

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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 13, 2018

ReWalk Robotics Ltd.

(Exact name of registrant as specified in its charter)

Israel
(State or Other Jurisdiction
of Incorporation)

001-36612
(Commission File Number)

Not applicable
(IRS Employer
Identification No.)

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

2069203
(Zip Code)

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

Not applicable

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

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

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Emerging growth company

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

Item 7.01 Regulation FD Disclosure.

On November 13, 2018, ReWalk Robotics Ltd. (the “Company”) posted to the “Investors” section of its website (ir.rewalk.com) an investor presentation slideshow (the “Presentation”), which is furnished herewith as Exhibit 99.1. The Company intends to use the Presentation from time to time in making presentations to analysts, potential investors, and other interested parties.

The information in this Current Report on Form 8-K, including Exhibit 99.1 (this “Report”), shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “1934 Act”), nor shall it be deemed “incorporated by reference” into any filing under the Securities Act of 1933, as amended, or the 1934 Act, except as may be expressly set forth by specific reference in such filing. Information contained on, or that can be accessed through, the Company’s website does not constitute a part of, and is not incorporated by reference into, this Report.

Item 9.01 Financial Statements and Exhibits.

(d)

99.1 [Investor presentation.*](#)

* Furnished herewith

SIGNATURES

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

ReWalk Robotics Ltd.

By: /s/ Ori Gon
Name: Ori Gon
Title: Chief Financial Officer

Dated: November 13, 2018

ReWalkTM Take the Next Step



Human and Robotic Intersection

November 2018



Disclaimer

This presentation contains statistical data that were obtained from industry publications and reports generated by third parties. Although ReWalk believes that the publications and reports are reliable, it has not independently verified this statistical data.

The trademarks included herein are the property of the owners thereof and are used for reference purposes only. Such use should not be construed as an endorsement of the products or services of ReWalk.

This document may not be retained, reproduced or distributed, in whole or in part, by any means (including electronic) without the prior written consent of ReWalk.

This document will not be left behind after this presentation, and by accepting this document and attending the presentation, you agree to be bound by the foregoing limitations.

Forward Looking Statements

In addition to historical information, this presentation contains forward-looking statements within the meaning of Section 27A of the Securities Act, Section 21E of the Exchange Act, and the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, that are based on our management's beliefs and assumptions and on information currently available to our management. Forward-looking statements include information concerning our possible or assumed future results of operations, business strategies, financing plans, competitive position, industry environment, potential growth opportunities, potential market opportunities and the effects of competition. Forward-looking statements may include projections regarding our future performance and, in some cases, can be identified by words like "anticipate," "assume," "believe," "could," "seek," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "future," "should," "will," "would" or similar expressions that convey uncertainty of future events or outcomes and the negatives of those terms. These forward-looking statements are based on our management's current expectations, which are subject to uncertainty, risks and changes in circumstances that are difficult to predict, and many of which are outside of our control. Important factors that could cause our actual results, levels of activity or performance to differ materially from those indicated in the forward-looking statements include, among others: our expectations regarding future growth, including our ability to increase sales in our existing geographic markets, expand to new markets and achieve our planned expense reductions; our management's conclusion, and our independent registered public accounting firm's statement in its opinion relating to our accompanying consolidated financial statements, that there is a substantial doubt as to our ability to continue as a going concern; our ability to regain compliance with the continued listing requirements of the Nasdaq Capital Market and the risk that our ordinary shares will be delisted if we cannot do so; our ability to maintain and grow our reputation and the market acceptance of our products; our ability to achieve reimbursement from third-party payors for our products; our expectations as to our clinical research program and clinical results; our expectations as to the results of the FDA's regulatory developments with respect to our mandatory 522 postmarket surveillance study; the outcome of ongoing shareholder class action litigation relating to our IPO; our ability to repay our secured indebtedness; our ability to improve our products and develop new products; our ability to close periodic issuances of our ordinary shares to, and to form a joint venture in China with, Timwell and the resulting effect on our liquidity and financial condition; the risk of substantial dilution resulting from additional issuances, if any, of our ordinary shares to Timwell; the significant voting power and de facto voting control Timwell may acquire upon additional issuances, if any, of our ordinary shares to Timwell; our ability to maintain adequate protection of our intellectual property and to avoid violation of the intellectual property rights of others; our ability to gain and maintain regulatory approvals; our ability to secure capital from equity and debt financings in light of limitations under our effective registration statement on Form S-3, the price range of our ordinary shares and conditions in the financial markets, and the risk that such financings may dilute our shareholders or restrict our business; our ability to use effectively the proceeds of offerings of our securities; the impact of the market price of our ordinary shares on the determination of whether we are a passive foreign investment company; our ability to maintain relationships with existing customers and develop relationships with new customers; and our compliance with medical device reporting regulations to report adverse events involving our products and the potential impact of such adverse events on ReWalk's ability to market and sell its products. Any forward-looking statement made in this presentation speaks only as of the date hereof. Factors or events that could cause our actual results to differ from the statements contained herein may emerge from time to time, and it is not possible for us to predict all of them. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this presentation to conform these statements to actual results or to changes in our expectations, whether as a result of new information, future developments or otherwise.

