 2015, the Company responded by asking the FDA to discuss what was deemed "one issue" that the Company was not in a position to respond to. The FDA made multiple attempts via mail and telephone during mid-July 2015 to coordinate a teleconference with the Company, to no avail. *See* Warning Letter at 2.

11. During the interim, on June 24, 2015, the FDA notified the Company that the Company's study was "out of compliance." *See id.*

12. On July 29, 2015, the Company sent the FDA an email stating that the Company would have proposed dates for the teleconference by August 3, 2015. But, on August 10, 2015, the Company told the FDA "for the first time that it was proposing substantial changes to the methods and study plan," and asked for "an in-person meeting with the FDA if the Agency had any questions regarding these major proposed changes." *See id.*

13. On September 5, 2015, the FDA "provided feedback" to the Company and told the Company to submit a revised post-surveillance study plan addressing both the "feedback" and the deficiencies identified in the FDA's February 14, 2015 letter "as soon as possible." As of September 30, 2015, when the FDA issued the Warning Letter to ReWalk, it had not received any response to its September 5, 2015 communication providing feedback to the Company. *See id.*

14. Accordingly, on September 30, 2015, the FDA sent the Company its Warning Letter, noting that the Company did not submit a revised plan as requested in the September 5,

2015 communication, and that "there has been a substantial lack of progress towards commencement of the [post-surveillance study]" as required by statue. The Warning Letter explained to the Company that, pursuant to statue, the post-surveillance study was required to be approved within 15 months after the day the order directing the study was issued, and that the 15 month statutory time period had closed on September 28, 2015. *See id.*

15. The Warning Letter specifically itemized the Company's failures in complying with the statute with respect to the post-surveillance study plan, and concluded, thereby, that the Company committed a prohibited act under the FD&C Act by failing to comply with the requirements for the post-market surveillance study plan. As such, the ReWalk device was deemed "misbranded" under the FD&C Act. *See id.*

16. Throughout the Exchange Act Period, ReWalk and the Individual Defendants failed to disclose to investors the material facts regarding the specific compliance failures noted above, as well as the specific risk to authorization given the failure of the Company to comply with FDA regulations, and the risks resulting from Defendants' dilatory actions. Instead, rather than disclosing the truth faced by the Company, including the problems and risks specifically noted by the FDA throughout the relevant period, Defendants misleadingly touted self-serving anecdotes and studies, and claims to "innovative" research and development program to artificially inflate and/or maintain the price of ReWalk common stock and attract investors.

17. Despite the serious consequences identified in the FDA's Warning Letter, and a growing concern internally among senior executives regarding the Company's failure to initiate a post-market surveillance study, the Company continued to submit deficient plans for the study to the FDA in response to the Warning Letter. In February 2016, the FDA again warned the

Company that then current proposed plan it had submitted for the post-market surveillance study was inadequate.

18. On March 1, 2016, the text of the September 30, 2015 Warning Letter was published on the FDA's website.

19. Following the publication of the Warning Letter, the price of ReWalk common stock price fell by nearly 13%, a statistically significant amount, to close at $9.07 from its previous day closing price of $10.48 on heavy trading volume. The price continued to decline over the next two trading days until it bottomed out at $8.53 per share. In total, ReWalk's stock price has plummeted over 88% since the IPO.

20. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in market value of the Company's securities, upon the disclosures thereof, Lead Plaintiff and other members of the Class have suffered significant damages.

JURISDICTION AND VENUE

21. The claims asserted herein arise under Sections 11 and 15 of the Securities Act (15 U.S.C. §§ 77k, 77l, and 77o), and under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)), and SEC Rule 10b-5 promulgated thereunder (17 C.F.R. § 240.10b-5).

22. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1337, Section 27 of the Exchange Act (15 U.S.C. § 78aa), and Section 22 of the Securities Act (15 U.S.C. § 77v).

23. Venue is proper in this District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa), Section 22 of the Securities Act (15 U.S.C. § 77v), and 28 U.S.C. § 1391(b), given that ReWalk's principal place of business in the United States is located in Marlborough,

Massachusetts, and a significant portion of the Defendants' actions, and the subsequent damages, took place within this District.

24. In connection with the acts, conduct and other wrongs alleged in this Amended Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of a national securities exchange.

PARTIES

25. Lead Plaintiff Wang Yan, as set forth in his previously-filed Certification (Docket No. 7-2), purchased ReWalk securities pursuant and/or traceable to the Registration Statement during the relevant Class Periods, and suffered damages as a result of the federal securities laws violations alleged herein.

26. Defendant ReWalk is an Israeli corporation formerly known Argo Medical Technologies Ltd. ReWalk's principal executive offices are located at 3 Hatnufa Street, Floor 6, Yokneam Ilit, Israel, and the Company's headquarters in the United States are located at 200 Donald Lynch Boulevard, Marlborough, Massachusetts. ReWalk's shares trade on the NASDAQ national market system under the ticker symbol "RWLK."

27. Defendant Larry Jasinski ("Jasinski") is, and was at the time of the IPO, ReWalk's CEO and a member of its Board of Directors. Jasinski signed the Registration Statement, signed ReWalk's annual reports on Form 20-F and 10-K, and signed the certifications attached to those reports pursuant to the Sarbanes-Oxley Act of 2002.

28. Defendant Kevin Hershberger ("Hershberger") was appointed as ReWalk's Chief Financial Officer ("CFO") in January 2015. Hershberger signed ReWalk's annual reports on

Form 20-F and 10-K, and signed the certifications attached to those reports pursuant to the Sarbanes-Oxley Act of 2002.

29. Defendant Ami Kraft ("Kraft") was ReWalk's CFO at the time of the IPO. Kraft signed the Registration Statement. Kraft has served as the general manager of ReWalk's Israel headquarters since January 2015. He also served as Senior Vice President of the Company from July 2015 until August 2016 when he was appointed as ReWalk's President.

30. Defendant Amit Goffer ("Goffer") is the founder of ReWalk and was, at the time of the IPO, a Director of ReWalk, the Company's President and Chief Technical Officer. Goffer served as the Company's CEO from 2001 until 2012. He signed the Registration Statement. Goffer retired from ReWalk and resigned from the Board on November 18, 2015.

31. Defendant Hadar Ron ("Ron") was, at the time of the IPO, a Director of Rewalk. Ron signed the Registration Statement. She resigned from the Board in April 2015.

32. Defendant Jeff Dykan ("Dykan") is, and was at the time of the IPO, the Chairman of ReWalk's Board of Directors. Dykan signed the Registration Statement.

33. Defendant Asaf Shinar ("Shinar") was, at the time of the IPO, a Director of ReWalk. Shinar signed the Registration Statement. He resigned from the Board in February 2015.

34. Defendant Wayne B. Weisman ("Weisman") is, and was at the time of the IPO, a Director of ReWalk. Weisman signed the Registration Statement.

35. Defendant Yasushi Ichiki ("Ichiki") is, and was at the time of the IPO, a Director of ReWalk. Ichiki signed the Registration Statement.

36. Defendant Glenn Muir ("Muir") is, and was at the time of the IPO, a Director of ReWalk. Muir signed the Registration Statement.

