

# for the Six Months ended September 30, 2022

CYBERDYNE, Inc. November 14, 2022







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**CYBERDYNE**, Inc.

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## SDGs for Society5.0/5.1



**CYBERDYNE**, Inc.

**Consolidated financial statements** 



## **Consolidated financial results (IFRS)** Year-on-year comparison for the six months ended September 30, 2022

# **Revenue: 1,542M (+87% YoY)** Operating profit: ¥-442M (Improved 39M YoY) Final profit: ¥268M (Improved by 696M YoY)

## (Unit: Millions of yen)

	FY2021 Q1+Q2	FY2022 Q1+Q2	+/-
Revenue (Gross profit)	825 (619)	1,542 (989)	+717 <sup>*1</sup> (+370)
Operating profit	-481	-442	*2 +39
Profit before tax	-389	*3 *4 373	+763
Profit attributable to owner of the parent	-428	268	+696





## **Consolidated financial results (IFRS) Performance trends**

# [Q2 results] Revenue +78% profit 27M (in black)

<b>Consolidated statement</b>	FY2021		FY2022		Quarter o	n Quarter	Year o	n Year
of profit or loss	Q2	Q1	Q2	Q1-Q2	+/-	+/-%	<b>+/-</b>	+/-%
Revenue	445	751	791	1,542	+39	+5.2%	+346	+77.7
Cost of sales	103	261	292	553	+31	+11.8%	+189	+183.1
Gross profit	342	490	499	989	+9	+1.7%	+157	+45.9
R&D expenses	162	151	182	333	+31	+20.4%	+19	+12.0
Other SG&A	390	568	594	1,162	+25	+4.4%	+203	+52.2
Other income/ expenses	12	51	12	63	-38	-75.5%	+0	+2.3
Operating profit	-198	-178	-264	-442	-86	-	-66	
Finance income/ expense	21	541	134	675	-408	-75.3%	+113	+539.7
Other	53	9	132	140	+123	+1436.9%	+79	+148.0
Profit before tax	-124	372	1	373	-370	-	+126	
Profit attributable to owner of the parent	-152	241	27	268	-215	-89.0%	+178	





(Unit : Millions of yen)



## **Consolidated financial results (IFRS)** by types of transaction

## Increase service sales by acquiring treatment service locations in the U.S.



FY2021 Q1+Q2 FY2022 Q1+Q2





6

Income from treatment services of RISE Group in the U.S., etc.

### Sales revenue from Acoustic X\* sold outside Japan, etc.

\*Acoustic X : Photoacoustic Imaging device using LED Light array

Increase of HAL rented outside Japan Revenue from sleeping app, etc.



Service: Revenue from service at a point of time

Sales: Revenue from sales at a point of time

Rental and maintenance: revenue over time

## Number of operating units

## Growth of Medical Lower Limb Type (overseas) and Single Joint Type (domestic) rentals

	Product classification	FY2021 Q1+Q2	FY2022 Q1+Q2	(Ratio)
	HAL Lower Limb Type (Medical)	269	<b>328</b> * <sup>1</sup>	40%
For Hospitals (improving function)	HAL Lower Limb Type (Non-medical)	94	90	11%
	HAL Single Joint Type	60	<b>90</b> *2	11%
Care support and well-being	HAL Lumbar Type	131	118	14%
Labor Support HAL Lumbar Type		55	35	4%
Cleaning/disinfection/transportation robot		27	26	3%
Other		37	<b>134</b> * <sup>3</sup>	16%
	Total	672	820	100%

## (Unit: Millions of yen)

#### \*1 HAL Lower Limb Type (Medical)

The main factors of the increase in sales were from APAC and Europe

### \*2 HAL Single Joint Type

The main factors of the increase in sales were Japanese hospitals

#### \*3 Subscription fee from JUKUSUI Sleeping app

Due to M&A in the previous fiscal year







## **Consolidated financial results (IFRS)** by geographical region

## Siginificant increase of oversea sale (22% to 53% of total revenue)



APAC : Asia-Pacific \* Revenue from Japan is stated separately





# Ref) by geographical regions and type of transaction

FY2022 - Q1+Q2 (FY2021 - Q1+Q2)	Rental	Sales	Service	Total
Japan	<b>562</b>	<b>57</b>	<b>106</b>	<b>726</b>
	(526)	(32)	(87)	(645)
Americas	14	<b>17</b>	491	522
	(10)	(0)	(0)	(10)
EMEA	86	0	41	127
	(44)	(0)	(31)	(76)
APAC	158	9	0	167
	(93)	(1)	(0)	(94)
Total	820	83	639	1,542
	(672)	(34)	(119)	(825)