Our Mission

Fundamentally change the
Quality of Life for individuals with lower limb disability
through the creation and development of **market leading
robotic technologies**



ReWalk Overview

Market leading global developer of robotic therapy and mobility assistance solutions

ReWalk rigid exoskeleton

- Assists individuals with spinal cord injury to stand and walk
- FDA & CE mark clearance
- Sixth generation device
- Commercialized with 450+ systems worldwide
- First mover advantage

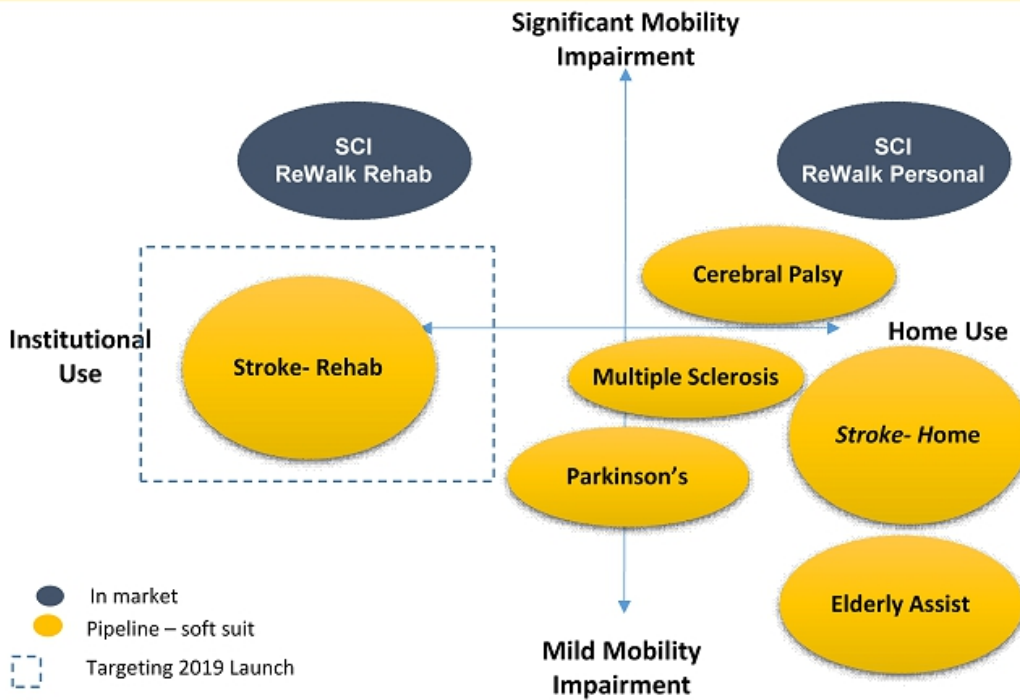


ReStore soft exo-suit

- In development for stroke patients and other lower limb disabilities
- Clinical testing underway
- Potential for additional indications including multiple sclerosis, cerebral palsy, Parkinson's disease and elderly assistance



Multiple Markets for Growth



TODAY

- 282,000 people in the U.S. living with SCI¹
- 17,000 new cases annually

FUTURE POTENTIAL

- 1,000+ US primary stroke centers², ~100,000 general rehab clinics³
- 7000-9000 rehab hospitals in China⁴
- EU market similar to US
- 200,000+ Licensed Physical Therapists in US⁵
- 1 million MS diagnosis in US, 2.3 million worldwide⁶
 - 75% will experience clinically significant walking disturbance⁷
- Potential additional markets
 - 10M WW Parkinson's⁸
 - Cerebral Palsy
 - Elderly assistance

1. <https://www.nscisc.uab.edu/Public/Facts%202016.pdf>

2. https://www.heart.org/stc/groups/heart-public/@wcmv/@hcmf/@ml/documents/downloadable/ucm_455522.pdf

