



## Human and Robotic Intersection

UNDERWAY: **Markets** spring into being when economic actors shift resources to that firm's solution

May 2022

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



## Company Overview

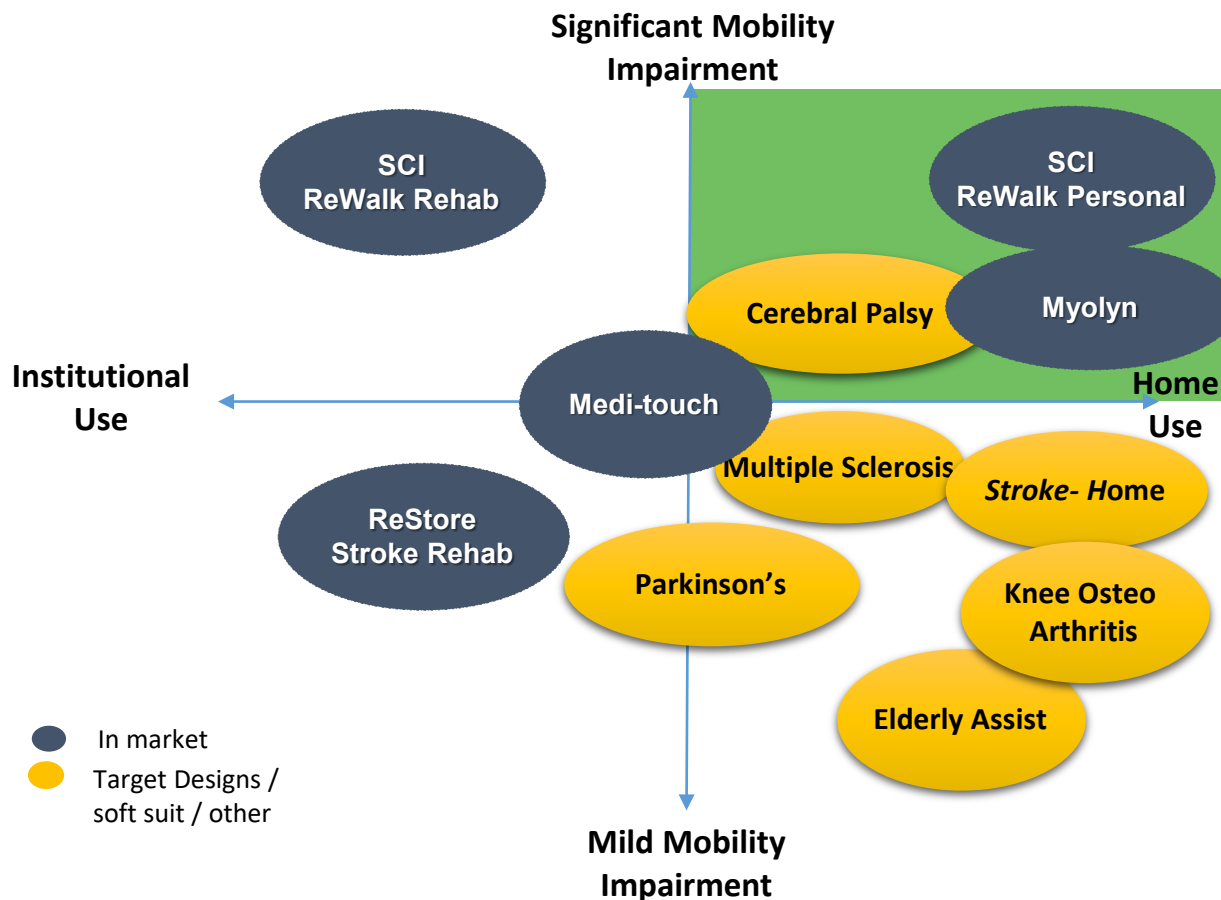
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# Our Mission

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

# Current Portfolio of Target Markets



## Spinal Cord Injury ("SCI")

- U.S prevalence 291,000 patients and 17,730 new cases annually<sup>1</sup>

## Stroke

- ~16,900 rehab centers<sup>3</sup> with 1,000+ US primary stroke centers<sup>2</sup>
- US personal ~500,000<sup>7</sup>