37. Defendant Aryeh Dan ("Dan") is, and was at the time of the IPO, a Director of ReWalk. Dan signed the Registration Statement.

38. Defendant Barclays Capital Inc. ("Barclays") was identified in the Registration Statement as an underwriter and a Joint-Book-Running manager of the IPO. Barclays maintains an office in this District at 125 High Street, 16th Floor, Boston, Massachusetts 02110.

39. Defendant Jefferies LLC ("Jefferies") was identified in the Registration Statement as an underwriter and a Joint-Book-Running manager of the IPO. Jefferies maintains an office in this District at 125 High Street, Suite 2501, Boston, Massachusetts 02110.

40. Defendant Canaccord Genuity Inc. ("Canaccord") was identified in the Registration Statement as an underwriter and co-manager of the offering. Canaccord maintains an office in this District at 99 High Street, Suite 1200, Boston, Massachusetts 02110.

41. Defendants Jasinski, Hershberger, Kraft, Goffer, Dykan, Ron, Shinar, Weisman, Ichiki, Dan and Muir are sometimes referred to herein, collectively, as the "Individual Defendants."

42. Defendants Barclays, Jefferies and Canaccord are sometimes referred to herein, collectively, as the "Underwriter Defendants."

43. All of the defendants referenced above are referred to collectively herein as "Defendants."

SUBSTANTIVE ALLEGATIONS

Background

44. ReWalk is a medical device company that designs and develops exoskeletons that aspire to allow individuals in wheelchairs to stand upright and walk again. The Company claims that its exoskeletons are meant for individuals with spinal cord injuries, including

paraplegia, that cause complete or partial paralysis of the legs. The exoskeleton is powered by a battery, integrated at the joints, and contains sensors and a computer-based control system that allow paralyzed individuals to move their knees and hips. According to the Company, the exoskeleton "controls movement using subtle shifts in the user's center of gravity. A forward tilt of the upper body is sensed by the system, which initiates the first step. Repeated body shifting generates a sequence of steps which allows for natural gait with functional walking speed." *See* ReWalk's 2016 Annual Report, filed on February 29, 2016.

45. ReWalk was founded in Israel by Defendant Goffer over a decade ago. On September 12, 2014, the Company went public in the United States. While the Company maintains a facility in Israel, ReWalk's principal activities take place in Marlborough, Massachusetts. Defendants Jasinski and Hershberger reside in Marlborough, Massachusetts, and they conduct substantial business on behalf of the Company from its headquarters in the United States.

46. Currently, the Company offers two different devices: ReWalk Personal and ReWalk Rehabilitation. The ReWalk Personal is meant to be used by individuals in their home or communities, and the device is custom fit for each individual user. The ReWalk Rehabilitation is meant to be used in a rehabilitation facility to provide device users with training exercise and physical therapy. In July 2015, the Company launched the ReWalk Personal 6.0, and touted that the new device provided a faster walking experience that was superior to any prior design of the ReWalk, and unparalleled in terms of efficacy when compared to any other device in clinical trials around the world.

47. In June 2013, the Company submitted a petition for "de novo" classification of the ReWalk to the FDA. A "de novo" classification is a mechanism that allows a manufacturer

to market a device that is low to moderate risk, but not substantially equivalent to a currently marketed predicate device.

48. In June 2014, the FDA exercised its enforcement discretion to grant ReWalk's petition for "de novo" classification and classified the ReWalk as a Class II device subject to special controls. Class II devices are those for which general controls alone cannot provide any assurance of safety or efficacy. As a Class II device, the ReWalk is required to comply with special controls, including compliance with medical device consensus standards, performance of a post-market surveillance clinical study that demonstrates safety and efficacy, nonclinical performance testing of the system's function and durability, a training program, and labeling related to device use and user training.

49. On June 26, 2014, the FDA authorized the Company to market the ReWalk as a Class II device subject to special controls. Indeed, the FDA issued an order pursuant to Section 522 of the FD&C Act directing the Company to conduct post-market surveillance of the ReWalk device. The FDA specifically determined that a post-market surveillance study was required 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. In addition, an individual assisting the user could be placed at risk of harm from a potential fall." *See FDA's Warning Letter to Argo Medical Technologies Inc.*, sent on September 30, 2015.

50. Section 522 of the FD&C Act permits the FDA to require manufacturers to conduct post-market surveillance studies of certain class II and III devices. *See* 21 U.S.C.S. § 3601.

51. Under Section 522, the FDA may issue an order that requires manufacturers to provide a post-market surveillance study if (1) the potential failure of the device would be reasonably likely to have serious adverse health consequences, (2) the device is intended to be implanted in the human body for more than one year, (3) the device is a life-sustaining or life-supporting device used outside a device user facility or (4) the device is expected to be used in certain pediatric populations. *Id.*

52. The FDA may issue a post-market surveillance order at the time the device is approved or cleared or at any time thereafter. *Id.* Section 522 requires device manufacturers to start post-market surveillance no more than 15 months after the day the FDA issues its order. *Id.*

53. Section 522(b)(1) of the FD&C Act allows the FDA to order that a manufacturer conduct a post-market study for up to 36 months unless the manufacturer and the FDA agree to a different timetable.

54. The FDA can order a post-market surveillance study for numerous public health related reasons, including but not limited to (1) "understand the nature, severity or frequency of suspected problems reported in adverse event reports or in the published scientific literature," (2) "obtain more information on device performance associated with real-world clinical practice," (3) "address the long term or infrequent safety and effectiveness issues for implantable and other devices for which the premarket testing provided more limited information," and (4) "to better define the association between problems and devices when unexpected or unexplained serious adverse events occur after a device is marketed, if there is a change in the nature of serious adverse events (e.g., severity), or if there is an increase in the

frequency of serious adverse events." *See Guidance for Industry and FDA Staff, Postmarket Surveillance Under Section 522 of the FD&C Act*, Issued on May 16, 2016.

55. A 522 order issued by the FDA typically identifies the public health questions to be addressed, the reasons for the issuance of the order, and the FDA's recommendations regarding the design of the post-market surveillance study. *Id.*

56. After a Section 522 order is issued by the FDA, a device manufacturer must submit its post-market surveillance plan within 30 days of its receipt of the order, and the device manufacturer must commence a post-market surveillance study no later than 15 months after the 522 order is issued. *Id.*

57. A device manufacturer's failure to meet the requirements of a Section 522 order, including the failure to commence a post-market surveillance study within 15 months of the issuance of the 522 order, is considered a prohibited acted under the FD&C Act that renders the medical device misbranded. *Id.*

58. A determination that a medical device is misbranded may lead to enforcement actions by the FDA, including seizure of the medical device, injunction, prosecution and/or civil money penalties. *Id.*

59. On July 31, 2014, ReWalk submitted a proposed post-market surveillance study plan synopsis to the FDA. On September 29, 2014, the FDA reviewed ReWalk's proposed plan synopsis and informed the Company that the proposal was deficient and lacked the required information needed to complete the agency's review. The FDA's September 29, 2014 letter further required ReWalk to submit a complete response within 30 days, but the Company failed to comply with the FDA's request within the required time period.