3. <https://www.ibisworld.com/industry-trends/market-research-reports/healthcare-social-assistance/ambulatory-health-care-services/physical-therapists.html>

4. Number represents anticipated figure for 2021. See <http://www.chyx.com/industry/201609/450634.html>

5. <http://www.apta.org/WorkforceData/ModelDescriptionFigures/>

6. <https://www.healthline.com/health/multiple-sclerosis/facts-statistics-infographic>

7. [Evaluating Walking in Patients with Multiple Sclerosis Which Assessment Tools Are Useful in Clinical Practice? Francois Bethoux, MD; Susan Bennett, PT, DPT, EdD, NCS, MSCS](#)

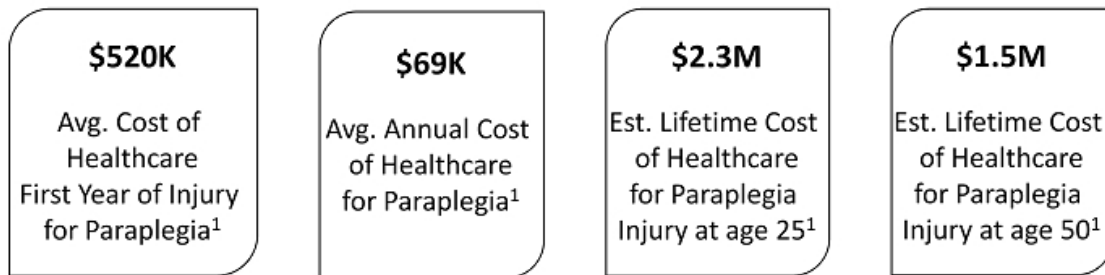
8. [Parkinson's Disease Foundation](#)

Breakthrough Technology Addresses the SCI Need

Wheelchair confinement can cause severe physical and psychological deterioration resulting in significant costs to the healthcare system

Secondary Medical Consequences of Paralysis:

- Difficulty with bowel and urinary tract function
- Osteoporosis
- Loss of lean mass / gain in fat mass
- Insulin resistance
- Diabetes
- Heart disease



87% of spinal cord injury patients discharged to private, non-institutional residences²

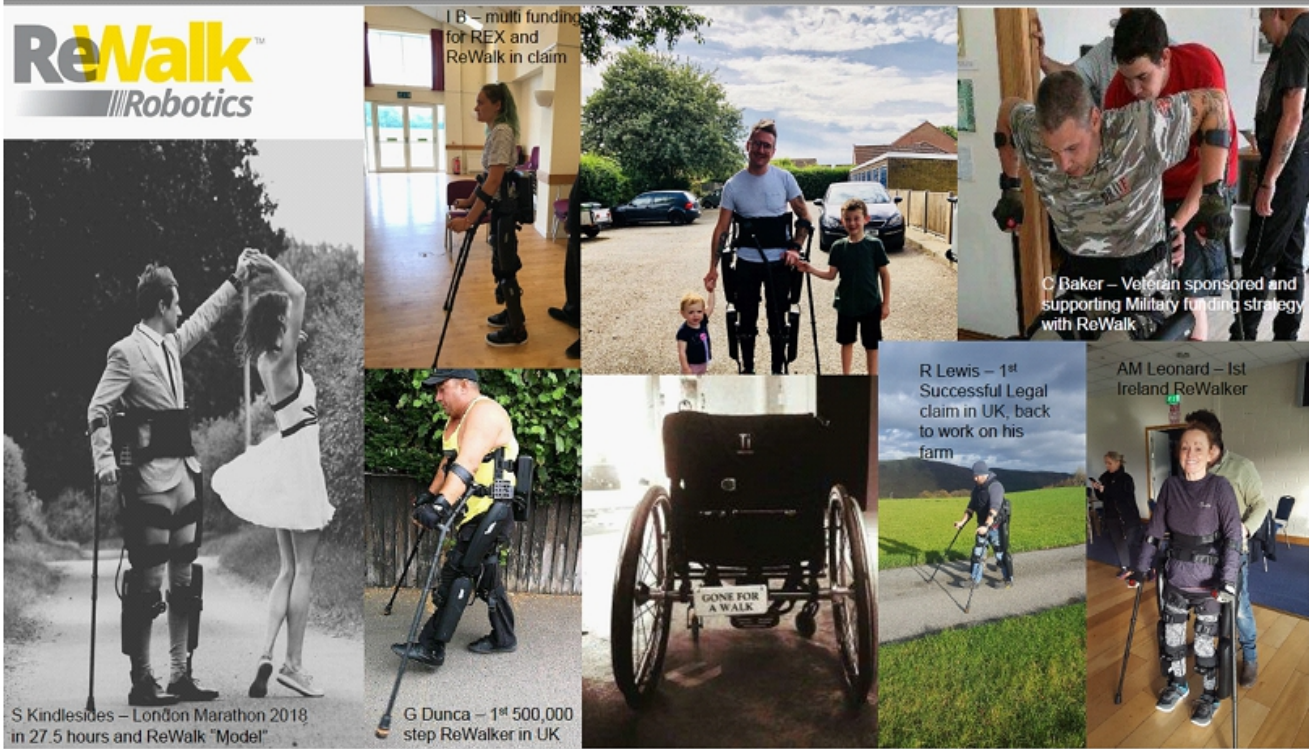
1. Source: <https://www.nscisc.uab.edu/Public/Facts%202016.pdf>

