

# Human and Robotic Intersection

UNDERWAY: <u>Markets</u> spring into being when economic actors shift resources to that firm's solution

March 2021

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# **Company Overview**

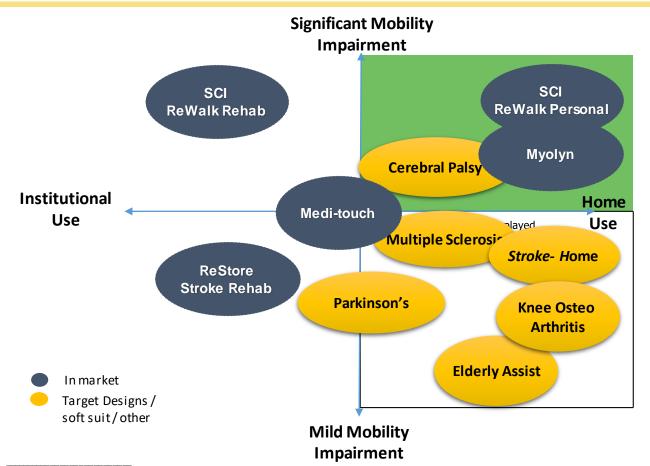
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### **Our Mission**

Fundamentally change the

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

# **Current Portfolio of Target Markets**



- https://www.nscisc.uab.edu/Public/Facts%20and%20Figures%202019%20-%20Final.pdf
- 2. <a href="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/@nl/documents/downloadable/ucm\_455522.pdf</a>
- Primary + Skilled Nursing facility figures <a href="https://www.kff.org/other/state-indicator/number-of-nursing-facilities/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22.%22sort%22:%22asc%22%7D</a>
- 4. <a href="https://www.healthline.com/health/multiple-sclerosis/facts-statistics-infographic">https://www.healthline.com/health/multiple-sclerosis/facts-statistics-infographic</a>
- 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
- Nature & Nurture in KOA; Magnusson K [PubMed]

### **Spinal Cord Injury ("SCI")**

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

### **Stroke**

- ~16,900 rehab centers³ with 1,000+ US primary stroke ctrs²
- ➤ US personal ~500,000 <sup>7</sup>

### **Knee Osteo Arthritis**

➤ 10% population over 60 up to 40% population over 708

### **Multiple Sclerosis**

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

### **Parkinson's**

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

# Key Results / Forward Milestones

### 2020

- ✓ German SCI coverage contracts <u>COMPLETE!</u> = DGUV; TK; DAK; BKK Mobile Oil; 2 others
- ✓ US VA ReWalk randomized study 161
  ENROLLED!, 28 delayed follow up with Covid
- ✓ US CMS HCPCS code application <u>SUCCESSFUL!</u> <u>K1007</u>
- ✓ ReStore stroke system data <u>PUBLISHED! 2 June</u> <u>publications; 14 Topics in NeuroRehab</u>
- ✓ Addition of an external product offering Planned in H2 2020 TWO LAUNCHED!
- ✓ ReWalk sales and field team expanded by > 33%; driver for YOY sales growth <u>TRAINING</u>
   <u>COMPLETE</u>; <u>FULLY OPERATING!</u>

### 2021

- German Federal Social Court decision anticipated on direct compensation for disability
- German SCI expanded coverage with 2 or more additional supply agreements
- Build on CMS SCI code issuance with applications and progress on coverage contracts
- ☐ Expand on National account utilization for our stroke product in the UK and US
- □ Achieve YOY growth with contracts and expanded sales team assuming increasing market access
- ☐ Pursue breakthrough R&D projects that qualify for CMS coverage under the new MCIT guidelines

# 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 ~600 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

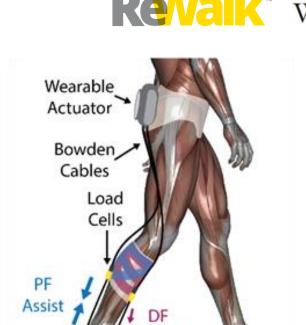
### MediTouch

- 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.



