



Human and Robotic Intersection

September 2019



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### Our Mission

Fundamentally change the

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

### **Current Product Overview**

### **ReWalk™ Rigid Exoskeleton**

- Assists individuals with Spinal Cord Injury ("SCI") to stand and walk
- > FDA & CE mark clearance; 6<sup>th</sup> generation
- ➤ Reimbursement: VA, Germany, Italy, 2 major US insurances case by case
- First mover advantage with extensive IP portfolio

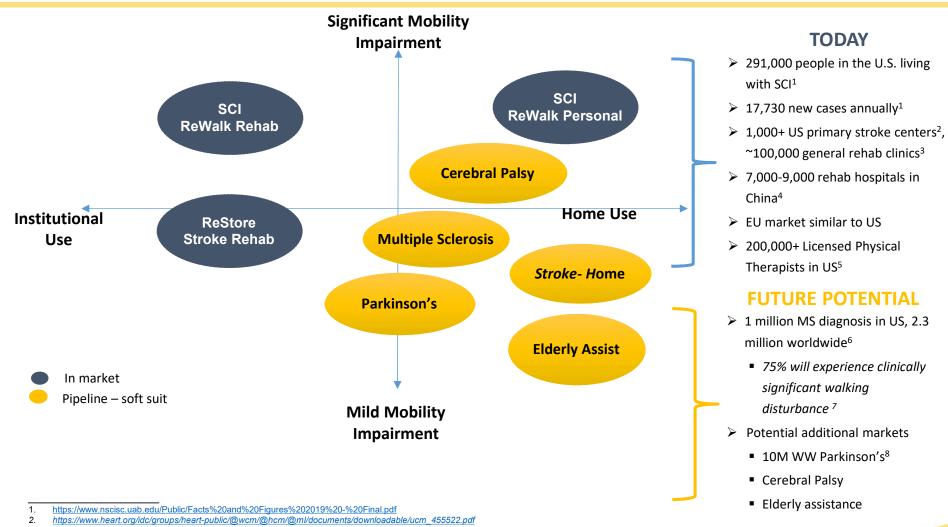
### **ReStore™ Soft Exo-suit**

- Functional natural gait training for stroke
- ➤ Launched in June 2019 following FDA & CE mark clearance
- Reimbursement for stroke therapy and gait training established
- ➤ Light wearable highly versatile assistive design with extensive IP portfolio





### Target Market Applications for Technologies



<sup>3. &</sup>lt;a href="https://www.ibisworld.com/industry-trends/market-research-reports/healthcare-social-assistance/ambulatory-health-care-services/physical-therapists.html">https://www.ibisworld.com/industry-trends/market-research-reports/healthcare-social-assistance/ambulatory-health-care-services/physical-therapists.html</a>

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

http://www.apta.org/WorkforceData/ModelDescriptionFigures/

<sup>6. &</sup>lt;a href="https://www.healthline.com/health/multiple-sclerosis/facts-statistics-infographic">https://www.healthline.com/health/multiple-sclerosis/facts-statistics-infographic</a>

<sup>.</sup> 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

Parkinson's Disease Foundation

### 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>

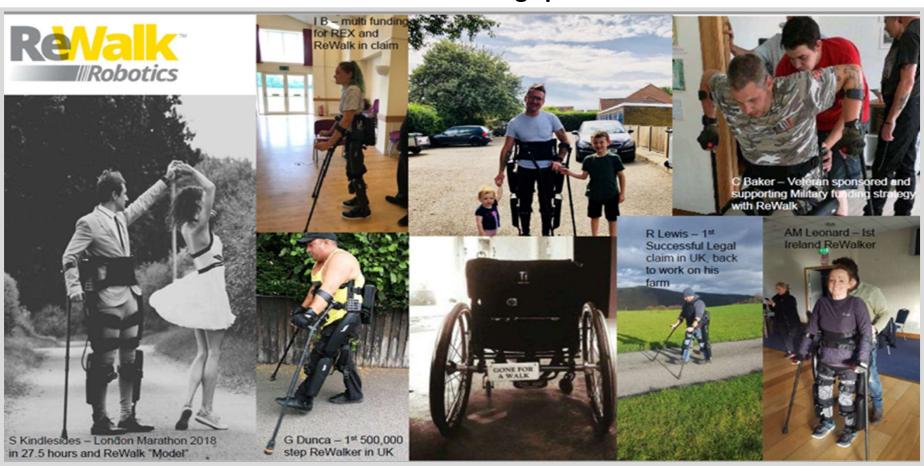
87% of spinal cord injury patients discharged to private, non-institutional residences<sup>2</sup>