## Knee Osteo Arthritis

- 10% population over 60 up to 40% population over 70<sup>8</sup>

## Multiple Sclerosis

- 1 million MS diagnosis in U.S, 2.3 million worldwide<sup>4</sup>
- 75% will experience significant walking disturbance<sup>5</sup>

## Parkinson's

- 10 million WW Parkinson's patients<sup>6</sup>

1. <https://www.nscisc.uab.edu/Public/Facts%20and%20Figures%202019%20-%20Final.pdf>

2. [https://www.heart.org/idc/groups/heart-public/@wcm/@hcm/@ml/documents/downloadable/ucm\\_455522.pdf](https://www.heart.org/idc/groups/heart-public/@wcm/@hcm/@ml/documents/downloadable/ucm_455522.pdf)

3. Primary + Skilled Nursing facility figures - <https://www.kff.org/other/state-indicator/number-of-nursing-facilities/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>

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

5. 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

6. Parkinson's Disease Foundation

7. See Slide on ReStore Market : Stroke

8. Nature & Nurture in KOA; Magnusson K [PubMed]

# Key Results / Forward Milestones

## 2021

- ❑ German Federal Social Court decision anticipated on direct compensation for disability- [Delayed into 2022](#)
- ❑ German SCI expanded coverage with 2 or more additional supply agreements [Completed!](#)
- ❑ Build on CMS SCI code issuance with applications and progress on coverage contracts – [Built foundational data and infrastructure](#)
- ❑ Expand on National account utilization for our stroke product in the UK and US- [NHS and US national pilots on going](#)
- ❑ Achieve YOY growth with contracts and expanded sales team assuming increasing market access- [36% growth in 2021 vs 2020](#)
- ❑ Pursue breakthrough R&D projects that qualify for CMS coverage under the new MCIT guidelines – [Two Achieved](#)

## 2022

- ❑ Achieve YOY growth with contracts and expanded sales team assuming increasing market access- [Expected to continue with Court ruling, VA opening, CMS, WC](#)
- ❑ New Business Development – [Add one new commercial product line to leverage sales team and shorten path to profitability](#)
- ❑ Advance Medicare benefit category for CMS category, pricing and coverage– [DMEPOS rules issued Dec. 2021; CMS interaction; HCPCS June 8](#)
- ❑ Two FDA submissions to launch in 2022 and 2023 - [expected mid-year and end year](#)
- ❑ Invest in reimbursement infrastructure, product development, market development, investor relations – [On track](#)

# Product Overview - Community / Home Focus

## ReWalk™ Exoskeleton

- Assists individuals with Spinal Cord Injury (“SCI”) to stand and walk
- FDA & CE mark clearance; 6<sup>th</sup> generation - ~630 systems placed to date; 6 years of use
- Reimbursement coverage: VA, Germany, Italy; CMS in progress
- First mover advantage with extensive IP portfolio
- US CMS HCPCS code established



## MYOLYN FES System

- Home exercise with an easier and less expensive electrical stimulation system
- Broader indications offers a solution for a larger pool of veterans within our VA database and synergistic with ReWalk 6.0
- Automatically adjusts resistance/assistance to user ability , easy to use
- Extremely cost-effective compared to competitive products
- FSS Contract in place for VA sales.



# Product Overview - Clinic Focus

## ReStore™ Soft Exo-suit

- Provides functional, intense and repetitive gait training for stroke
- Launched in June 2019 following FDA & CE mark clearance
- Established reimbursement codes for stroke therapy and gait training
- Light wearable highly versatile assistive design with extensive IP portfolio



## MediTouch

- Sensing biofeedback that utilizes Interactive games for balance, range of motion, motor movement and motivation for rehab
- primarily neuro focus strengthens relationships within ReStore “strike zone”
- Personal unit pricing fits well within VA model
- Interface enables tele-therapy visits with remote sensing and evaluation of progress.