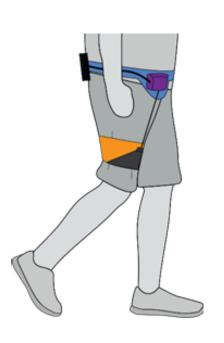


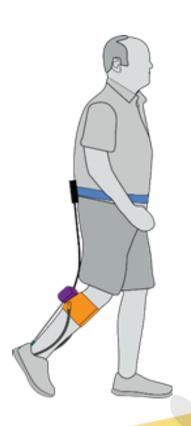
# Exo-Suit for Stroke, Multiple Sclerosis, Parkinson's











**IMUs** 





# 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

#### \$550K

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

### \$73K

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

### \$2.4M

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

### \$1.6M

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

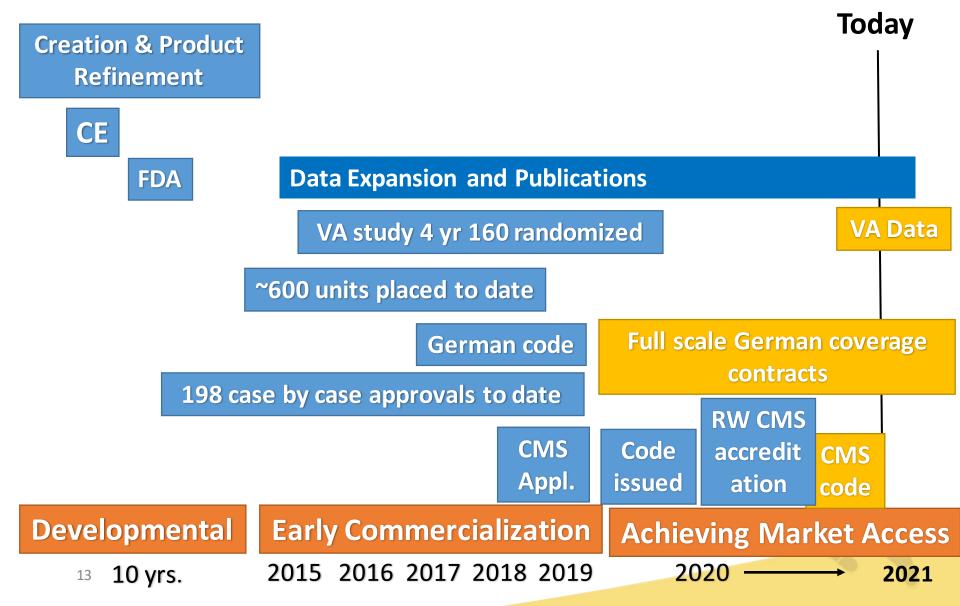
87% of spinal cord injury patients discharged to private, non-institutional residences<sup>2</sup>

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

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

# Spinal Cord Injury: ReWalk Market Creation Status





# SCI Population Covered is Growing



### **United States**

- > SCI Population is ~ 291,000 with 33% of the population meet medical criteria = **97,000** 1,2
- ➤ Incidence SCI 17,730, using metrics qualifies **6,000** new candidates per year
- > Total over **100,000** realizable market
- $\triangleright$  >50% of these patients are covered by Medicare / Medicaid + VA <sup>3</sup>

### Germany

- ➤ Estimates often range between 60,000 80,000⁴ total, using same US estimates = 20,000-26,667 potential candidates
- ➤ Contracts already completed with payors cover >25% of the population = 5,000 Candidates