2. Source: <https://www.nscisc.uab.edu/public/2016%20Annual%20Report%20-%20Complete%20Public%20Version.pdf>



ReWalk's Breakthrough Technology

Patented tilt-sensor technology mimics natural gait



<https://www.youtube.com/watch?v=d5zI7fglMgo>

Refined Reimbursement Strategy

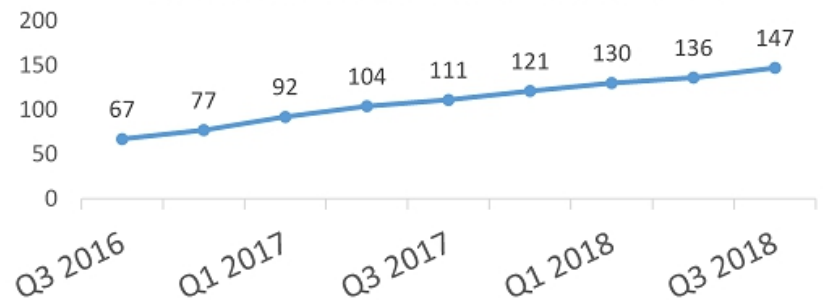
Coverage Decisions Insurers and Direct

- Complete 30+ policy submissions for coverage with regional and national insurers in 2018
- US - Utilize VA SOP updated in June 2018 with new Veterans Choice Program to optimize coverage
- Secured near universal coverage in Germany-
 - Barmer – Large German social health insurance coverage Sept 2017
 - DGUV – German Social Accident Insurance Provider Sep 2017
 - ReWalk P6.0 was issued a code and is now included in the Medical Aid list

Case-by-Case

- Patient-driven process
- Leverage ACA limits on claim review times for better efficiency and transparency

WW Cumulative Units Reimbursed



To date 38 different U.S payors and 39 different German payors have approved the ReWalk personal 6.0 on a case-by-case basis

Strong Partnership with the VA



National Coverage Policy

Research Study⁽¹⁾

	<ul style="list-style-type: none"> • First national coverage policy updated in June 2018 • For evaluation, training and issuance of ReWalk exoskeletons • Exclusive to ReWalk exoskeletons 	<ul style="list-style-type: none"> • Large multi-center community based exoskeleton study • Evaluating quality of life and health benefits of walking
Scope	<ul style="list-style-type: none"> • ~44,000 Paralyzed Individuals are eligible for VA Benefits⁽²⁾ 	<ul style="list-style-type: none"> • 160 SCI veterans • Duration: 4 years
Facilities	<ul style="list-style-type: none"> • Evaluation - 24 SCI "Hub" Centers⁽³⁾ • Training with the VA "Choice" program through - <ul style="list-style-type: none"> • Trained VA "Spoke" sites , or • 113 certified ReWalk training centers 	<ul style="list-style-type: none"> • Currently 12 centers active over 18 months
VA Department	<ul style="list-style-type: none"> • Clinical group – prosthetics (same area that provides legs and arms) 	<ul style="list-style-type: none"> • Research department only
Units	<ul style="list-style-type: none"> • 19 • Over 60% conversion rate 	<ul style="list-style-type: none"> • 88

(1) ExoskCSP #2003 exoskeleton Assisted-Walking in Persons With SCI: Impact on Quality of Life

(2) <http://imperial.networkofcare.org/veterans/library/article.aspx?id=1687>

(3) https://www.sci.va.gov/VAs_SCID_System_of_Care.asp



Medical Aid Code : 23.29.01.2001

ReWalk Personal 6.0: first and only exoskeleton officially recognized as a medical aid throughout Germany.