## **Profit Structure: Rebalancing Business Structure for Growth**



![](_page_9_Picture_4.jpeg)

![](_page_9_Picture_5.jpeg)

CYBERDYNE, Inc.

**Outline of the business** 

## Realization of Techno-peer Support Society, Where human and technology lives together and supports each other

## Promote innovation that "leaves no one behind"

Maintain and manage their health even in old age and exercise their long-cultivated abilities to the fullest even if they have a disability due to a decline in physical functions caused by disease, accident, or aging, they can live with a higher degree of independence.

![](_page_11_Figure_3.jpeg)

## → Create "Cybernics Industry", a new industry that follows Robot and IT Industry

![](_page_11_Picture_5.jpeg)

## Cybernics Technology: Innovative core technology of Cybernics Industry

![](_page_12_Figure_1.jpeg)

### **\*Cybernics:**

New academic field that fuses and combines cross-disciplinary fields. It is centered around humans, robots, and information systems, as well as other fields.

![](_page_12_Picture_4.jpeg)

## Integrated Cybernics System : Fusion of "Human" + "Cyber/Physical Space"

![](_page_13_Picture_2.jpeg)

Realization of physical and informational interaction with 'people' to solve various issues in a super-aging society Create a "Cybernics Industry" for people and society, focusing on medical care, welfare, daily life, workplace, and production

![](_page_13_Picture_5.jpeg)

![](_page_13_Picture_6.jpeg)

# Main business model

![](_page_14_Picture_1.jpeg)

CYBERDYNE

# CYBERDYNE

## **For individuals** (B to C)

# Service

- HALF
- \*1 Includes revenue from sales and maintenances
- \*2 Includes revenue from rental

![](_page_14_Picture_10.jpeg)

![](_page_14_Picture_11.jpeg)

![](_page_14_Picture_12.jpeg)

![](_page_14_Picture_13.jpeg)

![](_page_14_Picture_14.jpeg)

## **C-Startup : Innovation ecosystem to create Cybernics Industry**

![](_page_15_Figure_1.jpeg)

![](_page_15_Picture_2.jpeg)

![](_page_15_Picture_7.jpeg)

# **Cybernics Medical Innovation Base**

## Creation of new treatment with Cybernics Treatment combined with regenerative medicine and drug discovery

![](_page_16_Picture_2.jpeg)

### (Schedule)

2022/3	Main building completed
2022/9	Additional interior work in progress
2023/1	Scheduled to start occupancy

![](_page_16_Picture_5.jpeg)

![](_page_16_Picture_6.jpeg)

Kingsky Front Tonomachi, Kawasaki New base with a view to global expansion (Directly connected to Haneda Airport)

![](_page_16_Picture_8.jpeg)

![](_page_16_Picture_9.jpeg)

![](_page_16_Picture_10.jpeg)

![](_page_16_Picture_11.jpeg)

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[Medical] Cybernics Treatment

![](_page_17_Picture_3.jpeg)

## [Medical] Cybernics Treatment (functional improvement/rehabilitation treatment)

## Cybernics Treatment: Innovative method utilizing HAL for treating brain-nerve-musculoskeletal disorders

![](_page_18_Picture_2.jpeg)

HAL Lumbar Type

![](_page_18_Picture_5.jpeg)

![](_page_18_Picture_6.jpeg)

### HAL Single Joint Type

#### HAL Lower Limb Type

![](_page_18_Picture_9.jpeg)

![](_page_18_Picture_10.jpeg)

![](_page_18_Picture_19.jpeg)

# **Development pipeline**

Target disease	Product Development	Clinical Trial (Exploratory)	Clinical Trial (Validation)
Neuromuscular Disease (8 types of disease such as ALS)			
Spastic paraplegia (HAM etc.)			
Spinal Cord Injury			
Stroke			
Cerebral Palsy			
Multiple Sclerosis			
Parkinsons' Disease			

The above situation encompasses HAL products (Lower Limb Type and Lumbar Type).