# Exo-Suit for Stroke, Multiple Sclerosis, Parkinson's<sup>1</sup>

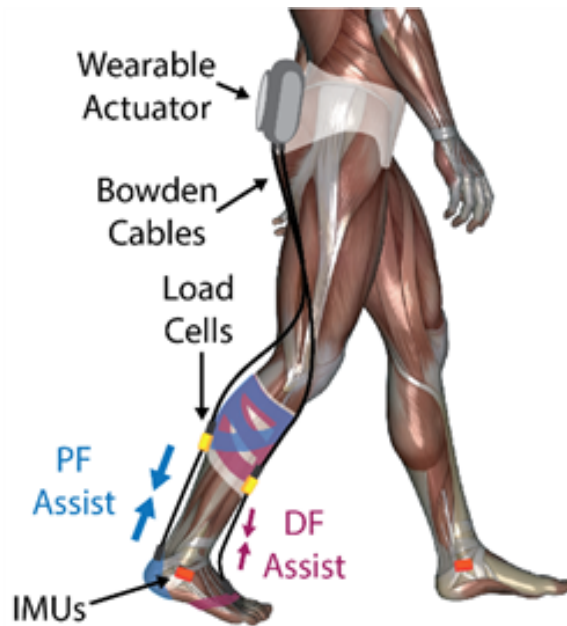
ReWalk™

WYSS INSTITUTE



HARVARD

School of Engineering and Applied Sciences



1. Currently available for Stroke use only following FDA and CE approval in 2019



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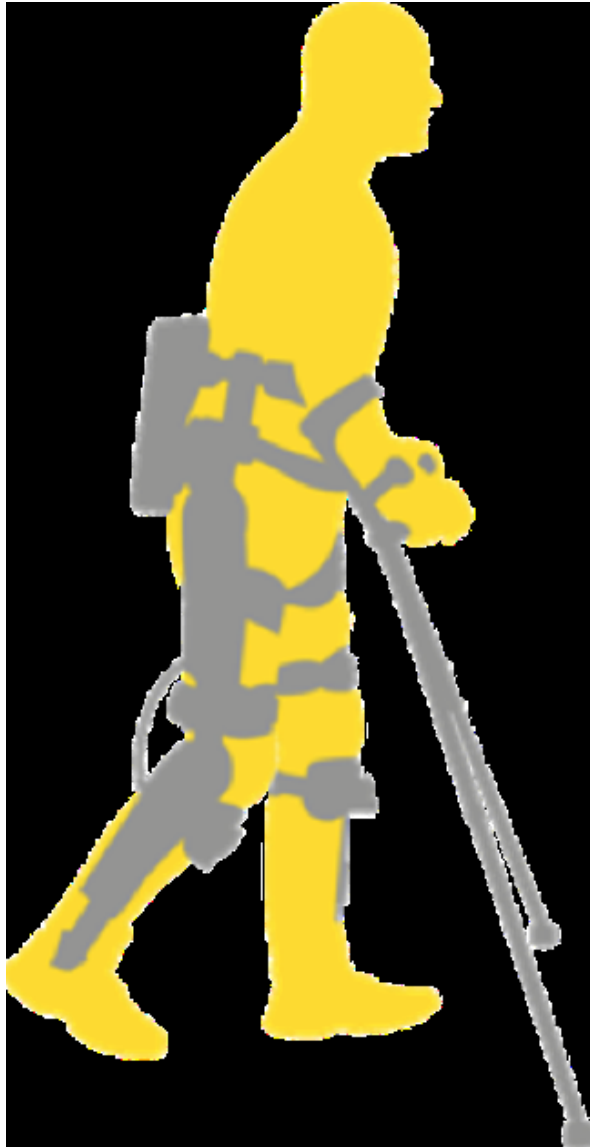


## ReWalk Community Use System

### Version 6.0

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# ReWalk Personal 6.0 System – How it Works