German SCI market has 80,000¹ paralyzed individuals

Official publication in Federal Gazette on June 11, 2018

The listing enables any medically qualified individual to obtain reimbursement for ReWalk Personal 6.0 exoskeleton through German Statutory Health Insurance Funds (GKV)

Medical Aid Code confirms

- General product safety
- Safe use in home environment confirmed
- Individual supply requirements
- Trial/Rental period
- Companion training

Since medical aid confirmation –

7 more Statutory Health Insurers (SHI) have approved ReWalk Personal 6.0

Next Steps

- Contract the different payors with a formal training and supply agreement
- There are 134 claims in the pipeline that we are working to process

1. Source: https://www.dqn.org/images/red_leitlinien/LL_2012/pdf/ll_71_2012_querschnittlhmuna.pdf. 10-30 SCI paralyzed individuals per 1 million population

ReStore - Shaping the Future



Leveraging ReWalk's technology and commercial expertise to develop a lightweight, wearable soft exosuit that facilitates a natural gait

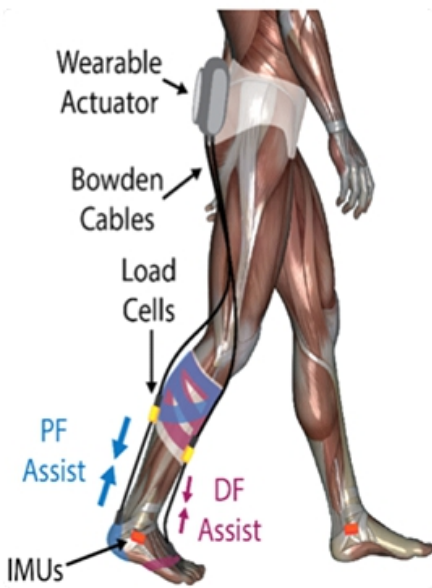
- Initially targeting rehabilitation related to stroke
- Technology licensed from Harvard
- Provides powered plantarflexion
- Clinical trial enrollment underway
- CE mark submission at the beginning of Q4 2018; FDA submission is planned by Q1 2019; commercialization in EU and US planned for Q3 2019

www.rewalk.com

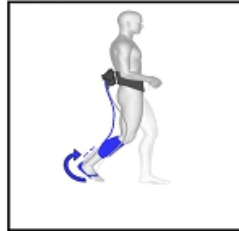
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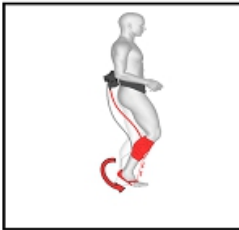
ReStore in Action



1 Sensors detect gait event



2 Rear cable contracts to provide PF assistance for forward propulsion



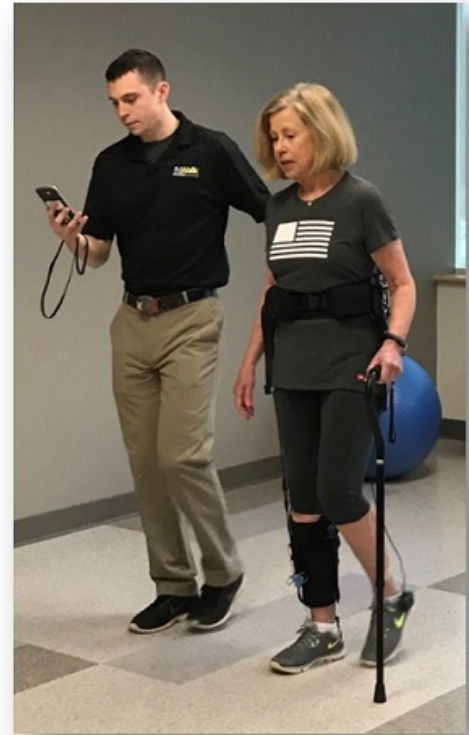
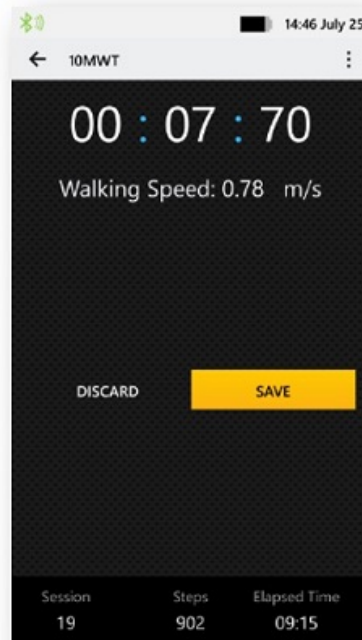
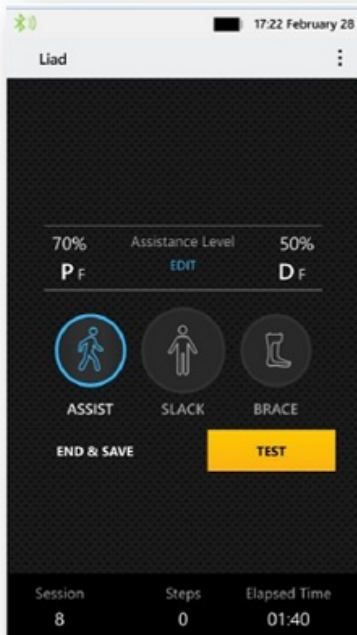
3 Front cable contracts to provide DF assistance for swing phase

