

# ReWalk<sup>TM</sup> Take the Next Step



Human and  
Robotic  
Intersection

November 2018



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# Our Mission

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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

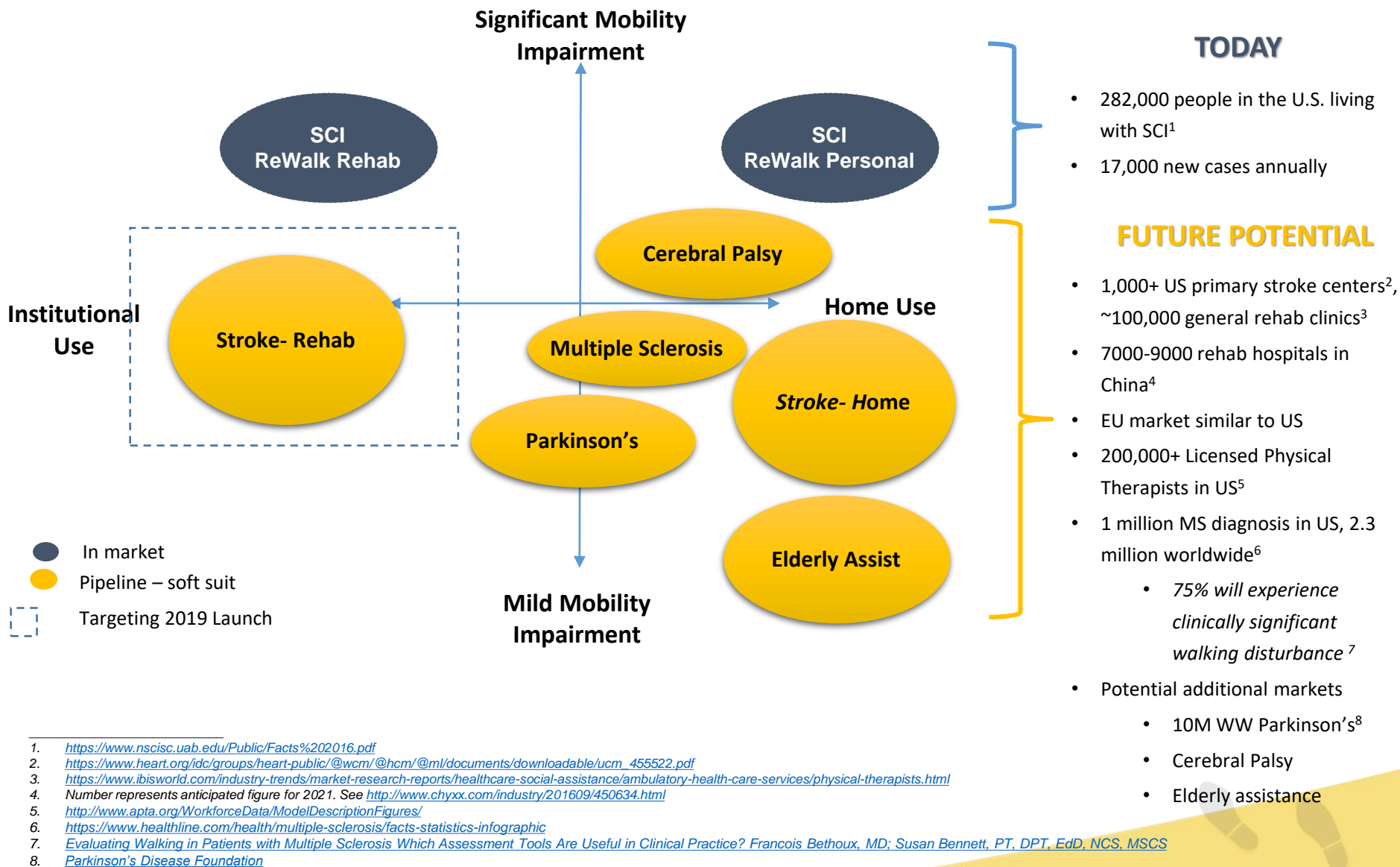


## ReStore soft exo-suit

- 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



# 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

**\$520K**

Avg. Cost of  
Healthcare  
First Year of Injury  
for Paraplegia<sup>1</sup>

**\$69K**

Avg. Annual Cost  
of Healthcare  
for Paraplegia<sup>1</sup>

**\$2.3M**

Est. Lifetime Cost  
of Healthcare  
for Paraplegia  
Injury at age 25<sup>1</sup>

**\$1.5M**

Est. Lifetime Cost  
of Healthcare  
for Paraplegia  
Injury at age 50<sup>1</sup>