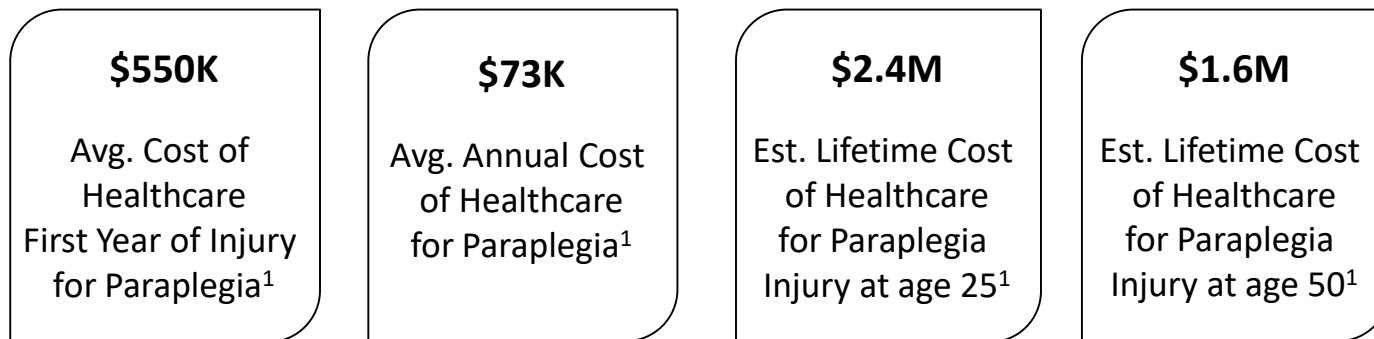


# Spinal Cord Injury Impact: Need for Technical Solutions

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 residences<sup>2</sup>
- VA 160 patient randomized trial expected to be published in the next 12 months and will support safety and quality of life measurements<sup>3</sup>

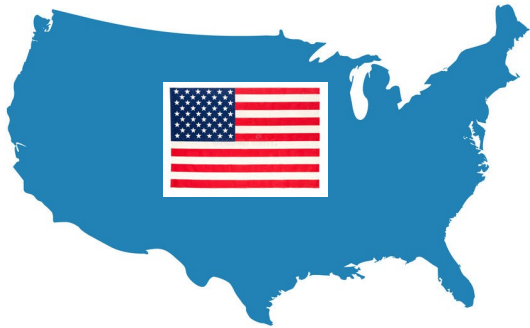
1. Source: <https://www.nscisc.uab.edu/Public/Facts%20and%20Figures%202019%20-%20Final.pdf>

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

3. ExoskCSP #2003 exoskeleton Assisted-Walking in Persons With SCI: Impact on Quality of Life - <https://ichgcp.net/clinical-trials-registry/NCT02658656>