Key Differentiators

- Light, soft components and powered dorsi/ plantar flexion facilitate natural gait pattern
- Provides therapist real-time analytics and enhanced session control for optimized results
- Multiple modes of function and rapid donning/ doffing and adjustment for efficient therapy sessions
- Session data capture with reporting and comparison across sessions

<https://www.youtube.com/watch?v=kreK8VDh0ZI>

Real Time Analytics and Control



Near-term ReStore Market: Stroke



Prevalence

US: 7 million stroke survivors¹
 EU: 9.6 million stroke survivors²
 China: 11 million stroke survivors⁸

Annual Incidence



US: ~ 795K³
 EU / Western Europe: ~ 1.1 million⁴
 China: ~ 2.4 million⁸

Eligible population adjusted by physical qualifications

Addressable Market - Prevalence

US: 2.5 million^{5,6} potentially eligible for ReStore system
 EU: 3.4 million⁷ potentially eligible for ReStore system
 China: 3.9 million⁷

Annual Addressable Market - Incidence

US: ~370K^{5,6}
 EU: ~500K⁷
 China: ~1.1M⁷

Penetration strategy -

PHASE I: Top Tier Stroke Rehab Centers

US
 1,000 primary stroke centers⁹

EU
 1,000 clinics¹⁰

China
 7000-9000 rehab hospitals in China¹¹

PHASE II: Thousands of Hospitals & Physical Therapy Clinics

1. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3250269/pdf/13311_2011_Article_53.pdf

2. Extrapolated from the incidence numbers based on the rate for US.

3. American Heart Association 2017 Heart Disease and Stroke Statistics 2017

4. European Journal of Neurology 6JUN2016, Vol 13, Issue 6 "Stroke Incidence and Prevalence in Europe: a review of available data"; as of 2000.

5. Assumption, 60% lower limb disability rate after stroke- Source: Rehabilitation after Stroke Bruce H. Dobkin, M.D. N Engl J Med 2005; 352:1677-1684 April 21, 2005 DOI: 10.1056/NEJMcp043511.

6. Assumptions: For the incidence pool, 60% have lower limb disability per (6), and estimate 22% fall our rate; for prevalence pool, estimate 40% fall our rate of the 60% with lower limb disability

7. Assuming similar rates as the US market in 5 and 6 above.

8. Prevalence, Incidence, and Mortality of Stroke in China - Results from a Nationwide Population-Based Survey of 480 687 Adults

<https://pdfs.semanticscholar.org/f59d/209fe597e6dabdf966628b99b44762273497.pdf>

9. US prevalence 2014, American Heart Association

10. Estimate similar to US

11. Number represents anticipated figure for 2021. See <http://www.chyxx.com/industry/201609/450634.html>

ReStore Value Proposition for Clinics

Efficiency and Cost Effectiveness

- Reduce staffing or equipment needs, reduce strain on staff

Improved Standard of Care

- Higher level and consistency of care at less specialized facilities and across PT capability levels

Enhanced Facility Marketing

- Current technology in competitive marketplace, attract clients and staff

Session Optimization

- Feedback and adjustment lead to better clinical outcomes; more progress in less time to maximize ROI in captive payment model

Recording of Results and Evidence for Additional Reimbursement

- Insurers want to see progress - *and proof of it* – in order to approve additional sessions