![](_page_19_Figure_3.jpeg)

**Conducting pilot research** 

Conducting pilot research

![](_page_19_Picture_7.jpeg)

![](_page_19_Picture_12.jpeg)

## Status of approvals by diseases and countries

## Significant progress in medical devices in the U.S., Europe, and Asia

## [HAL for Medical Use Lower Limb Type]

		Stroke	Spinal Cord Injury	Neuromuscular disease*
Japan		(Discussing the result of the clinical trial)	Planning clinical trial	<b>Approved</b> (expand the approval for Medical HAL to treat HTLV-1-related myelopathy and hereditary spastic paraplegia)
	USA	Approved	Approved	Approved
	EU	Approved	Approved	Approved
EMEA	Saudi Arabia	Approved	Approved	Approved
Turkey		Approved	Approved	Approved
	Malaysia	Approved	Approved	Approved
	Indonesia	Approved	Approved	Approved
	Thailand	Approved	Approved	Approved
APAC	Taiwan	(application in progress)	Approved	(application in progress)
	Singapore	Approved	Approved	Approved
	Australia	Approved	Approved	Approved

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\*Spinal muscular atrophy, spinal and bulbar muscular atrophy, amyotrophic lateral sclerosis, Charcot-Marie-Tooth disease, distal muscular dystrophy, inclusion body myositis, congenital myopathy, muscular dystrophy

![](_page_20_Picture_7.jpeg)

As of October 28, 2022

![](_page_20_Picture_9.jpeg)

![](_page_20_Picture_10.jpeg)

## **Oversea expansion of HAL**

![](_page_21_Figure_2.jpeg)

![](_page_21_Picture_4.jpeg)

# Malaysia (1)

## Public Social Security System Accelerates Cybernics Treatment Penetration in Malaysia

## 98 HALs rented for a fee at **10 facilities in Malaysia**

## More locations to be added in the future

### **SOCSO (Malaysian Public Social Security Organization)**

SOCSO has four functions: disability pension, survivor's pension, medical coverage and occupational injury coverage, and is compulsory for Malaysian and foreign workers in Malaysia to join the program. It provides medical compensation, disability compensation, funeral benefits, child support and nursing care benefits for illness or injury that occurs while commuting to and from work.

![](_page_22_Picture_6.jpeg)

![](_page_22_Picture_7.jpeg)

As of October 28 2022

![](_page_22_Picture_10.jpeg)

# Malaysia (2)

## Largest medical complex in Southeast Asia "National Centre for Neuro-Robotics and Cybernics"

## SOCSO constructs "National Neuro-Robotic and Cybernics Centre" in the northern region of Malaysia

![](_page_23_Picture_3.jpeg)

![](_page_23_Picture_4.jpeg)

#### National Centre for Neuro-Robotics and Cybernics

It is being built in Bandar Meru Raya, a new area being developed in Ipoh, Perak, northern Malaysia. It is expected to cover an area of 37 hectares, and will be the largest medical complex in Southeast Asia operated by SOCSO, with the capacity to provide comprehensive treatment to about 700 patients at the same time for a certain period of time.

Schedule June 2022 Begin construction End of 2024 complete construction

![](_page_23_Picture_8.jpeg)

![](_page_23_Picture_9.jpeg)

# Singapore

# Installed to the largest medical institute in Singapore (Singapore General Hospital)

1) Obtained medical approval for HAL Lower Limb (December 2020) 2) Ships out HAL to Singapore General Hospital (July 2022)

![](_page_24_Picture_3.jpeg)

![](_page_24_Picture_4.jpeg)

## **Singapore General Hospital**

The hospital is the first and largest hospital in Singapore. It provides affordable specialist care for patients, training for doctors and other healthcare professionals, and research to bring better care to its patients. Every year, the SGH Campus caters to over 1 million patients. With a 10,000strong workforce, SGH accounts for about a quarter of the total acute hospital beds in the public sector and about one-fifth of acute beds nationwide.