**87% of spinal cord injury patients discharged to private, non-institutional residences<sup>2</sup>**

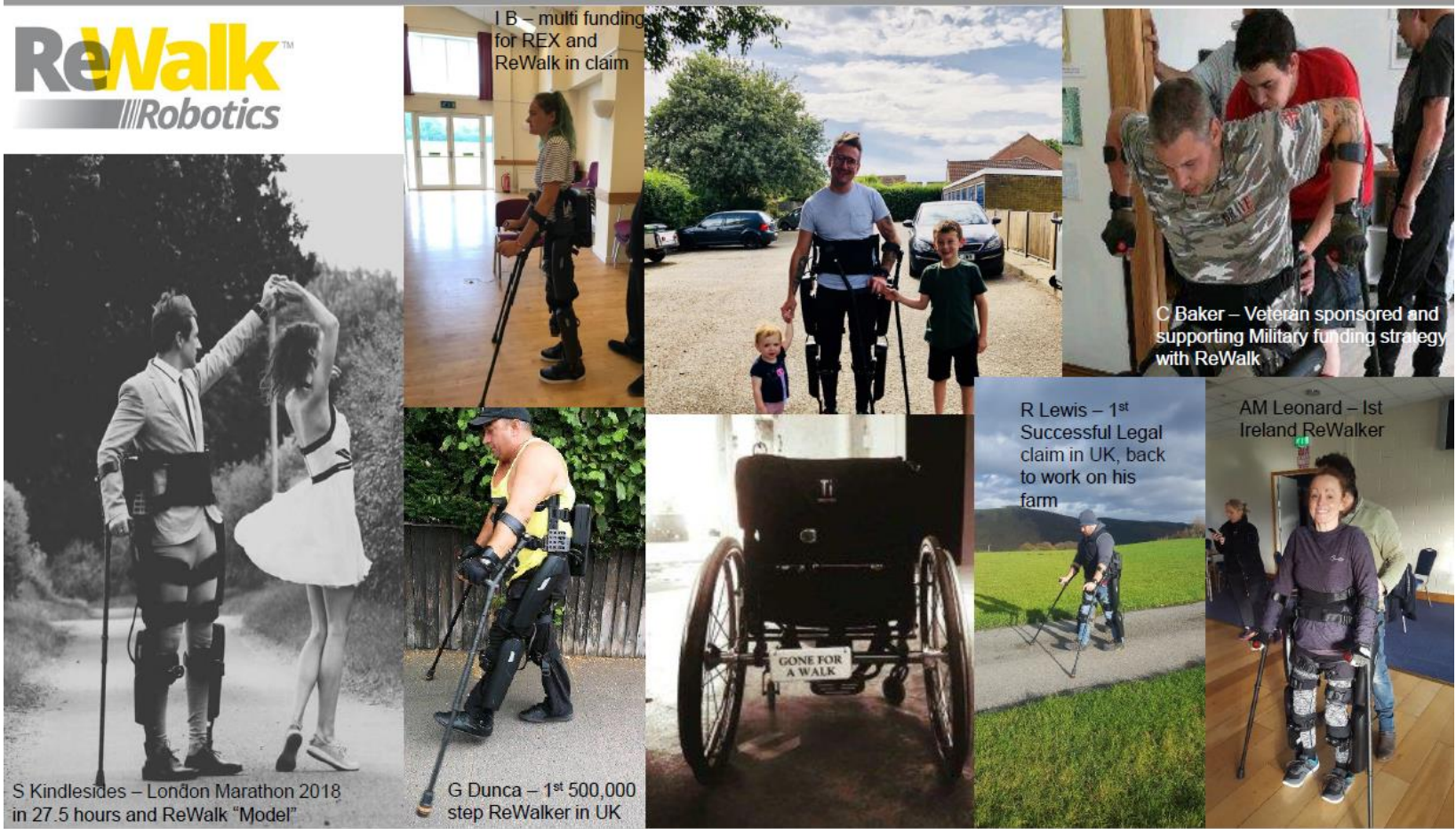
1. Source: <https://www.nscisc.uab.edu/Public/Facts%202016.pdf>