SHI/ PHI/ Private

Contracts completed - 25% of population

Contract In process - 50% of population

**BG For Accidents** 

90+% Covered for at work, school or commuting accidents

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

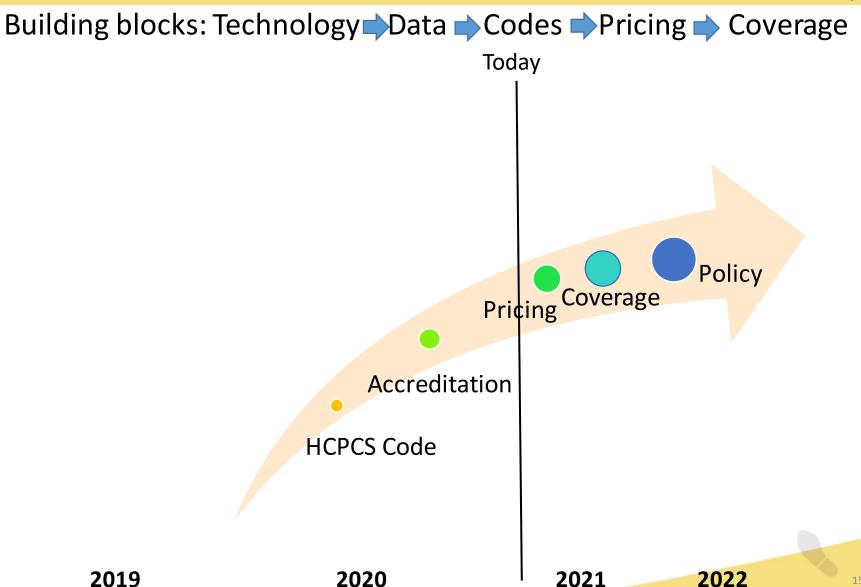
<sup>2.</sup> Based on information from a 2017 report by the NSCISC, 40.6% of the total U.S. population of SCI patients suffered injuries between levels T4 and L5. Three published ReWalk trials with respect to such eligible SCI patients had an aggregate screening acceptance rate of 79% considering all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

<sup>3. &</sup>lt;a href="https://www.nscisc.uab.edu/Public/2017%20Annual%20Report%20-%20Complete%20Public%20Version.pdf">https://www.nscisc.uab.edu/Public/2017%20Annual%20Report%20-%20Complete%20Public%20Version.pdf</a> (Table 50 as shown in the report)

<sup>4.</sup> Source: https://www.dgn.org/images/red\_leitlinien/LL\_2012/pdf/ll\_71\_2012\_querschnittlhmung.pdf. 10 -30 SCI paralyzed individuals per 1 million population 14

# Roadmap US CMS Coverage







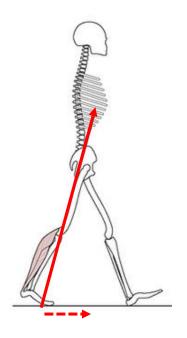


# ReStore Soft Exosuit for Stroke Rehabilitation

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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.

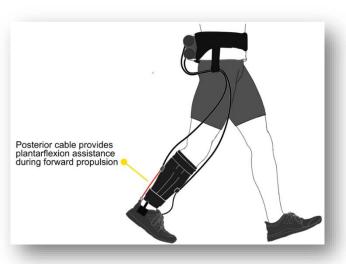


- The paretic limb's ability to generate propulsion during walking is a critical determinant of long-distance walking function after stroke<sup>1</sup>
- Rehabilitation techniques that target both plantarflexor function and leg extension may restore paretic limb function and improve gait asymmetries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

<sup>&</sup>lt;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>&</sup>lt;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.