![](_page_24_Picture_7.jpeg)

- Singapore General Hospital
- SingHealth

![](_page_24_Picture_10.jpeg)

# Turkey

# Gradually installs 36 units of HAL to private medical center (Diagenics)

# 1st shipment towards Diagenics Medical Center completed (July 2022)

![](_page_25_Picture_3.jpeg)

![](_page_25_Picture_4.jpeg)

![](_page_25_Picture_5.jpeg)

## Diagenics

The Diagenics Group was established to provide Precision Medicine through the comprehensive use of innovative medical technologies, including Cybernics Treatment utilizing HAL, Stem-cell therapy, and epidural stimulation therapy.

![](_page_25_Picture_8.jpeg)

![](_page_25_Picture_9.jpeg)

![](_page_25_Picture_23.jpeg)

## Neuromuscular Diseases

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![](_page_26_Picture_2.jpeg)

# 進行性神経筋難病:市販後使用成績調査の結果

# Performance test suggests high efficacy and safety

![](_page_27_Picture_2.jpeg)

## Ambulatory function remained above level at the beginning of the treatment over long duration

Distance covered in 2 min walk (Rate of change from the level before HAL Treatment)

![](_page_27_Figure_5.jpeg)

\*Due to its progressive nature, typically ambulatory function will decline over time

Target disease: Spinal muscular atrophy, spinal and bulbar muscular atrophy, amyotrophic lateral sclerosis, Charcot-Marie-Tooth disease, distal muscular dystrophy, inclusion body myositis, congenital myopathy, muscular dystrophy

![](_page_27_Picture_8.jpeg)

Safety

![](_page_27_Picture_9.jpeg)

![](_page_27_Figure_11.jpeg)

Reduced damage to the muscle tissue

#### \*Conventional exercise therapy will accelerate the damage on the muscle tissue

# **Amyotrophic Lateral Sclerosis (ALS)**

## Journal showing the long-term walking function maintenance effect of medical HAL for the intractable ALS

## Key points

Published journal

Name: Internal Medicine volume 61 (2022) 10 (May 15, 2022)

Title: Effects of Long-term Hybrid Assistive Limb Use on Gait in Patients with Amyotrophic Lateral Sclerosis Author: Harumi Morioka, Kiyoko Murata, Tatsuki Sugisawa, Mari Shibukawa, Junya Ebina, Masahiro Sawada, Sayori Hanashiro, Junpei Nagasawa, Masaru Yanagihashi, Takehisa Hirayama, Masayuki Uchi, Kiyokazu Kawabe, Satoru Ebihara, Yoshitaka Murakami, Takashi Nakajima, Osamu Kano DOI Number: 10.2169/internalmedicine.8030-21

URL: <u>https://www.jstage.jst.go.jp/article/internalmedicine/61/10/61\_8030-21/\_pdf/-char/ja</u>

![](_page_28_Picture_9.jpeg)

![](_page_28_Picture_10.jpeg)

## All three subjects showed improvement on all three occasions before and after the HAL treatment The average 2-minute walk distance remained higher than before the start of treatment at 300 days

# Progressive spinal cord disease: expansion of indications

## Additional indications: HTLV-1-associated myelopathy (HAM) and hereditary spastic paraplegia (approved)

## **Existing indication (2015/11)**

#### **Progressive neuromuscular diseases (8 diseases)**

- 1. Spinal and bulbar muscular atrophy
- 2. Amyotrophic lateral sclerosis,
- 3. Spinal muscular atrophy
- 4. Charcot-Marie-Tooth disease
- 5. Inclusion body myositis
- 6. Distal muscular dystrophy
- 7. Congenital myopathy
- 8. Muscular dystrophy

Cybernics Treatment promotes the regeneration of neurological function in many diseases. It improves gait instability and functional disability caused by progressive intractable diseases for which no effective treatment has been established

![](_page_29_Figure_13.jpeg)

![](_page_29_Picture_14.jpeg)