<sup>1</sup> Source: https://www.nscisc.uah.edu/Public/Eacts%20and%20Figures%202019%20\_%20Final.nd

Source: https://www.nscisc.uab.edu/public/2016%20Annual%20Report%20-%20Complete%20Public%20Version.pd

### ReWalk Personal 6.0 System – How it Works

### Patented tilt-sensor technology that provides more natural gait and functional walking speed

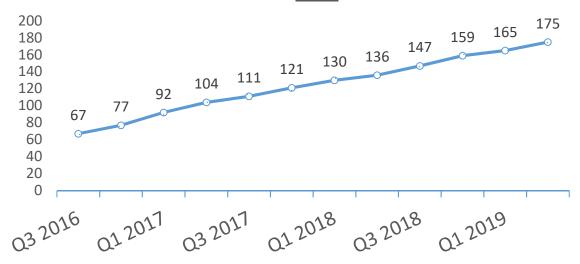


### Reimbursement Advances for Exoskeletons

### **US Coverage Status**

- <u>Cigna</u> revised its policy in 2019 and will now review submissions on a case-by-case basis to consider providing coverage based on medical criteria
- VA SOP updated in June 2018 with new Veterans Choice Program to optimize coverage

### WW Cumulative Units Reimbursed as of June 30, 2019



#### **Germany**

- Secured near universal coverage in Germany with the inclusion of the ReWalk P6.0 in the Medical Aid list
- In discussion with different payers on frame contracts

As of June 30, 2019 42 different
U.S payors and 37 different
German payors have approved
the ReWalk Personal 6.0 on a
case-by-case basis

### US - Strong Partnership With the VA



### ReWalk is Reimbursed Under a National Coverage Policy

Scope	<ul> <li>First national coverage policy released on December 2015 and was updated on June 2018<sup>(1)</sup></li> </ul>				
	<ul> <li>Covers evaluation, training and issuance of ReWalk exoskeletons for personal usage</li> </ul>				
Market	<ul> <li>~44,000 Paralyzed Individuals are eligible for VA Benefits<sup>(2)</sup></li> </ul>				
Process	<ul> <li>Evaluation – Up to 24 potential SCI "Hub" Centers<sup>(3)</sup></li> </ul>				
	<ul> <li>Training is available under the VA "Choice" program through -</li> </ul>				
	<ul> <li>Trained VA "Spoke" sites<sup>(4)</sup></li> </ul>				
	<ul> <li>Up to 121 certified ReWalk training centers<sup>(5)</sup></li> </ul>				

### VA Research Study – Future Support for Coverage Decisions

Scope	<ul> <li>Large multi-center community-based exoskeleton study<sup>(6)</sup></li> <li>Evaluating quality of life and health benefits of walking</li> </ul>
Study size	<ul> <li>160 SCI veterans (120 participants already enrolled)</li> <li>Duration: 4 years (Started in August 2016, completion expected in 2020)</li> </ul>
ReWalk	Once completed the study can support future reimbursement coverage decision
benefits	<ul> <li>Study participants can receive a unit for personal usage once they complete the study</li> </ul>

<sup>(1)</sup> Link to the updated policy - https://www.sci.va.gov/docs/VA Exoskeleton Clincal Protocol 6-7-18.pdf

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

<sup>(3)</sup> https://www.sci.va.gov/VAs SCID System of Care.asp. Out of the 24 sites, 21 Hub centers are ReWalk certified as of Dec 31, 2018.