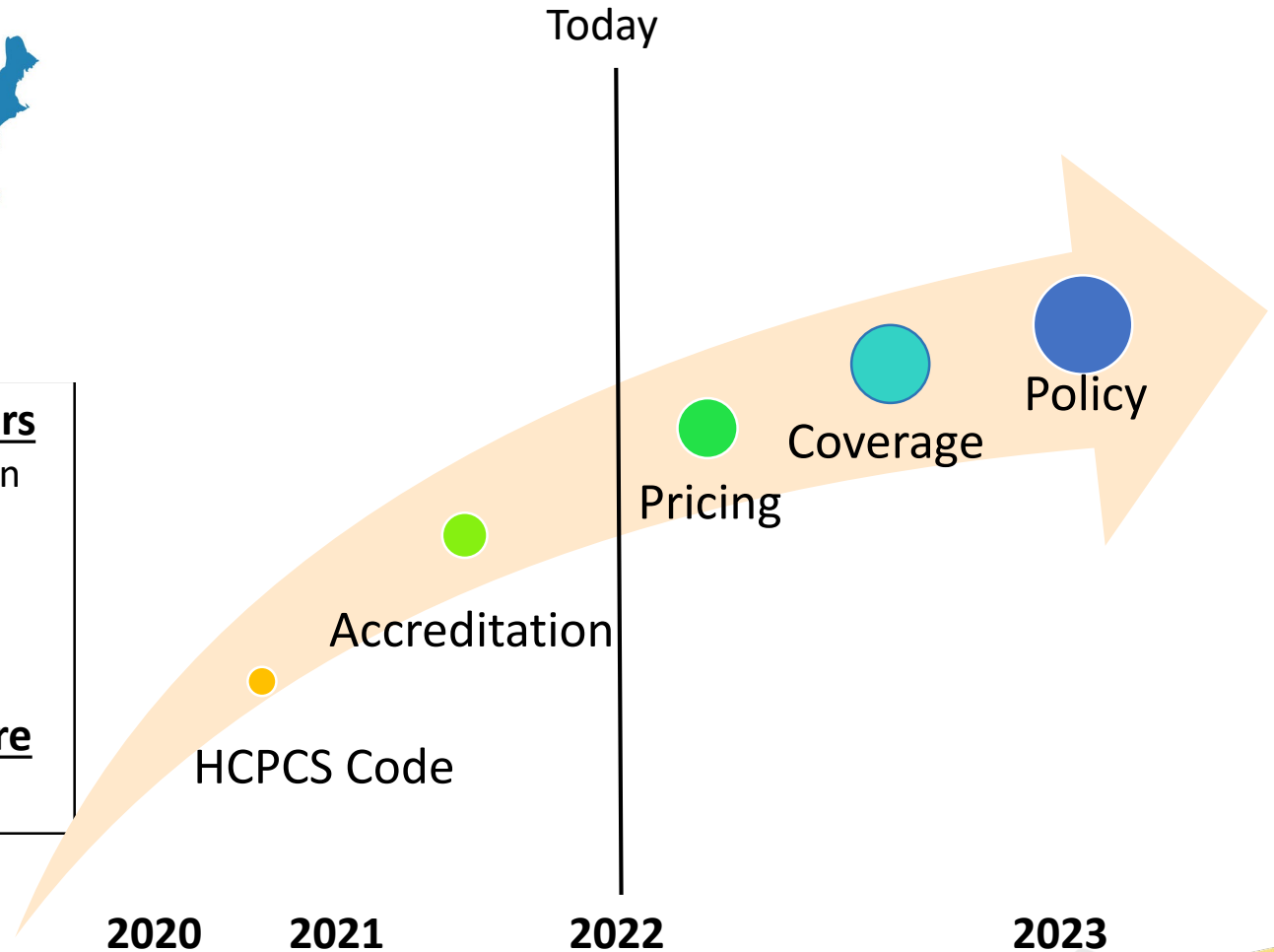
# Roadmap US CMS Coverage

Building blocks: Technology → Data → Codes → Pricing → Coverage



## U.S market by the numbers

- With 33% of the population meet medical criteria  
**>100,000 potential candidates** <sup>1,2</sup>
- **>50% of these patients are covered by Medicare / Medicaid + VA** <sup>3</sup>



1. <https://www.nscisc.uab.edu/Public/Facts%20and%20Figures%202019%20-%20Final.pdf>

2. Based on information from a 2017 report by the NSCISC, 40.6% of the total U.S. population of SCI patients suffered injuries between levels T4 and L5. Three published ReWalk trials with respect to such eligible SCI patients had an aggregate screening acceptance rate of 79% considering all current FDA limitations

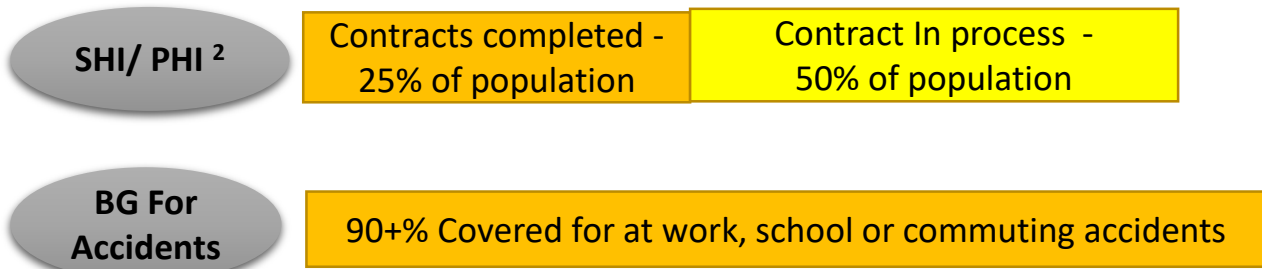
3. <https://www.nscisc.uab.edu/Public/2017%20Annual%20Report%20-%20Complete%20Public%20Version.pdf> (Table 50 as shown in the report)