# **Establishing Cybernics Treatment as standard treatment**

# Information added on the Intractable Disease Information Center HP

Intractable Disease	Name of intractable diseases	Intractable Disease Information Center	Intractable Disease	Associated Medical Society
No.		(For general users)	(Summary, diagnostic criteria,	etc.) (Guideline)
1	Spinal and Bulbar Muscular Atrophy	Available		
2	Amyotrophic Lateral Sclerosis	Available		
3	Spinal Muscular Atrophy	Available		Available
10	Charcot-Marie-Tooth Disease	Available	Available	
15	Inclusion Body Myositis	Available		
18	Distal Muscular Dystrophy			
26	Congenital Myopathy		Group will c	ontinue to coordinate
30	Muscular Dystrophy	Available	with associa targ	eting doctors
111	Spinal and Bulbar Muscular Atrophy			
113	Amyotrophic Lateral Sclerosis	Available		

Under the support and guidance of the Ministry of Health, Labor and Welfare, the Intractable Disease Information Center provides patients with intractable diseases, their families, and medical professionals with information necessary for their medical care and treatment on its website https://www.nanbyou.or.jp

As of October 28 2022

![](_page_30_Picture_5.jpeg)

![](_page_30_Figure_6.jpeg)

## Information magazine for patients with intractable diseases

-3. 中島孝, 宇都昆宏太, 脳神経内利2019.90(2): 154-160

## Published a magazine to support patients with progressive neuromuscular diseases and their families

![](_page_31_Picture_2.jpeg)

Medical Supervisor: Takashi Nakajima, Neurologist

![](_page_31_Figure_4.jpeg)

#### HALって何だろう

生体電位信号と重心や関節角度 **青龗を開時に処理し、自然なタイミングで** パワーユニットを駆動させアシストします。

体を励かそうとすると躍で指令信号が発生し、その信号は 生体電位信号となり体の各部位へと伝達される

膨から始まりHALのアシストを介して脳へと戻る インタラクティブなバイオフィードバック(iBF) ループ(※)を構築し、低い運動負荷で繰り返し運動 することで、適切な脳神経系の繋がりが強化・調整さ れていきます。

![](_page_31_Figure_12.jpeg)

![](_page_31_Picture_13.jpeg)

![](_page_31_Picture_14.jpeg)

**CYBERDYNE Inc.** 

## **Spinal Cord Injury**

![](_page_32_Picture_3.jpeg)

## **Spinal Cord Injury: Clinical Trials by German Insurance Authorities**

## Clinical trials to be conducted on the premise of German public medical insurance coverage

## G-BA (German Federal Joint Committee) decides to conduct clinical trials under the premise of insurance coverage

G-BA approves Cybernics Treatment as the standard of care to be considered for spinal cord injury patients (in accordance with §137eSGB V of the Study Regulations) G-BA itself decides to conduct a clinical trial (the clinical trial will be covered by public health insurance for Cybernics Treatment in advance). The results of the clinical trial are expected to be included in the German public medical insurance system.

## **G-BA Preparing Protocol Framework for Clinical Trials**

2022/06 G-BA solicits public comments on the protocol framework

## 2022/07 CYBERDYNE submits comments

G-BA (Federal Joint Committee): Organization at the federal level that determines basic benefits, prices, standards, etc. for German insurance treatment. §137e SGB V (Trial Regulation): A system under which the G-BA conducts its own initiated clinical trials and makes final evaluations of promising treatments that could become the standard of care.

![](_page_33_Picture_9.jpeg)

![](_page_33_Picture_10.jpeg)

![](_page_33_Picture_11.jpeg)

![](_page_33_Picture_14.jpeg)

# Stroke

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![](_page_34_Picture_2.jpeg)

# Target diseases: Stroke

## Significant difference was observed for comparison of 6 min walking distance

- 6 min walking distance (important secondary endpoint: recommended by PMDA) : superiority of HAL group was suggested. The dispersion is less likely to influence the result and it achieved p<0.022
- and the result did to achieve p<0.05

As a result of the analysis based on the data of 49 patients, excluding 3 patients who had major accidents in their daily life during the trial period, the amount of change was larger in the HAL group than in the control group, and the difference was statistically significant.