<sup>(4) 5</sup> VA "spoke" sites were trained as of June 30, 2019

<sup>(5) 121</sup> certified ReWalk non-VA centers across the US .See further details on the Choice program eligibility criteria - https://www.va.gov/COMMUNITYCARE/providers/info VCP.asp.

<sup>(6)</sup> ExoskCSP #2003 exoskeleton Assisted-Walking in Persons With SCI: Impact on Quality of Life - https://ichgcp.net/clinical-trials-registry/NCT02658656

## Germany - 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 <u>any</u> 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 –

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



- Finalize contracts with two of the major payors until the end of 2019; these groups have 56 open claims in the pipeline
- As of June 30, 2019 there are a total of <u>126</u> claims in the pipeline
- Process the current 20 in-trial and pending cases = potential revenues of \$2 million

### Exo-suit Creation and Development



### **License Agreement**

- ReWalk has licensed all Soft-suit IP for all medical applications
- Exclusive and Worldwide
- Term for life of IP (> 20 years)
- Royalty payments to Harvard on all sales

### **Collaboration Agreement**

- Directed collaboration for designated research between Wyss / Harvard and ReWalk
- ReWalk funds staff at Harvard
- 6-year term with renewals
- Parallel direct agreement with
   Prof. Walsh as a ReWalk consultant

## Exo-suits: ReStore – Shaping the Future of Stroke Therapy



- Provides coordinated plantarflexion and dorsiflexion assistance to facilitate a natural gait
- > Rapid, automatic adaptation to patient's gait
- Versatile for "main street" clinics
- > Data driven
- Disposable elements provides recurring revenue stream
- ➤ Published clinical data through Harvard / Wyss; FDA study 5 of top 10 US research centers

### ReStore: How It Works

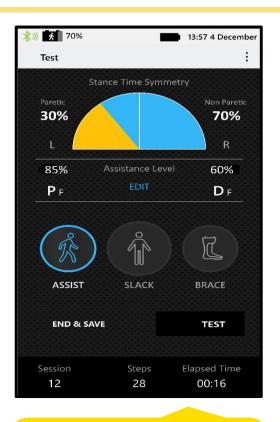
# Restore



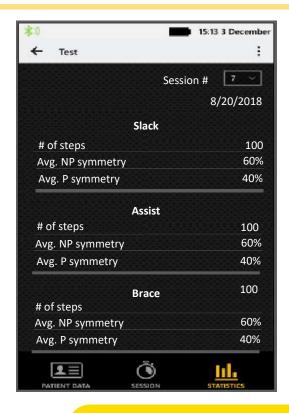
### **Key Differentiators**

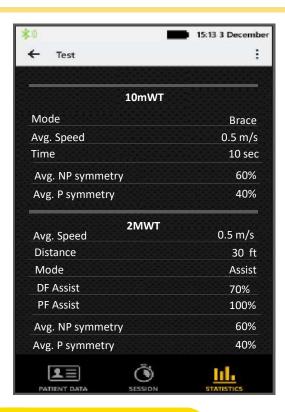
- ➤ Light, soft components and powered dorsi / plantar flexion facilitate natural gait pattern
- Provides therapist real-time analytics and enhanced session control for optimized results
- Multiple modes of function, rapid donning/ doffing and adjustment for efficient therapy sessions
- Session data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

### Restore: Real Time Analytics and Control



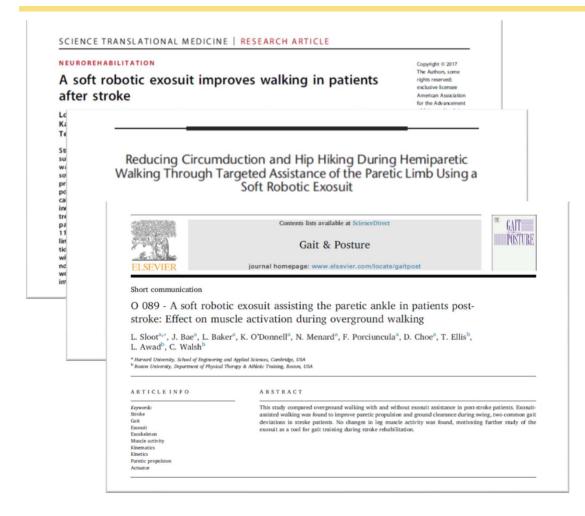
- Three modes of activation
- Real time adjusted assistance level
- Built in test sessions