60. On November 5, 2014, the FDA notified the Company that the requested response was overdue. On November 6, 2014, the Company submitted a revised post-market surveillance study plan. On February 13, 2015, the FDA informed ReWalk that the revised post-market surveillance plan was also deficient and failed to include the information needed to complete the agency's review. The FDA's February 13, 2015 letter enumerated specific deficiencies that the agency identified in ReWalk's proposed plan synopsis, and instructed the Company to submit a complete response within 30 days. ReWalk again failed to respond to the FDA within the required 30 day deadline for a timely response.

61. On March 16, 2015, the FDA sent an email to John V. Hamilton ("Hamilton"), the Vice President of Regulatory and Clinical at ReWalk, informing Hamilton that ReWalk's response to the FDA's February 13, 2015 letter was overdue, and the FDA asked when the Company planned to provide an adequate response. On March 30, 2015, Hamilton responded via email and promised that the Company would respond on April 15, 2015. However, the FDA did not receive any response on April 15, 2015.

62. On April 16, 2015, the FDA again requested the Company to provide an update on the overdue response regarding the plan synopsis for the post-market surveillance study. On May 22, 2015, ReWalk finally communicated with the FDA, and stated that the Company was prepared to respond on all matters related to the FDA's inquiry except for one issue, and requested the FDA staff to discuss that issue before the Company submitted a formal response.

63. Between June 12, 2015 and July 28, 2015, the FDA attempted to arrange a conference call with ReWalk to discuss the issue ReWalk had identified, but ReWalk failed to confer with the FDA. On June 24, 2015, the FDA sent an email to Hamilton, and informed the

Company that the agency considered ReWalk's post-market surveillance study plan to be out of compliance.

64. On July 29, 2015, Hamilton sent the FDA an email, in which the Company promised to propose dates for a teleconference by the week of August 3, 2015.

65. On August 10, 2015, however, the Company changed course and notified the FDA that substantial changes would be made to the methods and plan synopsis for the post-market surveillance study, and requested an in-person meeting with the FDA to discuss any questions the agency may have regarding the substantially changed methods and plan synopsis for the post-market surveillance study.

66. On September 2, 2015, after reviewing the Company's proposed changes to the post-market surveillance study, the FDA identified additional deficiencies with the Company's new proposal, and recommended that the Company submit a revised post-market surveillance study plan, and again implored the Company to address the problems identified in the FDA's February 13, 2015 letter. The Company again ignored the FDA's requests.

67. On September 30, 2015, the FDA sent the Company a warning letter describing the history of dereliction identified in paragraphs 59 through 66. The warning letter also stated that:

- The 15-month time frame from which the Company's post-market surveillance plan must be approved, and the study must be commenced elapsed on September 28, 2015.
- The Company's failure to submit a revised post-market surveillance study plan that addressed the deficiencies described in the FDA's September 29, 2014 and February 13, 2015 letters; failure to design a post-market surveillance study plan

that addressed the issues identified by the FDA; failure to have an approved post-market surveillance study plan; and failure to commence surveillance by September 28, 2015 constituted violations of Section 522 of the FD&C Act and the ReWalk device was considered misbranded under Section 502(t)(3) of the FD&C Act.

- The Company's failure to immediately rectify its Section 522 violations may result in regulatory actions by the FDA, including but not limited to seizure, injunction and/or civil money penalties.
- The FDA ordered the Company to respond within 15 days from the date the Company received the September 30, 2015 warning letter with a new proposal for post-market surveillance that addressed the deficiencies previously identified by the FDA, and to notify the FDA in writing regarding the specific steps taken to correct the Company's Section 522 violations.

68. ReWalk and the Individual Defendants failed to disclose to investors the material facts regarding the specific compliance failures noted above, as well as the specific risk to authorization given the failure of the Company to comply with FDA regulations, and the risks resulting from Defendants' dilatory actions. Instead, rather than disclosing the truth faced by the Company, including the problems and risks specifically noted by the FDA throughout the relevant period, Defendants misleadingly touted self-serving anecdotes and studies, and claims to "innovative" research and development program to artificially inflate and/or maintain the price of ReWalk common stock and attract investors. Indeed, the true facts regarding the ReWalk devices and their approval by the FDA were not known until March 1, 2016 when the Warning Letter appeared on the FDA website.

Confidential Witnesses

69. The problems identified by the FDA and risk to approval for the ReWalk devices was known by the Defendants, as well as discussed and known throughout the Company during the Class periods.

70. Confidential Witness 1 ("CW1") served as the Executive Assistant to Defendant Jasinski from April 2015 to December 2016. Prior to her role as the Executive Assistant to Jasinksi, CW1 served as the Executive Assistant to several CEOs at other companies and the President of a large University. CW1 described Jasinksi as micromanaging the day-to-day operations of the Company and involved himself in every single aspect of the business.

71. According to CW1, the Company had a culture of waiting until the last minute to complete important assignments and tasks, which was exacerbated by Jasinski's micromanagement style with respect to the completion of important projects.

72. As Jasinski's Executive Assistant, CW1 sat in on weekly meetings between Jasinski and his direct reports, and recalled a discussion regarding the FDA's September 30, 2015 Warning Letter within a week after the letter was received by the Company in September 2015. CW1 also knew that Defendant Hershberger was aware of the Warning Letter because he mentioned the letter to CW1.

73. CW1 recalled that Jasinski, Hershberger and other senior managers at ReWalk were concerned by the Warning Letter due to the dire consequences the Company could face for a continuous failure to rectify its Section 522 violations.

74. CW1 also confirmed that the Warning Letter was brought to the attention of ReWalk's Board of Directors. With respect to the inner workings of the Board itself, CW1

stated that Defendant Dykan, the Chairperson of ReWalk's Board of Directors was actively involved in the day-to-day management of the Company.

75. Confidential Witness 2 ("CW2") was a Clinical Training Manager at ReWalk Robotics from November 2015 to August 2016. CW2 reported directly to ReWalk's Worldwide Training Manager. As a Clinical Training Manager, CW2 trained physical therapists at hospitals and rehabilitation centers on how to use the ReWalk device. The physical therapists, in turn, trained patients at the hospitals and rehabilitation centers regarding how to use the ReWalk device.

76. CW2 recalled that Jasinski conducted a companywide teleconference in December 2015 to discuss ReWalk's plans to start a post-market surveillance study. According to CW2, while the Company and its senior management openly discussed that the FDA had required the Company to submit an adequate plan for a post-market surveillance study, and commence enrollment of that study within 15 months from the date the 522 Order was issued, ReWalk and the Individual Defendants showed no sense of urgency at all to even start the post-market surveillance study before February 2016.

77. In February 2016, the FDA again sent a letter to ReWalk, in which the agency citied deficiencies in the Company's then current proposed protocol for the mandatory post-market study required for the ReWalk device, and the FDA instructed ReWalk to submit a second premarket notification for the ReWalk Personal 6.0.