Value Will Vary
By Setting and
Situation

ReStore Multi-Center Clinical Trial

OBJECTIVES:

- Assess safety of ReStore device during gait training in post-stroke individuals
- Evaluate use of ReStore device during common assessments (e.g. 6 minute walking test (6MWT), 10 meter walking test (10MWT))

DESIGN:

- 40 patients; 7 sessions
- 5 of Top 10 stroke research centers in the US interested in participating in the study

TIMELINE:

- Enrollment near completion
- Applied for CE mark clearance
- FDA submission planned around Q1 2019
- EU / US launch anticipated by Q3 2019

Research Partners

Shirley Ryan
Abilitylab

MossRehab
EINSTEIN HEALTHCARE NETWORK

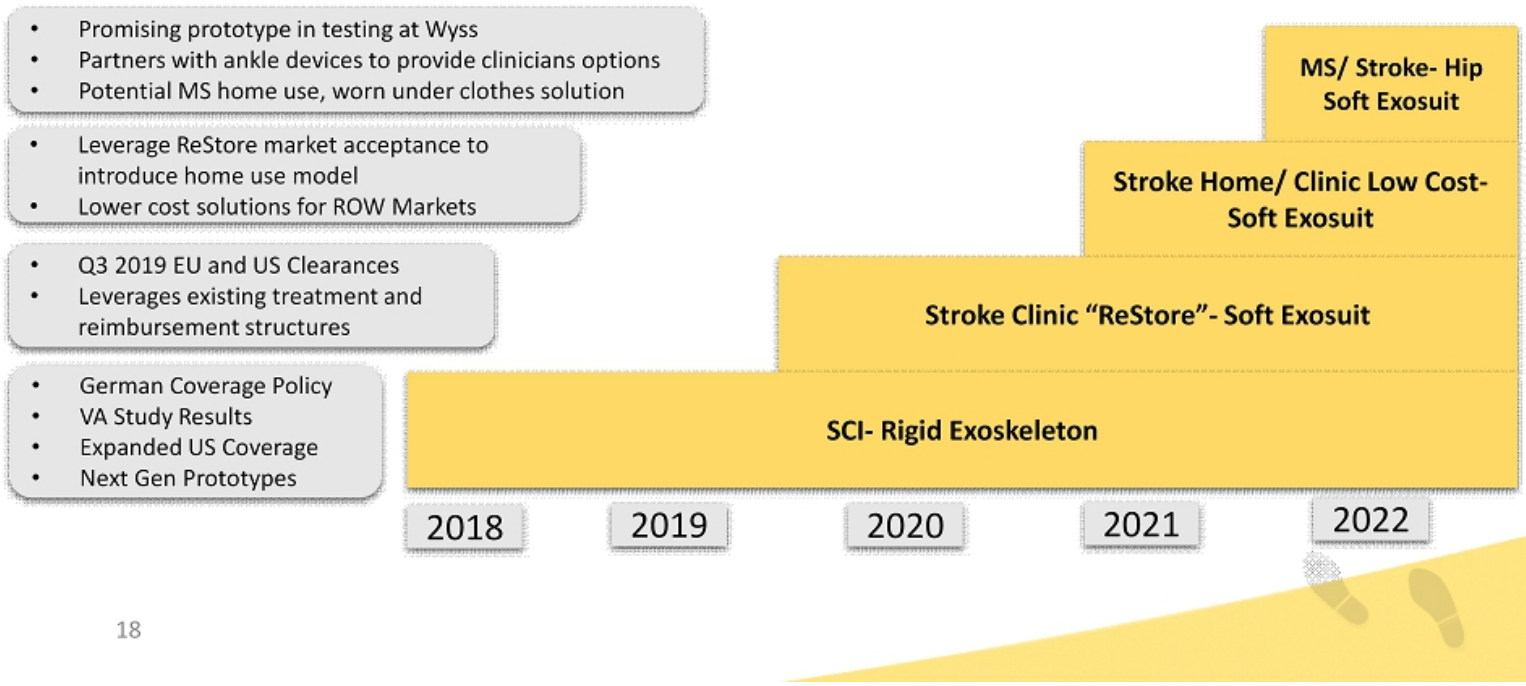
 **SPAULDING**TM
REHABILITATION NETWORK

 **KESSLER**
FOUNDATION

TIRR
MEMORIAL
HERMANN
Rehabilitation & Research

Planned Steps For Growth – Growing Current Business and Expanding to New Markets

ReWalk plans to grow the SCI, Rigid exoskeleton business through expanded coverage policies and develop new soft exosuit technologies through the Wyss partnership to address other lower limb disabilities and create a broad portfolio of solutions