- Variery of statistics to support patient progress -
  - Assistance level , Symmetry
  - Distance
  - Steps
  - Speed

### Clinical Exo-Suit Data (Harvard Studies)



### **Highlighted Findings:**

- Improved forward propulsion symmetry [1]
- Reduction in metabolic burden associated with post-stroke walking [1]
- Improved ankle dorsiflexion angle during swing phase [1]
- Reductions in compensatory behaviors including paretic hip hiking and circumduction [2]
- Reductions in atypical EMG activity during early stance for a subset of stroke participants [3]
- No evidence of reduction in muscle activity for DF or PF during swing and push-off with exosuit-assisted walking in stroke participants [3]
- [1] Awad, Louis N., et al. "A soft robotic exosuit improves walking in patients after stroke." Science translational medicine 9.400 (2017): eaai9084.
- [2] Awad, Louis N., et al. "Reducing Circumduction and Hip Hiking During Hemiparetic Walking Through Targeted Assistance of the Paretic Limb [3] Using a Soft Robotic Exosuit." American journal of physical medicine & rehabilitation 96.10 (2017): S157-S164.
- [3] Sloot, L., et al. "O 089-A soft robotic exosuit assisting the paretic ankle in patients post-stroke: Effect on muscle activation during overground walking." Gait & posture (2018).

### 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), 10meter walking test (10MWT)

#### Design:

- 40 patients; 7 sessions (1 fitting evaluation, 5 treatment, 1 testing)
- 5 of top stroke research centers in the US

#### Results and Feedback:

- Study completed in December 2018
- Primary end point was safety
  - No device related serious adverse events
  - No falls or loss of balance noticed during device use
- A majority increased their walking speed from first to the seventh visit.
  - 63.9% of patients experiencing an improved baseline comfortable walking speed and 77.7% of patients experiencing an improved baseline maximal walking speed after only 7 sessions

#### **Research Partners**











### 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: ~ 795K<sup>3</sup>

EU / Western Europe: ~ 1.1 million<sup>4</sup> China: ~ 2.4 million<sup>8</sup>

#### Addressable Market – Prevalence = 9.8 M

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 = 2 M

US: ~390K<sup>5, 6</sup> EU: ~540K<sup>7</sup> China: ~1.1M<sup>7</sup>

## PHASE I: Top Tier Stroke Rehab Centers

### Penetration strategy -

US

EU

China

1,000 primary 1,000 clinics<sup>10</sup> stroke centers<sup>9</sup>

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.
- 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, 2005DOI: 10.1056/NEJMcp043511.
- 6. Assumptions: for prevalence pool, estimate 40% fall our rate of the 60% with lower limb disability, for the incidence pool assume 82% survival rate see https://www.cdc.gov/stroke/facts.htm
- 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 and increase patient scheduling flexibility

#### **Improved Standard of Care**

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

#### **Enhanced Facility Marketing and Patient Retention**

• Current technology in competitive marketplace, attract clients and staff, price point is accessible for satellite and regional clinics

#### **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 Clinic Setting and Situation

Our 2019 target is to penetrate 40 accounts by year end

### 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				$\sqrt{}$	
	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.					
	Adjustable & Measurable Assistance		$\sqrt{}$		$\sqrt{}$	$\sqrt{}$
	Quantifiable gait metrics	$\sqrt{}$				$\sqrt{}$

Clinics seek versatile and easy to use tools so their staff can gain proficiency and avoid having to purchase and dedicate training time to multiple technologies