78. According to CW2, in February 2016, ReWalk also hosted a companywide meeting at its headquarters in Marlborough, Massachusetts, and the need to conduct a post-market surveillance study was discussed in detail at this meeting. After this meeting, CW2

noticed for the first time that there appeared to be some urgency at the Company to start post-market surveillance.

79. However, CW2 recalled that the Company's effort to conduct an adequate post-market surveillance study after February 2016 was stymied by a failure to recruit subjects for the study, and the fact that most insurance companies refused to reimburse users for the ReWalk device. Although CW2 had no experience in conducting clinical trials, the Worldwide Training Director at ReWalk requested CW2 to recruit subjects for the study because the Company was desperate to find enough subjects to enroll in the study for the results to be adequate and effective.

80. Confidential Witness 3 ("CW3") served as the Associate Director of Clinical Operations at ReWalk from February 15, 2016 to June 2, 2017. CW3 was based in ReWalk's headquarters in Marlborough, Massachusetts and reported directly to Hamilton, the Vice President of Regulatory and Clinical at ReWalk. After Hamilton stepped down from his position in the beginning of 2017, CW3 reported directly to Jasinski.

81. In February 2016, CW3 was specifically hired to oversee the development and execution of ReWalk's post-market surveillance study. CW3 stated that the executive committee and the Board of Directors knew that commencement of the post-market surveillance study was an urgent matter in light of the FDA's Warning Letter.

82. CW3 explained that, prior to the IPO, the Company hired Clinivation Inc. ("Clinivation"), a third party Contract Research Organization, to prepare documents for the post-market surveillance study plan and any forms required to be submitted to the FDA for approval of the study design. Immediately after CW3 joined the Company in February 2016, CW3 concluded that the work Clinivation provided to the Company was "quite garbage."

83. CW3 stated that he convinced Hamilton to terminate the Company's contract with Clinivation. CW3 opined that Hamilton did not understand that Clinivation provided subpar work as Hamilton had virtually no experience with clinical trials.

84. Like CW2, CW3 also confirmed that the Company's effort to conduct an adequate post-market surveillance study was stymied by a failure to recruit subjects for the study because most insurance companies refused to reimburse users for the ReWalk device.

MATERIAL MISSTATEMENTS AND OMISSIONS IN THE REGISTRATION STATEMENT

85. On September 12, 2014, Defendants sold 3,000,000 shares of common stock in its IPO to the Registration Statement. The Registration Statement omitted material facts necessary to make the statements made not misleading under the circumstances in which they were made.

86. For example, Defendants touted the following regarding ReWalk's allegedly "compelling clinical data":

> **Compelling Clinical Data.** We believe that ReWalk's clinical data differentiates us from our competitors. Clinical data published in established medical journals has demonstrated ReWalk's potential as a safe ambulatory device. We are not aware of any comparable clinical data generated in rigorous trials that has been published with respect to competing exoskeleton products. In addition, our interim analysis of an ongoing clinical study demonstrates improvements in secondary physical conditions, such as reduction in pain and spasticity and improvements in bowel and urinary tract function, body and bone composition, metabolism and physical fitness, as well as reduced hospitalizations and dependence on medications. We believe that continued results of this nature will greatly assist our ability to obtain regulatory clearances and third-party reimbursement.

87. The statements identified in paragraph 86 above were materially false and misleading when made because they omitted the following material information necessary to make them not misleading under the circumstances in which they were made: the FDA

specifically determined, in June 2014, that the Company was required to conduct a post-market surveillance study because the ReWalk device's failure to prevent a fall would be reasonably likely to cause serious injury or death to the user and place individuals assisting the user at the risk of harm from a potential fall.

88. The Registration Statement also made the following misleading statements regarding the Company's ability to further demonstrate the health and economic benefits of the ReWalk device:

> **Continue Clinical Studies to Further Demonstrate Health and Economic Benefits to Support Reimbursement.** We intend to continue to work with hospitals, rehabilitation centers, patient advocacy and support groups and individual users to generate additional data regarding functionality and that supports the health and economic benefits of ReWalk. We will continue to engage and fund researchers and organizations to conduct clinical studies to demonstrate the functionality and utilization of ReWalk and to highlight economic benefits of reductions in medical complications associated with spinal cord injury. We believe that this data will position us to pursue additional third-party reimbursement for our products.

89. The statements identified in paragraph 88 above were materially false and misleading when made because they omitted the following material information necessary to make them not misleading under the circumstances in which they were made: the FDA specifically determined, in June 2014, that the Company was required to conduct a post-market surveillance study because the ReWalk device's failure to prevent a fall would be reasonably likely to cause serious injury or death to the user and place individuals assisting the user at the risk of harm from a potential fall.

90. The Registration Statement misleadingly described the ReWalk as a "breakthrough product," touted the device's health benefits based on "published studies," which allegedly were not shown in studies for any competing product, and misled investors to believe

that ReWalk had the potential for secondary benefits based on "interim analysis of an ongoing clinical study" and the Company's experience working with health care practitioners:

> ReWalk is a breakthrough product that can fundamentally change the health and life experiences of users.
>
> *****
>
> Published clinical studies demonstrate ReWalk's ability to deliver a natural gait and functional walking speed, which has not been shown in studies for any competing exoskeleton. In addition, our interim analysis of an ongoing clinical study and our experience working with health care practitioners and ReWalk users suggests that ReWalk has the potential to provide secondary health benefits. These benefits include reducing pain and spasticity and improving bowel and urinary tract function, body and bone composition, metabolism and physical fitness, as well as reducing hospitalizations and dependence on medications. Because of these secondary medical benefits, we believe that ReWalk has the ability to reduce the lifetime healthcare costs of individuals with spinal cord injuries, making it economically attractive for individuals and third-party payors.

91. The statements identified in paragraph 90 above were materially false and misleading when made because the Company described the ReWalk device as a "breakthrough product" and touted the device's health and economic benefits, but omitted the following material information necessary to make the statements not misleading under the circumstances in which they were made: the FDA specifically determined, in June 2014, that the Company was required to conduct a post-market surveillance study because the ReWalk device's failure to prevent a fall would be reasonably likely to cause serious injury or death to the user and place individuals assisting the user at the risk of harm from a potential fall.

92. With respect to the post-market surveillance clinical study, the Company disclosed the following incomplete information that affirmatively led investors in the wrong direction:

> 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.
>
> *****
>
> As a manufacturer, we are subject to periodic scheduled or unscheduled inspections by the FDA. If the FDA believes we or any of our contract manufacturers are not in compliance with the quality system requirements, or other postmarket requirements, it has significant enforcement authority. Specifically, if the FDA determines that we failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:
>
> - warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
> - recalls, withdrawals, or administrative detention or seizure of our products;
> - operating restrictions or partial suspension or total shutdown of production;
> - refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;
> - refusal to grant export approvals for our products; or
> - criminal prosecution.
>
> Any such action by the FDA would have a material adverse effect on our business. In addition, these regulatory controls, as well as any changes in FDA policies, can affect the time and cost associated with the development, introduction and continued availability of new products. Where possible, we anticipate these factors in our product development processes.