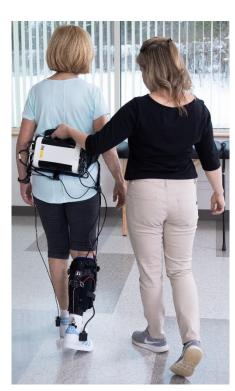
### ReStore: How It Works





### **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

Eligible

population

adjusted by

physical qualifications

#### 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: ~ 795K3

**EU / Western Europe:** ~ 1.1 million4

China: ~ 2.4 million<sup>8</sup>

### 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 -

**EU** 

1,000 primary 1,000 clinics<sup>10</sup>

stroke centers9

US

China

7,000-9,000 clinics by

2021<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
- 2. Extrapolated from the incidence numbers based on the rate for US.
- 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.
- 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
- 11. httl://www.chvxx.com/industry/201609/450634.html

## ReStore: Position in Market

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





# 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 MS/ Promising prototype in testing at Wyss Partners with ankle devices to provide clinicians options Stroke-Hip Potential MS home use, worn under clothes solution **Exo-suit** Stroke Home / Leverage ReStore and ReWalk Personal market **External Products Clinic Low** acceptance to introduce new products **MYOLYN & MediTouch Cost Exo-suit**  Leverages existing treatment and reimbursement structures Stroke Clinic "ReStore" - Soft Exosuit VA Study / Ability-BUStudy • Grow Revenue with device and disposables German Contracts VA Study Results **SCI- Rigid Exoskeleton Expanded US Coverage** Next Gen Prototypes 2022 2020 2019 2021 2018 In market Pipeline-external and soft suit

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## **Investment Highlights**

- Market leading global exoskeleton developer with breakthrough device platforms and various vectors
  - Sales team expanded with experienced capital equipment sales personnel
  - Rigid ReWalk exoskeleton for Spinal Cord Injury market -
    - German insurance contracts -- ReWalking as a standard of care for paralyzed individuals
    - VA study nearing publication / presentation in 2021
    - US CMS code received effective October 1, 2020; Contracts/Policy next target
  - ReStore soft-suit exoskeleton for stroke rehabilitation launched
    - Penetration developing / acceptance increasing
    - Publications from clinical studies
    - New studies underway with the VA; Abilities, BU, others
    - Contract discussions in process with key national rehab centers
  - Myolyn and Medi-Touch lines launched July 1
  - Improved financial results Strengthened cash position, reduced operating expenses; debt paid off Q4 2020

# Key Financial and Operational Data

Profit and Loss – Key Metrics (in Thousands \$)	Q4 2020 (Unaudited)	Q4 2019 (Unaudited)	FY 2020 (Audited)	FY 2019 (Audited)
Total Revenues	1,218	1,181	4,393	4,873
Personal unit revenues	1,141	1,150	4,220	4,674
Rehab Unit Revenues	77	31	173	199
Gross Margin %	33%	61%	50%	56%
Operating Expenses (-)	(3,183)	(3,923)	(14,193)	(16,774)
Operating (Loss)	(2,781)	(3,207)	(14,193)	(14,048)

Balance Sheet and Cash flow (in Thousand of \$)	Dec 31, 2020 (Audited)	Dec 31, 2019 (Audited)
Cash and Cash Equivalent	20,350	16,253
Long- and short-term debt (-)	(-)	(6,965)
Net Cash Used In Operating Activities	(12,589)	(14,815)

### Subsequent Dec 31, 2020 updates

- Closed a \$40 million private placement
- Received \$13.2 million through warrants exercise

See our SEC fillings and press releases for additional information







## Thank You!

## 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, including the intended use of net proceeds from the private placement, 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: 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 Nasdag 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 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 repay its secured indebtedness: 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 expectations as to the results of, and the Food and Drug Administration's potential regulatory developments with respect to its mandatory 522 postmarket surveillance study; 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 establish a pathway to commercialize its products in China; the impact of substantial sales of the Company's shares by certain shareholders on the market price of the Company's ordinary shares; ReWalk's ability to use effectively the proceeds of its offerings of securities; the risk of substantial dilution resulting from the periodic issuances of ReWalk's ordinary shares; the impact of the market price of the Company's ordinary shares on the determination of whether it is a passive foreign investment company; market and other conditions; and other factors discussed under the heading "Risk Factors" in ReWalk's annual report on Form 10-K for the year ended December 31, 2020 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, Re Walk undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.