### 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>
  - 62% of the Chinese stroke population can not walk independently after stroke<sup>2</sup>
  - China's medical rehabilitation industry is estimated to reach 100 billion yuan (\$14.4 billion) in annual sales by 2023<sup>3</sup>
  - Number of stroke rehabilitation centers in China expected to exceed those in the US and EU combined by 2021<sup>4</sup>
- Currently in discussion with regional strategic partners with one at advanced stage

<sup>1.</sup> 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

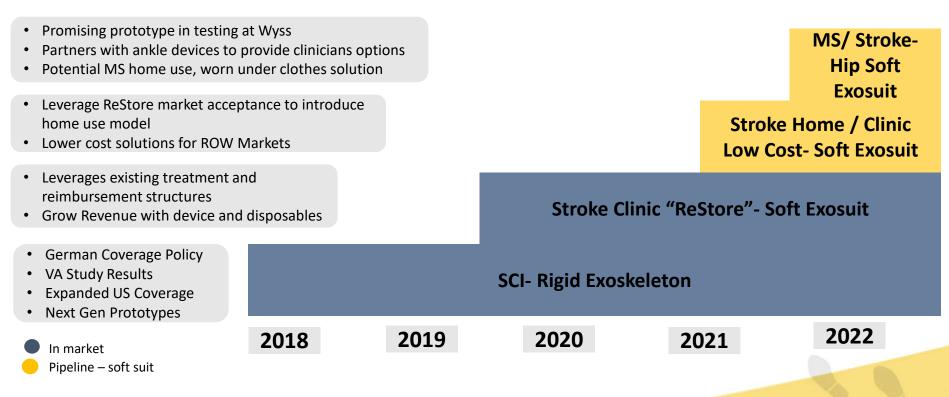
<sup>2.</sup> https://www.omicsonline.org/open-access/stroke-rehabilitation-in-china-today-2329-9096-S3-005.php?aid=24035

<sup>3.</sup> http://global.chinadaily.com.cn/a/201811/26/WS5bfb4c20a310eff30328afaa.html

<sup>4.</sup> http://www.chyxx.com/industry/201609/450634.html

## 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 exo-suit technologies through the Wyss partnership to address other lower limb disabilities and create a broad portfolio of solutions



### **Investment Highlights**

- Market leading global exoskeleton developer with two breakthrough device platforms and various vectors to growth -
  - Rigid ReWalk exoskeleton for Spinal Cord Injury market -
    - 500+ systems placed, with majority for home and community use; other systems used in rehab centers
    - **German market growth** potential shown in Q4 2018 with highest revenue in Europe since inception of **\$1.24M**
    - US Market gaining momentum on securing vast reimbursement coverage with VA multi-center study ending in 2020 and recent Cigna policy change
  - ReStore soft-suit exoskeleton for stroke rehabilitation launched-
    - High Value device intended to become the workhorse of a clinic with a recurring revenue stream
    - Build strong pipeline to support future growth
    - China represents a major opportunity for ReStore
  - Improved financial results Strengthened cash position, improved margins, reduced operating expenses and cash burn
  - R&D With Research performed in Harvard & Development in Israel we can increase our product portfolio
  - Extensive IP owned and licensed on both product lines

### Key Financial Data

Profit and Loss (in Thousands of \$)	H1 2019 (Unaudited)	H1 2018 (Unaudited)	FY 2018 (Audited)	FY 2017 (Audited)
Revenue	2,458	3,349	6,545	7,753
SCI - Units Placed	27	44	85	107
ReStore – Units Placed	1	-	-	-
Gross Margin %	55%	43%	43%	40%
Operating expenses (-)	(9,171)	(12,567)	(22,039)	(25,093)
Operating (Loss)	(7,810)	(11,118)	(19,214)	(21,992)
Balance Sheet and Cash flow (in Thousand of \$)	June 30, 2019 (Unaudited)	Dec 31, 2018 (Audited)	_	
Cash and Cash Equivalent	24,054	9,546		
·	21,031	3,3 .0		
Long and Short-Term Debt (-)	(7,866)	(8,687)		

# Take the Next Step