93. The statements identified in paragraph 92 above were materially false and misleading when made because the Company stated that the FDA required it to conduct a post-market surveillance study that demonstrated the device's safety and effectiveness, but the Company omitted the following material information necessary to make the statements not misleading under the circumstances in which they were made: (a) the FDA specifically determined, in June 2014, that the Company was required to conduct a post-market surveillance study because the ReWalk device's failure to prevent a fall would be reasonably likely to cause

serious injury or death to the user and place individuals assisting the user at the risk of harm from a potential fall, and (b) without disclosing that the FDA specifically ordered the Company to commence post-market surveillance because the device was reasonably likely to cause serious injury or death, the Company's boilerplate recitation of potential adverse regulatory consequences was rendered meaningless.

94. In a similar fashion, the Registration Statement contained the following misleadingly incomplete information about the potential consequences of the Company's failure to comply with the FDA's rules and regulations, but withheld material information concerning the Company's then potential failure to comply with those rules and regulations and withheld information about the ReWalk's deficiencies:

> 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 certain special controls. The special controls established in the *de novo* order include compliance with medical device consensus standards; performance of a post market 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. 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.
>
> *****
>
> In addition, if we fail to comply with applicable regulatory requirements, it could result in fines, delays or suspensions of regulatory clearances, closure of manufacturing sites, seizures or recalls of products and damage to our reputation. 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. 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.

95. The statements identified in paragraph 95 were materially false and misleading when made because the Company stated that the FDA required it to conduct a post-market surveillance study that demonstrated the device's safety and effectiveness, but the Company omitted the following material information necessary to make the statements not misleading under the circumstances in which they were made: (a) the FDA specifically determined, in June 2014, that the Company was required to conduct a post-market surveillance study because the ReWalk device's failure to prevent a fall would be reasonably likely to cause serious injury or death to the user and place individuals assisting the user at the risk of harm from a potential fall, and (b) without disclosing that the FDA specifically ordered the Company to commence post-market surveillance because the device was reasonably likely to cause serious injury or death, the Company's boilerplate recitation of potential adverse regulatory consequences was rendered meaningless.

Additional Allegations Applicable Only To Exchange Act Claims

96. Lead Plaintiff makes the additional allegations contained in paragraphs 96 to 111 below with respect to his claims under Sections 10(b) and 20(a) of the Exchange Act only. Lead Plaintiff disclaims any reliance upon these allegations or incorporation of these allegations in his Securities Act claims.

97. ReWalk and the Individual Defendants (with the exception of Hershberger) are makers of the statements contained in the Registration Statement because ReWalk is the Issuer of the statements and each of the Individual Defendants (with the exception of Hershberger) signed his or her name to those statements, indicating that he or she was a maker thereof.

98. Additional aspects of the Defendants' conduct indicate that they made at least the most significant misrepresentations and omissions contained in the Registration Statement with either deliberate recklessness or with fraudulent intent. All of the Individual Defendants were intimately involved in the day-to-day management of the Company. Defendant Dykan, Chairperson of the Board, also was heavily involved in the day-to-day management of the Company. Defendant Goffer was the Company's founder, Chief Technical Officer and a member of the Board of Directors. Because the ReWalk devices were the products that constituted the core operations of the Company, it is inconceivable that these Defendants were not aware of the FDA's order in June 2014 which specifically determined that the Company was required to conduct a post-market surveillance study because the ReWalk device's failure to prevent a fall would be reasonably likely to cause serious injury or death to the user and place individuals assisting the user at the risk of harm from a potential fall.

99. After the IPO, Defendants ReWalk, Jasinski and Hershberger continued to recklessly mislead investors about the Company's failure to comply with FDA rules and regulations in earnings conference calls and SEC filings. For example, on February 12, 2015, ReWalk held a conference call to discuss Q4 2014 earnings, in which Jasinski made the following materially misleading statements:

> ReWalk is the most used, most studied exoskeleton technology of its kind. Our ReWalkers have done extraordinary things with the system including completing marathons. More importantly, it has become routine for many ReWalkers to use the system while performing their daily activities, such as washing dishes, cooking or in the workplace. ReWalkers also use the system when shopping, attending church, hosting a party by walking to the road to greet each visitor or even walking with their children while trick or treating on a Halloween. ReWalk is truly becoming a part of everyday life. ReWalk is more than walking, it is fundamentally changing the health and life experiences of individuals with spinal cord injury.

> Recently, a non-company-sponsored study was conducted at the University of Hull, England to study the effects of using the ReWalk device on a range of motion in lower limb joints in patients with spinal cord injuries between C3 and T12. Significant increases in range of motion for the hip and ankle joints were observed. This study was published in the International Journal of Physical Therapy and Rehabilitation in November 2014. This demonstrates successful use of the product in higher level injuries.
>
> In November, results from two independent clinical studies conducted by the James J. Peters VA Hospital were presented at a scientific session at AAPM&R. These demonstrated the medical benefits of using the ReWalk system. This study showed improvements in quality of life measurements for pain reduction, fatigue and improved sleep. Restoration of physiologic loading to the legs was also measured. Improvements in bowel function, seated balance and reduction in fat mass were documented.
>
> *****
>
> The second peer-reviewed publication from these studies was accepted for publication in the Journal of Rehabilitation Research and Development in December 2014. We anticipate additional publications from these studies that will complete the peer review process in the first half of this year. ReWalk is the only exoskeleton system that has these types of independently generated supporting data.

100. The statements identified in paragraph 99 above were materially false and misleading when made because they omitted the following material information necessary to make them not misleading under the circumstances in which they were made: (a) ReWalk repeatedly failed to respond to FDA requests regarding the post-market surveillance study, (b) ReWalk failed to submit a revised post-market surveillance study plan that addressed the deficiencies described in the FDA's September 29, 2014 letter, (c) ReWalk failed to design a post-market surveillance study plan that addressed the issues identified by the FDA, (d) ReWalk failed to have an approved post-market surveillance study plan, and (e) ReWalk failed to disclose the risks to approval from their dilatory responses and failure to comply with the FDA's Section 522 order.

101. On February 27, 2015, ReWalk filed an Annual Report on Form 20-F, which contained the signed SOX certification of Defendants Jasinski and Hershberger. This Annual Report contained the same materially misleading statements identified in paragraph 86 to 87, paragraph 88 to 89 and paragraphs 92 to 95. Notably, this Annual Report deliberately omitted any information about the Company's need to conduct a post-market surveillance study to test the device's safety and effectiveness in an urban terrain as described in the Registration Statement.

102. The statements identified in paragraph 101 above were materially false and misleading when made because they omitted the following material information necessary to make them not misleading under the circumstances in which they were made: (a) ReWalk repeatedly failed to respond to FDA requests regarding the post-market surveillance study, (b) ReWalk failed to submit a revised post-market surveillance study plan that addressed the deficiencies described in the FDA's September 29, 2014 and February 13, 2015 letters, (c) ReWalk failed to design a post-market surveillance study plan that addressed the issues identified by the FDA, (d) ReWalk failed to have an approved post-market surveillance study plan, and (e) ReWalk failed to disclose the risks to approval from their dilatory responses and failure to comply with the FDA's Section 522 order.