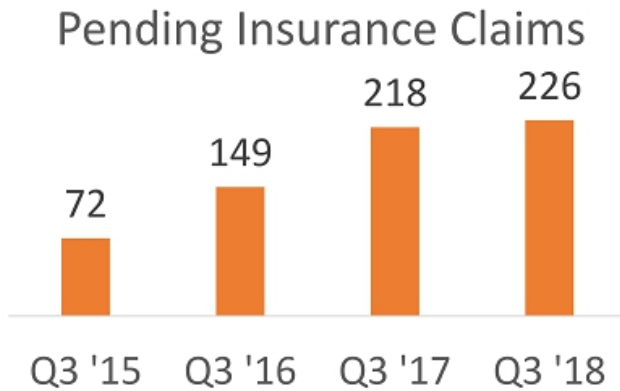
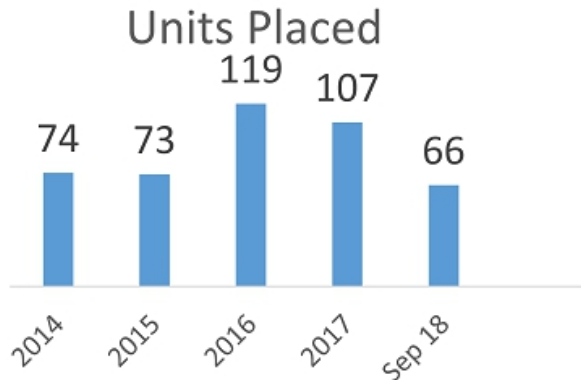
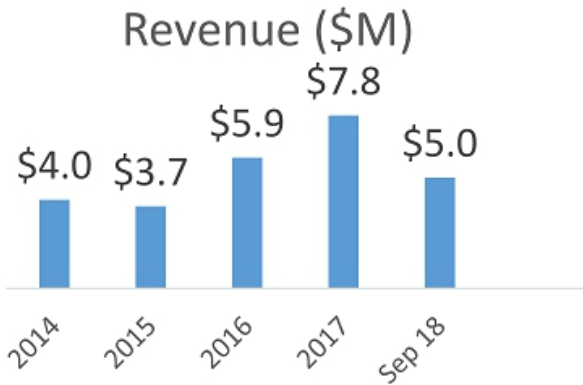
Strategic Approach – China

Developing a platform for accelerated growth in largest single stroke market

- Large market opportunity in China
 - 11 million stroke survivors¹
 - 2.4 million people suffer a stroke each year¹
 - Number of stroke rehabilitation centers in China expected to exceed those in the US and EU combined by 2021
- March 2018: ReWalk signed a \$20 million strategic investment which included establishment of JV, licensing, and supply agreements with Timwell Corporation (Realcan pharma affiliate)
- First tranche of \$5 million completed May 2018; later tranches of \$10 million with JV and \$5 million with manufacturing have not occurred due to complexity of structure
- Although we remain in dialogue with RealCan, and have discussed with RealCan various alternatives to the original investment agreement, we are also evaluating alternative paths with different groups to penetrate the Chinese market

1. Prevalence, Incidence, and Mortality of Stroke in China - Results from a Nationwide Population-Based Survey of 480 687 Adults
<https://pdfs.semanticscholar.org/f59d/209fe597e6dabdf966628b99b44762273497.pdf>

Financial Snapshot



Company Highlights

- Market leading global exoskeleton developer with two breakthrough device platforms
 - Rigid ReWalk exoskeleton for spinal cord injury market
 - FDA and CE mark clearance for both Personal and Rehabilitation use; sixth generation device
 - 500 systems placed, with majority for home and community use; other systems used in rehab centers
 - Global commercial infrastructure with first mover advantage
 - ReStore soft-suit exoskeleton for stroke rehabilitation
 - First study underway in collaboration with Harvard University's Wyss Institute
 - CE submission completed Q4 2018; FDA submission planned for early 2019; EU and US launch anticipated Q3 2019
 - Potential for other indications including multiple sclerosis and Parkinson's disease
- Innovation through research collaboration agreement with Wyss Institute at Harvard
- Proven insurance reimbursement success. Currently working with other groups in the US and Germany to secure broader coverage
- Extensive relationship with Department of Veterans Affairs, the single largest network of care for spinal cord injury (SCI) patients in the United States

ReWalk™

Take the Next Step