# German Covered SCI Population is Growing



- With 33% of the population meet medical over **25,000 potential candidates**<sup>1</sup>
- Contracts already completed with payors cover >**25%** of the population = >**6,000 can potentially apply**



- Supreme court ruling expected soon on the definition of exoskeleton as direct or indirect compensation to spinal cord injury disability

1. Source: [https://journals.lww.com/ajpmr/Citation/2017/02001/People\\_with\\_Spinal\\_Cord\\_Injury\\_in\\_Germany.10.aspx#:~:text=Regarding%20the%20paralysis%20level%2C%20there,were%20rarely%20affected%20\(1%25\).&text=Currently%2C%20Germany%20lists%20approximately%2080%2C000,total%20of%2081.1%20million%20inhabitant](https://journals.lww.com/ajpmr/Citation/2017/02001/People_with_Spinal_Cord_Injury_in_Germany.10.aspx#:~:text=Regarding%20the%20paralysis%20level%2C%20there,were%20rarely%20affected%20(1%25).&text=Currently%2C%20Germany%20lists%20approximately%2080%2C000,total%20of%2081.1%20million%20inhabitant)

2. SHI – Statutory Health Insurance/ PHI – Private Health Insurance



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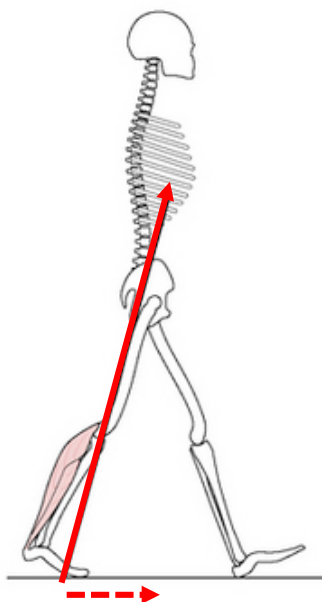


## ReStore Soft Exosuit for Stroke Rehabilitation

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# Breakthrough: Paretic Propulsion

**Paretic Propulsion** = a measure of the contribution of the affected (paretic) limb to advance the body forward during walking, in comparison to the contributions of the unaffected (nonparetic) limb.



- The paretic limb's ability to generate propulsion during walking is a critical determinant of long-distance walking function after stroke<sup>1</sup>
- Rehabilitation techniques that target both plantarflexor function and leg extension may restore paretic limb function and improve gait asymmetries in individuals post stroke<sup>2</sup>

<sup>1</sup>Awad, Louis N et al. "Paretic Propulsion and Trailing Limb Angle Are Key Determinants of Long-Distance Walking Function After Stroke." *Neurorehabilitation and neural repair* vol. 29,6 (2015): 499-508. doi:10.1177/1545968314554625