103. On May 7, 2015, ReWalk held a conference call to announce Q1 2015 earnings, in which Jasinski made the following materially misleading statements:

> In the May edition of Topics in Spinal Cord Rehabilitation, we had the sixth major peer reviewed publication on the ReWalk. It was examining walking velocity and the level of assistance with use of a ReWalk exoskeleton. The study concluded that the ReWalk is safe for in-hospital ambulation, and that for outdoor activity related community ambulation, the majority of users reached a speed of 0.40 meters per second or greater. We continue to learn about the daily impact of the system as ReWalkers are constantly sharing their experiences with us. One

> ReWalker proudly informed us that she wore a hole in her shoe from walking, something that would never have happened when she lived life in wheelchair.
>
> Another ReWalker, who walks to meet his daughters at the bus stop every day, recently attended a father-daughter dance with his 10-year-old. While on the dance floor, he stated, I do a great robot move, you know. He said the kids just saw him as another father of the dance floor. And it was – but it was the parents who really wanted to ask questions.

104. The statements identified in paragraph 103 above were materially false and misleading when made because they omitted the following material information necessary to make them not misleading under the circumstances in which they were made: (a) ReWalk repeatedly failed to respond to FDA requests regarding the post-market surveillance study, (b) ReWalk failed to submit a revised post-market surveillance study plan that addressed the deficiencies described in the FDA's September 29, 2014 and February 13, 2015 letters, (c) ReWalk failed to design a post-market surveillance study plan that addressed the issues identified by the FDA, (d) ReWalk failed to have an approved post-market surveillance study plan, and (e) ReWalk failed to disclose the risks to approval from their dilatory responses and failure to comply with the FDA's Section 522 order.

105. On August 6, 2015, ReWalk announced the Company's financial results for Q2 2015 and held a conference call, in which Jasinski bragged about the newly launched ReWalk 6.0, and made the following materially misleading statements:

> Turning now to R&D. Our ability to innovate is at the core of what we do. Research and development will fuel ReWalk's growth well into the future. The launch of the ReWalk 6.0 in July is a major advance in the technology that will allow more individuals to use the system and provide all users with a better walking experience. The enhanced design incorporates years of user feedback and thousands of hours of research and development. ReWalk Personal 6.0 now offers users highly customized fittings to better match the size and anatomy of each individual user. It has improved software and an overall better walking experience than any other known product in the clinical trials around the world. Each system is custom fitted based on the specific measurements of the

> individual, a more precise fit [indiscernible] (16:05), safety and the alignment of the users' joints for improved mobility.

106. The statements identified in paragraph 105 above were materially false and misleading when made because they omitted the following material information necessary to make them not misleading under the circumstances in which they were made: (a) ReWalk repeatedly failed to respond to FDA requests regarding the post-market surveillance study, (b) ReWalk failed to submit a revised post-market surveillance study plan that addressed the deficiencies described in the FDA's September 29, 2014 and February 13, 2015 letters, (c) ReWalk failed to design a post-market surveillance study plan that addressed the issues identified by the FDA, (d) ReWalk failed to have an approved post-market surveillance study plan, and (e) ReWalk failed to disclose the risks to approval from their dilatory responses and failure to comply with the FDA's Section 522 order.

107. On November 11, 2015, ReWalk announced financial results for Q3 2015 and held a conference call, in which Jasinski made the following materially misleading statements:

> Earlier this year, we outlined a series of publications and studies into various dependent research groups to collect data on the economics of life in a wheelchair. This expensive effort will be the broadest effort to utilize data from the largest U.S. domestic and international databases. This effort also included using the clinical results of the ReWalk Personal device to quantify the impact of lower limb paralysis and the health benefits of ambulation.
>
> The scope of these studies include detailing the incidence and cost per incidence of co-morbidities in SCI patients postsurgery and inpatient rehabilitation; quantifying in real dollars and quality-adjusted life years what the economic impact of spinal cord injury is in the healthcare system; and utilizing the data to show clinical and economic benefits of ambulation over a five-year period.

108. The statements identified in paragraph 107 above were materially false and misleading when made because they omitted the following material information necessary to

make them not misleading under the circumstances in which they were made: (a) ReWalk repeatedly failed to respond to FDA requests regarding the post-market surveillance study, (b) ReWalk failed to submit a revised post-market surveillance study plan that addressed the deficiencies described in the FDA's September 29, 2014 and February 13, 2015 letters, (c) ReWalk failed to design a post-market surveillance study plan that addressed the issues identified by the FDA, (d) ReWalk failed to have an approved post-market surveillance study plan, (e) ReWalk failed to commence post-market surveillance by September 28, 2015, which violated Section 522 of the FD&C Act, (f) ReWalk failed to disclose that the ReWalk device was considered misbranded under Section 502(t)(3) of the FD&C Act, (g) ReWalk failed to disclose that the Company's Section 522 violations may result in regulatory actions by the FDA, including but not limited to seizure, injunction and/or civil money penalties, and (h) ReWalk failed to disclose the risks to approval from their dilatory responses and failure to comply with the FDA's Section 522 order.

109. On February 25, 2016, ReWalk announced Q4 2015 financial results, and held a conference call, in which Jasinski made the following materially misleading statements:

> ReWalk is the most studied exoskeleton in the world. Last month, a first-of-its kind quality of life case study was published in the peer-reviewed journal Spinal Cord Series and Cases, which is published by the International Spinal Cord Society. The study tracked six months of ReWalk use and concluded that the patient was able to walk independently with limited supervision and demonstrated significant improvement in several quality of life measures, including mobility, risk of falling, motor skills, control of bladder and bowel function.
>
> Furthermore, the study also documented improvements in cardiovascular endurance and motor neurological status. The study used a SF-36 questionnaire, which is the standard for measuring quality of life results.
>
> As we mentioned last quarter, we are collaborating with various independent research groups to collect data on the economics of life in a wheelchair. Among other things, we want to understand the economic impact of spinal cord injury in

> patients and the healthcare system that supports them, whether that means the cost of treatments for comorbidity conditions or reduced earnings potential in quality of life.
>
> We believe this data will go a long way towards demonstrating the clinical and economic advantages of the ReWalk system, and on this basis, we expect it to help us achieve additional success in our coverage appeals and initial submissions. We expect the first economic publication to be available later this quarter.

110. The statements identified in paragraph 109 above were materially false and misleading when made because they omitted the following material information necessary to make them not misleading under the circumstances in which they were made: (a) ReWalk repeatedly failed to respond to FDA requests regarding the post-market surveillance study, (b) ReWalk failed to submit a revised post-market surveillance study plan that addressed the deficiencies described in the FDA's September 29, 2014 and February 13, 2015 letters, (c) ReWalk failed to design a post-market surveillance study plan that addressed the issues identified by the FDA, (d) ReWalk failed to have an approved post-market surveillance study plan, (e) ReWalk failed to commence post-market surveillance by September 28, 2015, which violated Section 522 of the FD&C Act, (f) ReWalk failed to disclose that the ReWalk device was considered misbranded under Section 502(t)(3) of the FD&C Act, (g) ReWalk failed to disclose that the Company's Section 522 violations may result in regulatory actions by the FDA, including but not limited to seizure, injunction and/or civil money penalties, and (h) ReWalk failed to disclose the risks to approval from their dilatory responses and failure to comply with the FDA's Section 522 order.