The opinion of the study coordinator that the 6-minute walking distance is an appropriate assessment "Although walking speed improves in both compensatory and physiological walking, distance measured tends to increase in physiological walking but not in compensatory walking. As HAL is thought to remover physiological walking, evaluation of walking distance could have been more suited for this trial. It was reasonable that the 6minute walking distance showed good results."

Target patient : 49\*\* acute stage stroke patient who have reached "plateau" state of improvement Method : Patient was separated into control group and HAL treatment group and result was compared after 20-25 session without wearing HAL **Result : Average improvement of walking distance before and** after the intervention was Control group : 17.34 ± 4.68 m HAL Treatment group: 34.10 ± 5.23 m

**Control group : 80 min conventional rehab** HAL Treatment : 60 min conventional rehab +20 min HAL Treatment)

10m walking speed (primary endpoint): Result suggest greater improvement of HAL Group, but due to the number of cases, effect of dispersion remained

![](_page_35_Figure_10.jpeg)

![](_page_35_Picture_11.jpeg)

# Status of medical device application for stroke

The <u>clinical significance</u> and <u>statistical significance of the primary endpoints</u>, which are considered the most important evaluation points of the clinical trial results, are being discussed with the authorities with the <u>study coordinating physicians and statistical experts</u>.

## Point (1) Clinical significance

In this clinical trial, the <u>HAL Group consistently showed greater improvement than the control group in</u> <u>all endpoints, etc</u>. Therefore, if HAL therapy is applied to stroke hemiplegia patients whose recovery is stalled by conventional rehabilitation, clinically and statistically effective improvement can be expected.

## Point (2) statistical significance of the primary endpoints

In this trial, the p-value did not reach 0.05 due to the effect of variance and other factors in the analysis results of the <u>primary endpoint of 10m maximum walking speed</u>, but the efficacy of HAL treatment should be considered based on the overall effect of clinically meaningful improvement (\*).

The ASA (American Statistical Association) statement also states the principle that "scientific conclusions and business and policy decisions should not be based solely on whether a p-value exceeds a certain value (significance level)."

![](_page_36_Picture_7.jpeg)

**CYBERDYNE**, Inc.

![](_page_37_Picture_2.jpeg)

![](_page_37_Picture_3.jpeg)

# **Neuro HALFIT**

## Program to improve brain-nerve-musculoskeltal function at Robocare Center

![](_page_38_Picture_2.jpeg)

## HAL Lumbar Type

![](_page_38_Picture_4.jpeg)

![](_page_38_Picture_5.jpeg)

## lackaltal function at Pohooaro Contor

HAL Single Joint Type

HAL Lower Limb Type

![](_page_38_Picture_9.jpeg)

![](_page_38_Picture_10.jpeg)

## Robocare Center: Nationwide expansion of Neuro HALFIT

## Expansion of hubs in the medical healthcare service business for individuals

![](_page_39_Figure_2.jpeg)

![](_page_39_Picture_3.jpeg)

# HAL care prevention program

## **Care prevention program (Kanagawa Mirai MIBYO Cohort Study)**

Interim evaluation results of short-term intervention twice a week for a total of 10 sessions

<b>Evaluation item</b>	<b>Before HAL</b> (Mean±SD)	<b>After HAL</b> (Mean±SD)	Improvement rate	P-valu
10m walk (walking speed m/sec)	1.04±0.22	1.45±0.25	39%	<b>&lt;0.001</b> <sup>°</sup>
Locomotiv 5 check *Signs of motor unit deterioration	8.15±2.48	3.96±3.15	105%	<b>&lt;0.001</b> <sup>°</sup>

Subject n=80 people (Average age : 74.8 ± 4.3 years old)

![](_page_40_Picture_7.jpeg)

## Significant improvement in mobility functions (daily activities such as standing, walking, running, sitting) of the elderly

![](_page_40_Picture_9.jpeg)

![](_page_40_Picture_10.jpeg)

Research and development of nursing care prevention programs utilizing healthcare robots

![](_page_40_Picture_13.jpeg)

CIERERDYNE

![](_page_40_Picture_14.jpeg)

![](_page_40_Picture_15.jpeg)

## [Healthcare] Neuro HALFIT at Home (for individuals in the life stage)

## Prevents the need for care by improving the function of the brain-nerve-muscular system through daily training at home

![](_page_41_Picture_2.jpeg)

HAL is data-linked with the Cyberdyne Cloud, which visualizes biopotential signals that command body movements and posture information, etc. This system enables the wearer to obtain visual feedback and allows the trains to customize a program for each user based on the results of data analysis.