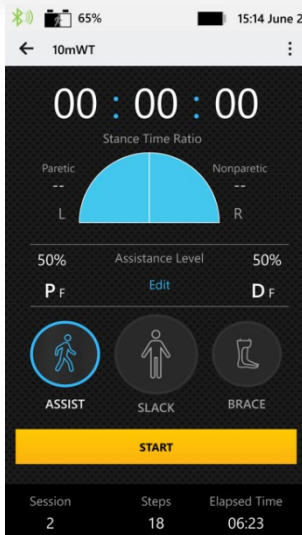
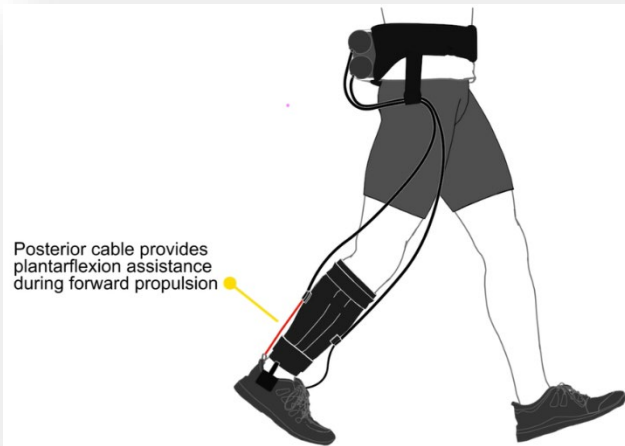
<sup>2</sup>Roelker, Sarah A., et al. "Paretic propulsion as a measure of walking performance and functional motor recovery post-stroke: a review." *Gait & posture* 68 (2019): 6-14.



# ReStore: How It Works

## 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, rapid donning / doffing and adjustment for efficient therapy sessions
- Session data capture with reporting and comparison across sessions



# ReStore Market: Stroke



## Prevalence = 27.6 M

**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 = 4.295 M

**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 = 13.2 M

**US:** 3.3 million<sup>5,6</sup> potentially eligible for ReStore system  
**EU:** 4.6 million<sup>7</sup> potentially eligible for ReStore system  
**China:** 5.3 million<sup>7</sup>

## Annual Addressable Market – Incidence = 2.4 M

**US:** ~500K<sup>5, 6</sup>  
**EU:** ~700K<sup>7</sup>  
**China:** ~1.5M<sup>7</sup>

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

Penetration strategy -  
**US**  
**1,000 primary**  
**stroke centers<sup>9</sup>**  
**EU**  
**1,000 clinics<sup>10</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, 80% lower limb disability rate after stroke- Source: A Review of Robot-Assisted Gait Training in Stroke Patients Ha Yeon Kim Joshua Sung Hyun You

6. Assumptions: for prevalence pool, estimate 40% fall our rate of the 80% with lower limb disability, for the incidence pool assume 80% survival rate – see Long-Term Survival and Function After Stroke by Stefan Sennfalt

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

# ReStore: Position in Market

		ReStore	Rigid Exoskeleton	Manual Therapy	FES Foot Drop System	Treadmill Gait Trainer
Functional	Plantarflexion Training	✓				
	Rapidly & automatically adapts to changes in patient gait	✓			✓	
	Natural Freedom of Movement	✓		✓	✓	
Versatile	Rapid transitions between assisted & unassisted/unrestricted walking	✓		✓	✓	
	Supplemental Support Aids Determined by Patient Needs	✓		✓	✓	
	Compatible with a wide range of functional walking tasks in clinics.	✓				
Data-Driven	Adjustable & Measurable Assistance	✓	✓		✓	✓
	Quantifiable gait metrics	✓	✓			✓



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## Commercialization and Financial Pathway to Breakeven

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# Path to Profitability: Multiple Products and Leveraged Distribution System

**ReWalk plans to grow the SCI, Rigid exoskeleton business through coverage and contracts; develop new soft exo-suit technologies through the Wyss partnership to address other lower limb disabilities; and add other mission related products**

Prototypes of new products completed; moving to project selection with clinical and regulatory planning

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

- Leverage ReStore and ReWalk Personal market acceptance to introduce new products

- Leverages existing treatment and reimbursement structures
- VA Study / Ability-BU Study
- Grow Revenue with device and disposables

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

**Stroke Home / Clinic Low Cost Exo-suit**

**External Products MYOLYN & MediTouch**

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

**SCI- Rigid Exoskeleton**

**2018**

**2019**

**2020**

**2021**

**2022**

**2023**

- In market
- Pipeline – external and soft suit

**Today**

# Investment Highlights

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- Market leading global exoskeleton developer with breakthrough device platforms and various vectors
- Pivotal year for the company and the industry for German and US Coverage progress
- Investing in coverage and implementation once achieved
- Increased VA focus with reopening post covid
- New SCI designs for continuing improvement and leadership as coverage achieved
- New Business Development to leverage operations long term