111. On February 29, 2016, ReWalk admitted for the first time that the FDA had sent the Company a letter in February 2016 stating that the Company's protocol for the post-market surveillance study was deficient:

> In February 2016, the FDA sent us a letter citing deficiencies in the protocol for the mandatory post-market study (conducted pursuant to a 522 order) on our ReWalk Personal 6.0 model and expressing the FDA's belief that we should submit a second premarket notification for the device.

112. On March 1, 2016, the FDA published on its website the warning letter that was sent to the Company on September 30, 2015, and which is described in detail in paragraphs 8 to 15 and paragraphs 59 to 67.

113. As a result of this disclosure, ReWalk's stock price fell by nearly 13% to close at $9.07 from its previous day closing price of $10.48 on heavy trading volume. The price continued to decline over the next two trading days until it bottomed out at $8.53 a share. In total, ReWalk's stock price has plummeted over 88% since the IPO.

POST CLASS PERIOD EVENTS

114. After several discussions between the Company and the FDA, at the end of March 2016, the FDA again exercised its enforcement discretion and allowed the Company to market the ReWalk device pursuant to the condition that the Company would initiate the post-market surveillance study before June 1, 2016.

115. On May 5, 2016, the FDA approved the protocol for the post-market surveillance study over seven months after the statutory deadline for initiating post-market surveillance had elapsed.

116. Despite being given another chance, the Company refused to change its ways. ReWalk's monthly reports to the FDA on the status of post-market surveillance were overdue in June and July 2016. The Company filed status reports for the month of June and July over one month after they were required to be submitted to the FDA.

117. To date, the FDA's post-market surveillance studies webpage shows the study status for ReWalk's post-market surveillance study as "progress inadequate."

118. The post-market surveillance study's protocol parameters require the targeted sample size to consist of 60 subjects to be recruited form up to 12 U.S. clinical sites. According to CW3, as of June 2017, the Company had recruited only 8 subjects for the study from only 3 sites largely due to a failure to recruit subjects and seek reimbursement from insurers for the ReWalk device.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

119. Lead Plaintiff bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of all persons or entities that: (1) purchased or otherwise acquired ReWalk common stock pursuant and/or traceable to ReWalk's Registration Statement issued in connection with its September 12, 2014 IPO, seeking to pursue remedies under §§ 11 and 15 of the Securities Act; and/or (2) purchased or otherwise acquired ReWalk common stock between September 12, 2014 and February 29, 2016, both dates inclusive, seeking to pursue remedies under §§10(b) and 20(a) of the Exchange Act. Excluded are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

120. Class members are so numerous that joinder of all members is impracticable. Throughout the Class Period, ReWalk common stock was actively traded on the NASDAQ Global Select Market. Because the overwhelming majority of owners hold shares in street name, and there are in excess of 21 million shares currently outstanding, Lead Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Potential Class members may be identified from records maintained by ReWalk, their transfer agents, and brokers and banks that hold shares beneficially for investors in street name, and may be notified

of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

121. Lead Plaintiff's claims are typical of the claims of those of the Class, as all Class members were similarly affected by Defendants' wrongful conduct in violation of federal law complained of herein.

122. Lead Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class action and securities litigation.

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

- whether the Registration Statement contained any material misrepresentations or omissions;
- whether the Individual Defendants or Underwriter Defendants have a viable good faith defense to the strict liability otherwise imposed by Section 11 of the Securities Act;
- whether Defendants can establish negative causation as a defense to or as a reduction of the strict liability otherwise imposed by Section 11 of the Securities Act;
- whether any of the Defendants was a control person of ReWalk for purposes of Section 15 of the Securities Act and Section 20(a) of the Exchange Act;
- whether the statements made by any of the Defendants during earnings conference calls, healthcare conferences or in SEC filings after the IPO contained any material misrepresentations or omissions;
- whether misrepresentations or omissions were made with scienter;
- whether the federal securities laws were violated by Defendants' acts as

alleged herein;

- whether the prices of ReWalk's securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

- whether the Classes have sustained damages and, if so, what is the proper measure of damages.

124. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for Class members to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

125. With respect to Exchange Act claims, Lead Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

- the omissions and misrepresentations were material;

- ReWalk's securities are traded in efficient markets;

- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;

- the Company traded on the NASDAQ, and was covered by multiple analysts;

- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

- Lead Plaintiff and Class members purchased and/or otherwise acquired ReWalk common stock between the time the Defendants failed to disclose

or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

126. Based upon the foregoing, Lead Plaintiff and other Class members are entitled to a presumption of reliance upon the integrity of the market.

127. Alternatively, Lead Plaintiff and Class members are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in violation of a duty to disclose such information, as detailed above.

COUNT I

(Against ReWalk, Jasinski, Kraft, Goffer, Dykan, Ron, Shinar, Weisman, Ichiki, Dan, Muir and the Underwriter Defendants for Violation of Section 11 of the Securities Act)

128. Lead Plaintiff repeats and realleges allegations of Paragraphs 1 through 95 as if fully set forth herein. The allegations contained in Paragraphs 96 through 111 are expressly excluded from this claim, which does not allege fraud, recklessness or intentional misconduct.

129. This claim is asserted by Lead Plaintiff on behalf of all persons who purchased shares of the Company's common stock pursuant to and/or traceable to the Company's IPO, in which the shares registered under the Registration Statement were sold.

130. The individuals named in this count are strictly liable under the Securities Act as signatories of the Registration Statement for the misrepresentations and omissions contained therein, as identified in Paragraphs 85 to 95 above.

131. ReWalk is strictly liable as the Issuer under the Securities Act for the misrepresentations and omissions it made in the Registration Statement, as identified in Paragraphs 85 to 95.

132. The Underwriter Defendants are strictly liable under the Securities Act as named underwriters for the misrepresentations and omissions made in the Registration Statement, as identified in Paragraphs 85 to 95.

133. None of the Defendants named herein conducted a reasonable investigation or possessed a reasonable basis for the belief that the statements contained in the Registration Statement and identified in Paragraphs 85 to 95 above were true, were without omissions of material fact or were otherwise not misleading.

134. By reason of the conduct alleged herein, each of the Defendants has violated Section 11 of the Securities Act.

135. Lead Plaintiff and the Class have sustained damages because the value of their ReWalk common stock has declined. This decline is attributable by law to Defendants in the absence of proof that it was caused by other factors, which proof has not been established.

136. At the time of their purchases, Lead Plaintiff and the Class were without knowledge of the wrongful conduct alleged herein, and could not have reasonably discovered those facts more than one year prior to the filing of the initial complaint in this action. The initial complaint was filed within three years of the time that ReWalk offered the shares covered by the Registration Statement to the investing public.

137. By virtue of the foregoing, Lead Plaintiff and the other Class members are entitled to damages under Section 11 as measured by the provisions of Section 11(e), from the Defendants and each of them, jointly and severally.