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=d5zl7fgIMgo>



# Refined Reimbursement Strategy

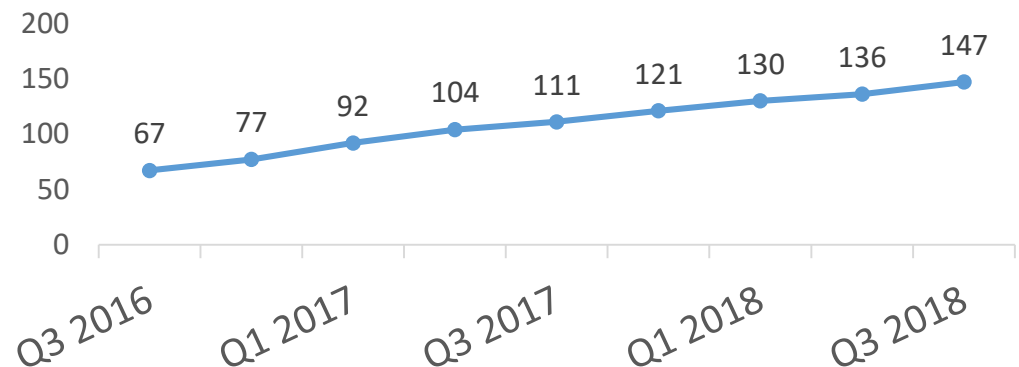
## Coverage Decisions Insurers and Direct

- 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<sup>(1)</sup>

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

(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](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 80,000<sup>1</sup> 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.dgn.org/images/red\\_leitlinien/LL\\_2012/pdf/ll\\_71\\_2012\\_querschnitt/hmung.pdf](https://www.dgn.org/images/red_leitlinien/LL_2012/pdf/ll_71_2012_querschnitt/hmung.pdf). 10 -30 SCI paralyzed individuals per 1 million population

# ReStore - Shaping the Future



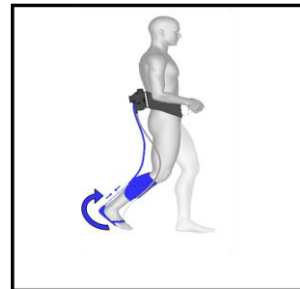
**Leveraging ReWalk's technology and commercial expertise to develop a lightweight, wearable soft exosuit that facilitates a natural gait**