# Key Financial and Operational Data

<b>Profit and Loss – Key Metrics (in Thousands \$)</b>	<b>Q1 2022 (Unaudited)</b>	<b>Q1 2021 (Unaudited)</b>	<b>2021 (Audited)</b>	<b>2020 (Audited)</b>
<b>Total Revenues</b>	<b>876</b>	<b>1,316</b>	<b>5,966</b>	<b>4,393</b>
Personal unit revenues	770	1,308	4,820	4,220
Rehab Unit Revenues	106	8	1,146	173
Gross Margin %	30%	54%	49%	50%
Operating Expenses (-)	(4,553)	(3,728)	(15,558)	(14,193)
Operating (Loss)	(4,288)	(3,021)	(12,655)	(12,004)

<b>Balance Sheet and Cash flow (in Thousand of \$)</b>	<b>March 31, 2022 (Unaudited)</b>	<b>Dec 31, 2021 (Audited)</b>
Cash and Cash Equivalent	82,632	88,337
Long- and short-term debt (-)	(-)	(-)
Net Cash Used In Operating Activities	(5,708)	(11,469)



# Forward Looking Statements

In addition to historical information, this press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, Section 27A of the U.S. Securities Act of 1933, and Section 21E of the U.S. Securities Exchange Act of 1934. Such forward-looking statements may include projections regarding ReWalk's future performance and other statements that are not statements of historical fact and, in some cases, may be identified by words like "anticipate," "assume," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "future," "will," "should," "would," "seek" and similar terms or phrases. The forward-looking statements contained in this press release are based on 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 ReWalk's control. Important factors that could cause ReWalk's actual results to differ materially from those indicated in the forward-looking statements include, among others: uncertainties associated with future clinical trials and the clinical development process, the product development process and FDA regulatory submission review and approval process; the adverse effect that the COVID-19 pandemic has had and may continue to have on the Company's business and results of operations; ReWalk's ability to have sufficient funds to meet certain future capital requirements, which could impair the Company's efforts to develop and commercialize existing and new products; ReWalk's ability to maintain compliance with the continued listing requirements of the Nasdaq Capital Market and the risk that its ordinary shares will be delisted if it cannot do so; ReWalk's ability to maintain and grow its reputation and the market acceptance of its products; ReWalk's ability to achieve reimbursement from third-party payors, including CMS, for its products; ReWalk's limited operating history and its ability to leverage its sales, marketing and training infrastructure; ReWalk's expectations as to its clinical research program and clinical results; ReWalk's expectations regarding future growth, including its ability to increase sales in its existing geographic markets and expand to new markets; ReWalk's ability to obtain certain components of its products from third-party suppliers and its continued access to its product manufacturers; ReWalk's ability to improve its products and develop new products; ReWalk's compliance with medical device reporting regulations to report adverse events involving the Company's products, which could result in voluntary corrective actions or enforcement actions such as mandatory recalls, and the potential impact of such adverse events on ReWalk's ability to market and sell its products; ReWalk's ability to gain and maintain regulatory approvals; ReWalk's ability to maintain adequate protection of its intellectual property and to avoid violation of the intellectual property rights of others; the risk of a cybersecurity attack or breach of the Company's IT systems significantly disrupting its business operations; ReWalk's ability to use effectively the proceeds of its offerings of securities; and other factors discussed under the heading "Risk Factors" in ReWalk's annual report on Forms 10-K and 10-K/A for the year ended December 31, 2021 filed with the SEC and other documents subsequently filed with or furnished to the SEC. Any forward-looking statement made in this press release speaks only as of the date hereof. Factors or events that could cause ReWalk's actual results to differ from the statements contained herein may emerge from time to time, and it is not possible for ReWalk to predict all of them. Except as required by law, ReWalk undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.



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Thank You!