COUNT II

(Against Jasinski, Kraft, Goffer and Dykan for Violation of Section 15 of The Securities Act)

138. Lead Plaintiff repeats and reallege allegations of Paragraphs 1 through 95 and 128 through 137 as if fully set forth herein. The allegations contained in Paragraphs 96 through 111 are expressly excluded from this claim, which does not allege fraud, recklessness or intentional misconduct.

139. Jasinski, by virtue of his office, directorship, relationship with other directors and executives, and proved ability to shape the structure and operations of ReWalk is a controlling person of ReWalk within the meaning of Section 15 of the Securities Act.

140. Kraft, as the Chief Financial Officer at the time of the IPO, exercised complete responsibility for the processing of financial information, and had intricate knowledge of ReWalk's medical devices as the general manager of its Israeli headquarters. Consequently, he was a controlling person of ReWalk within the meaning of Section 15 of the Securities Act.

141. Goffer, as the founder of ReWalk, a member of the Company's Board and the Company's Chief Technical Officer at the time of the IPO was in possession of information related to the Company's interactions with the FDA and the regulatory deficiencies associated with the ReWalk. Goffer, is therefore, a controlling person of ReWalk within the meaning of Section 15 of the Securities Act.

142. Dykan is, and was at the time of the IPO, the Chairperson of the Board of Directors, and heavily involved in the day-to-day management of the Company.

143. By virtue of the conduct alleged herein, Defendants Jasinski, Kraft, Goffer and Dykan are liable as control persons for the primary violations of Section 11 by ReWalk, as alleged in Count I.

144. The Defendants named in this count did not conduct a reasonable investigation or possess a reasonable basis for the belief that the statements contained in the Registration

Statement and identified in Paragraphs 85 to 95 above were true, were without omissions of material fact, and were not misleading.

145. Each of these Defendants is liable to the Lead Plaintiff and the Class for damages suffered as a result of the primary Securities Act violations of ReWalk.

COUNT III

(Against ReWalk and the Individual Defendants for Violations of Section 10(b) and Rule 10b-5)

146. Lead Plaintiff repeats and realleges the allegations contained in Paragraphs 1 to 118 above as if fully set forth herein except that Paragraphs 85 to 95 are not alleged against Defendant Hershberger.

147. This Count is asserted against ReWalk and each of the Individual Defendants for violations of Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

148. At the time of the Registration Statement and during the Class Period, these Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon the Lead Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Lead Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of

ReWalk securities; and (iii) cause Lead Plaintiff and other members of the Class to purchase or otherwise acquire ReWalk securities and options at artificially inflated prices.

149. Specifically, ReWalk issued a Registration Statement, which each of the Individual Defendants except for Defendants Hershberger signed as a maker of the representations contained therein, which was materially false and misleading as particularized in Paragraphs 85 to 95 above.

150. ReWalk, Jasinski and/or Hershberger also made materially false and misleading as particularized in Paragraphs 96 to 111 above. The primary violations alleged in Paragraphs 96 to 111 are brought only against Defendants ReWalk, Jasinski and Hershberger.

151. By virtue of their positions at ReWalk, Individual Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Lead Plaintiff and the other members of the Class, or, in the alternative, acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to ReWalk and the Defendants named in this Count. In addition to the facts alleged herein demonstrating a strong inference of scienter, certain information showing that the Defendants acted knowingly or with reckless disregard for the truth is peculiarly within these Defendants' knowledge and control. As the senior managers and/or directors of ReWalk, these Defendants had knowledge of the details of ReWalk's internal affairs.

152. As officers and/or directors of a publicly-held company, these Defendants had a duty to disseminate timely, accurate, and truthful information regarding ReWalk's business, operations, and financial controls. As a result of the dissemination of the aforementioned false

and misleading reports and filings, the market price of ReWalk securities was artificially inflated throughout the Class Period.

153. In ignorance of the adverse facts concerning ReWalk's operations and financial controls which were concealed by the misrepresentations and omissions alleged herein, Lead Plaintiff and the other members of the Class purchased or otherwise acquired ReWalk securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by the Defendants, and were damaged thereby.

154. During the Class Period, ReWalk securities were traded on an active and efficient market. Lead Plaintiff and the other members of the Class, directly relying on the materially false and misleading statements described herein, and/or relying upon the integrity of the market, purchased or otherwise acquired shares of ReWalk securities at prices artificially inflated by Defendants' wrongful conduct. Had Lead Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Lead Plaintiff and the Class, the true value of ReWalk securities was substantially lower than the prices paid by Lead Plaintiff and the other members of the Class. The market price of ReWalk securities declined sharply upon public disclosure of the facts alleged herein to the injury of Lead Plaintiff and Class members.

155. By reason of the conduct alleged herein, ReWalk and the Individual Defendants knowingly or recklessly violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

156. As a direct and proximate result of these Defendants' wrongful conduct, Lead Plaintiff and the other Class members suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period. ReWalk and Individual Defendants are liable for damages in connection with these losses under Section 10(b) of the Exchange Act and Rule 10b-5 proumlgated thereunder.

COUNT IV

(Violations of Section 20(a) of the

Exchange Act Against Defendants Jasinski and Hershberger)

157. Lead Plaintiff repeats and realleges allegations contained in Paragraphs 1 to 118 and 146 to 156 above, as if fully set forth herein.

158. During the Class Period, Defendants Jasinksi and Hershberger participated in the operation and management of ReWalk, and conducted and participated, directly and indirectly, in the conduct of ReWalk's business affairs. Because of their senior positions and/or directorships, they knew the adverse non-public information about ReWalk's medical device.

159. As officers and/or directors of a publicly owned company, these Defendants had a duty to disseminate accurate and truthful information with respect to ReWalk's reports and filings and to correct promptly any public statements issued by ReWalk which had become materially false or misleading.

160. Jasinski, by virtue of his office, directorship, relationship with other directors and executives, and proved ability to shape the structure and operations of Jasinski is a controlling person of ReWalk within the meaning of Section 20(a) of the Exchange Act.

161. Hershberger, as the CFO at the time the materially false and misleading Annual Reports were filed, exercised complete responsibility for the processing of financial

information and knew about ReWalk's deficiencies. Consequently, he was a controlling person of ReWalk within the meaning of Section 20(a) of the Exchange Act.

162. Because of their positions of control and authority as senior officers and/or directors, these Defendants were able to, and did, control the contents of the reports and public filings that ReWalk disseminated in the marketplace during the Class Period concerning its financial results and internal controls. Throughout the Class Period, these Defendants exercised their power and authority to cause ReWalk to engage in the wrongful acts complained of herein.

163. As control persons, Jasinski and Hershberger are liable pursuant to Section 20(a) of the Exchange Act for the primary violations of the Exchange Act committed by ReWalk as set forth in Count III.

PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Lead Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Lead Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Lead Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Lead Plaintiff hereby demands a trial by jury.

Dated: August 9, 2017

By his attorneys,

/s/Adam M. Stewart_____

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF System will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

Dated: August 9, 2017

/s/ Adam M. Stewart_____
Adam M. Stewart