- 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

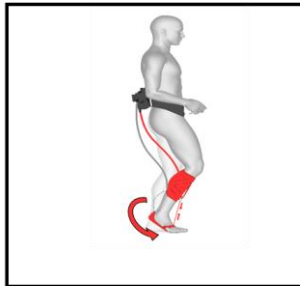
# ReStore in Action



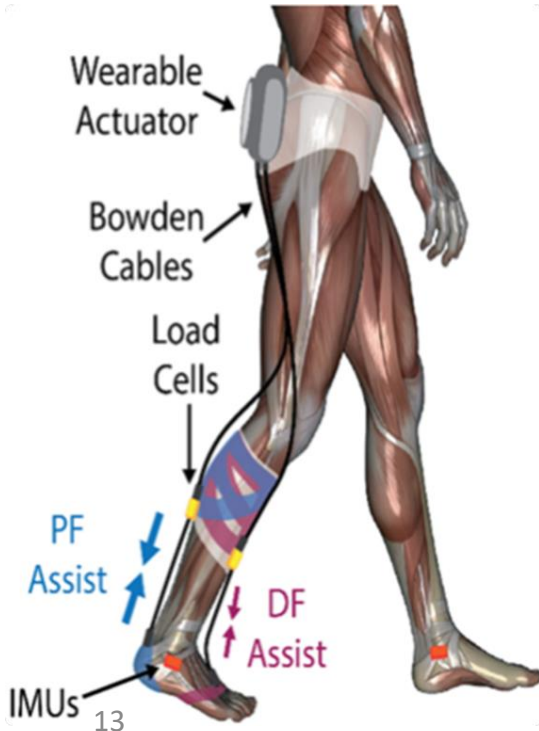
1 Sensors detect gait event



2 Rear cable contracts to provide PF assistance for forward propulsion



3 Front cable contracts to provide DF assistance for swing phase

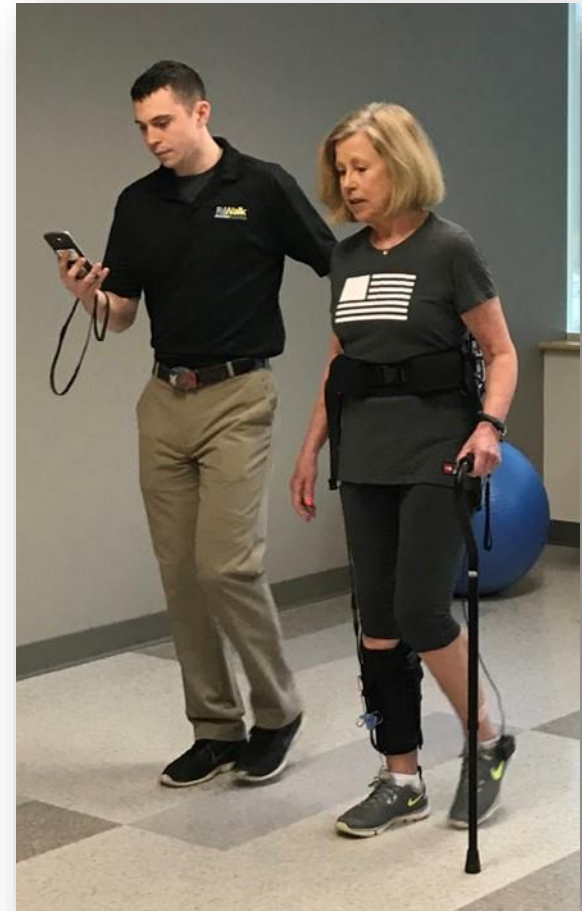
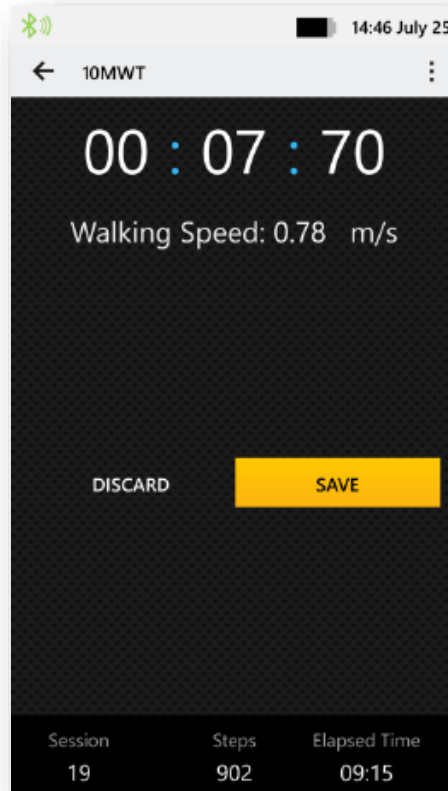
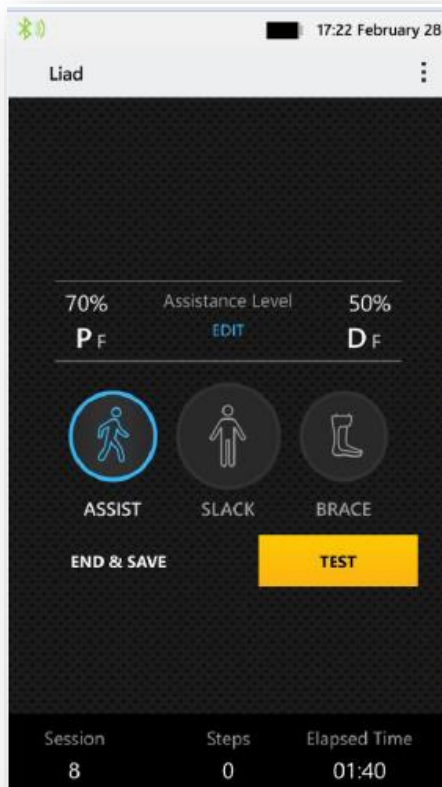


## Key Differentiators

- 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 survivors<sup>1</sup>  
**EU:** 9.6 million stroke survivors<sup>2</sup>  
**China:** 11 million stroke survivors<sup>8</sup>

## Annual Incidence

**US:** ~ 795K<sup>3</sup>  
**EU / Western Europe:** ~ 1.1 million<sup>4</sup>  
**China:** ~ 2.4 million<sup>8</sup>

Eligible  
population  
adjusted by  
physical  
qualifications

## Addressable Market - Prevalence

**US:** 2.5 million<sup>5,6</sup> potentially eligible for ReStore system  
**EU:** 3.4 million<sup>7</sup> potentially eligible for ReStore system  
**China:** 3.9 million<sup>7</sup>

## Annual Addressable Market - Incidence

**US:** ~370K<sup>5, 6</sup>  
**EU:** ~500K<sup>7</sup>  
**China:** ~1.1M<sup>7</sup>



**PHASE I: Top  
Tier Stroke  
Rehab Centers**

**Penetration strategy -**

<b>US</b>	<b>EU</b>	<b>China</b>
1,000 primary stroke centers <sup>9</sup>	1,000 clinics <sup>10</sup>	6,000 Rehab Hospitals <sup>11</sup>

**PHASE II:  
Thousands of  
Hospitals & Physical  
Therapy Clinics**

1. [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3250269/pdf/13311\\_2011\\_Article\\_53.pdf](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/NEJMc043511.