![](_page_41_Picture_4.jpeg)

Image of use

Image of HAL Monitor

![](_page_41_Picture_7.jpeg)

42

(C) CYBERDYNE

![](_page_42_Picture_0.jpeg)

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Strategy for growth

![](_page_42_Picture_3.jpeg)

# Image of growth scenario

![](_page_43_Picture_1.jpeg)

## **Reinforcing existing business**, pioneering new field (evolution of the business model, M&A)

[Progress of Business in the first half of the fiscal year]

- RHG (USA): Trial of New Service by HAL Begins
- RHG (USA): Expansion to 21 locations in Southern California

## **Expanding existing business** (expanding usage, business towards individual users, etc.)

[Progress of Business in the first half of the fiscal year]

- Robocare Business: Expansion to 18 facilities in Japan
- Neuro HALFIT at Home: Partnership with home-visiting service providers

## **Developing the business base** (Expanding product lineup, obtaining regulatory approvals in each countries)

[Progress of Business in the first half of the fiscal year]

- Start of new medical fees for medical-use HAL (volume calculation, increased points)
- Additional indications for HAM, etc. (medical device approval)
- Germany prepares clinical trial protocols for public medical insurance.
- New introduction of HAL in Turkey and Singapore

![](_page_43_Picture_16.jpeg)

![](_page_43_Picture_17.jpeg)

(C) CYBERDYNE

![](_page_43_Picture_18.jpeg)

![](_page_43_Picture_19.jpeg)

![](_page_43_Picture_20.jpeg)

# Future of medical healthcare and healthy life

![](_page_44_Figure_2.jpeg)

# **Cybernics Medical Healthcare System**

![](_page_45_Picture_2.jpeg)

physical function at home

Seamless data linkage between hospitals, facilities, homes, and workplaces with IoH/IoT

![](_page_45_Picture_5.jpeg)

![](_page_45_Picture_6.jpeg)

![](_page_45_Picture_7.jpeg)

![](_page_45_Picture_8.jpeg)

# **Medicalcare Pit**

# Efficient Cybernics Treatment with reduced therapist burden

# Roboticized left-right independent unloading control

![](_page_46_Picture_3.jpeg)

The right and left are controlled separately. If the trunk leans strongly to one side, the weight reduction will automatically be increased to adjust the leaning

![](_page_46_Picture_5.jpeg)

If the body trunk position drops

The weight reduction will automatically be increased to get back to the original position

![](_page_46_Figure_8.jpeg)

![](_page_46_Picture_9.jpeg)

![](_page_46_Picture_10.jpeg)

## Medical Healthcare Service for Individuals Neuro HALFIT at Home

## Expansion of remote services connecting home and hospitals/facilities through cloud computing

![](_page_47_Figure_2.jpeg)

![](_page_47_Picture_3.jpeg)

# Medical service business for individuals: US Business (1)

## Promotion of in-house platform development of medical services for individuals

# **RHG** (**RISE** Healthcare Group Inc.)

(Company in charge of the Group's medical service business)

## **Expanding business with outpatient physical** therapy as a starting point

- **Starting with San Diego, expanding to Los Angeles**  $\checkmark$ (2nd largest metropolitan area in the U.S.)
- **Currently 21 locations (up 5 locations since the**  $\checkmark$ beginning of the year)  $\rightarrow$  Several more locations to be added by the end of the year
- **Considering expansion into northern California** (through M&A, etc.)