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. <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



**SPAULDING**<sup>TM</sup>  
REHABILITATION NETWORK



# 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**

- Promising prototype in testing at Wyss
- Partners with ankle devices to provide clinicians options
- Potential MS home use, worn under clothes solution

- Leverage ReStore market acceptance to introduce home use model
- Lower cost solutions for ROW Markets

- Q3 2019 EU and US Clearances
- Leverages existing treatment and reimbursement structures

- German Coverage Policy
- VA Study Results
- Expanded US Coverage
- Next Gen Prototypes

**MS/ Stroke- Hip  
Soft Exosuit**

**Stroke Home/ Clinic Low Cost-  
Soft Exosuit**

**Stroke Clinic “ReStore”- Soft Exosuit**

**SCI- Rigid Exoskeleton**

2018

2019

2020

2021

2022

# Strategic Approach – China

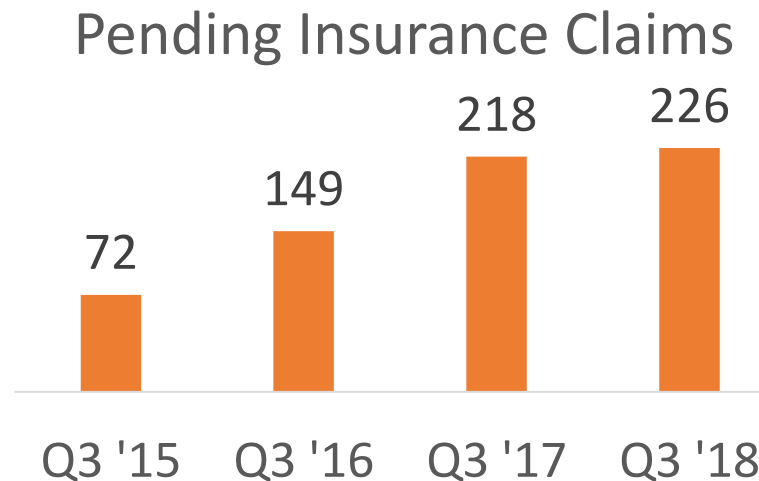
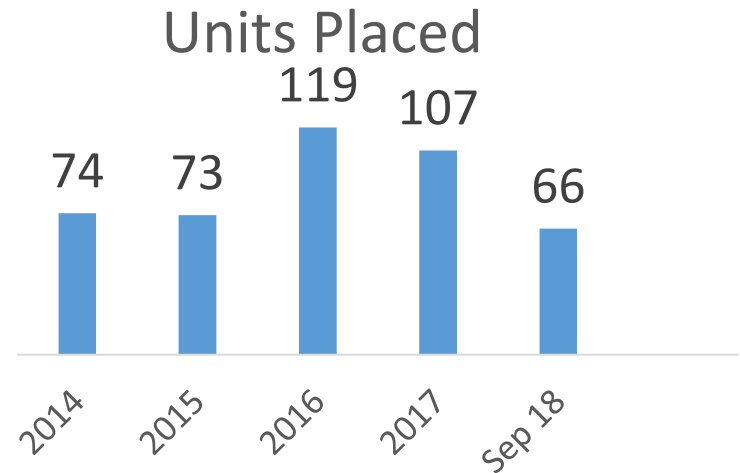
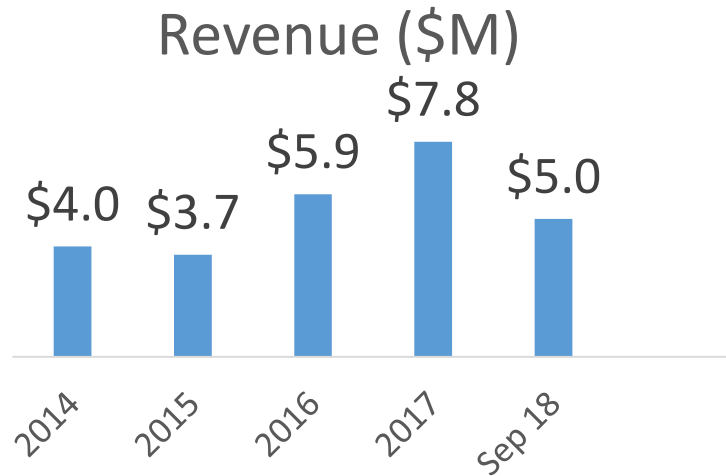
## Developing a platform for accelerated growth in largest single stroke market

- Large market opportunity in China
  - 11 million stroke survivors<sup>1</sup>
  - 2.4 million people suffer a stroke each year<sup>1</sup>
  - 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

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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