![](_page_48_Figure_8.jpeg)

\* https://en.wikipedia.org/wiki/List\_of\_core-based\_statistical\_areas

![](_page_48_Picture_10.jpeg)

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![](_page_48_Picture_12.jpeg)

# Medical service business for individuals: US Business (2)

## Accumulated Cybernics Treatment results and cases in our own group

![](_page_49_Picture_2.jpeg)

https://youtu.be/FsV7\_KATh94

"...I felt myself getting closer walking with every session that will drastically help because if I can walk I can do so much more for myself..."

![](_page_49_Picture_5.jpeg)

https://youtu.be/VnAWHvGTbbQ

"...I really just enjoyed getting my independence back getting back into where I can walk out in the yard, playing with the kids more and now *it's a really wonderful thing to be able to get back into that again."* 

![](_page_49_Picture_8.jpeg)

https://youtu.be/L59PFcyAOj4

"... when I first started going to RISE I was in a wheelchair and now I am walking and standing."

![](_page_49_Picture_11.jpeg)

![](_page_49_Figure_12.jpeg)

![](_page_49_Picture_13.jpeg)

# Medical service business for individuals: US Business (3)

# Formulating platform that could reach individuals directly

![](_page_50_Figure_2.jpeg)

- Orthopedic+brain-nerve diseases (target of HAL)
- Typically done manually by PT (can differentiate with HAL)
- Growing market due to aging population (Annually 33.1 billion=3.7 trillion yen)\*
- Players are dispersed (potential for further growth through M&A)

## **RISE Healthcare Group Inc.** → First facility in the west coast area

Functional recovery at home and daily healthcare monitoring **Preparing for launch of service towards individuals (consider further M&A)** 

\* "Physical Therapists in the US" IBIS World

![](_page_50_Picture_11.jpeg)

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## [Prevention and early detection] Ultra small vital sensor Cyvis

# Healthcare monitoring on daily basis with Cyvis

## Daily accumulation, analysis, and Al processing of various vital data

- Cardiac activity
- brain activity
- body temperature
- · SpO2
- Body movements
- Breathing (optional)

**Check for arrhythmia and atrial fibrillation to prevent** myocardial infarction and cerebral infarction Option to check breathing conditions during sleep for early detection of sleep apnea risk

\*Cyvis-1 medical device notification filed (April 2022), trial provision to users started (May 2022)

![](_page_51_Picture_12.jpeg)

![](_page_51_Picture_13.jpeg)

![](_page_51_Picture_14.jpeg)

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## [Prevention and early detection] Ultra small vital sensor Cyvis

## Expands remote service that connects households to hospitals and facilities

![](_page_52_Figure_2.jpeg)

![](_page_52_Picture_3.jpeg)

## **(Prevention and early detection)** Photoacoustic Imaging Device using LED light array

# Contrast-free, non-invasive, real-time, high-resolution 3D imaging

## LED array method (patent held by the company)

![](_page_53_Picture_3.jpeg)

Adopted as the cover of BioPhotonics, a U.S. industry journal dealing with biophotonics

![](_page_53_Picture_5.jpeg)

Peripheral vascular and blood conditions, etc.

Currently promoting medical device commercialization as a next-generation medical diagnostic imaging device

Peripheral level examination, which could not be done with conventional imaging equipment, is now possible!

## Example of application

- Routine examination and diagnosis of diabetic foot lesions
- Examination of vascular regeneration status by regenerative medicine
- Examination and diagnosis of cancer lacksquare
- Examination of aging skin, etc.

![](_page_53_Picture_15.jpeg)

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![](_page_53_Figure_16.jpeg)

![](_page_53_Figure_17.jpeg)

![](_page_53_Figure_18.jpeg)

![](_page_53_Picture_19.jpeg)

## **(Prevention and early detection)** Photoacoustic Imaging Device using LED light array

![](_page_54_Figure_1.jpeg)

![](_page_54_Picture_3.jpeg)

![](_page_54_Picture_8.jpeg)

# [Workplace] HAL Lumbar Type (Labor Support)

## Visualization of workers' workload and physical condition (labor management and work efficiency)

## **Active type and** light weight

**Compact design** (back won't be covered)

## **Assist walking**

Able to move in midback position.

## **IoH/IoT device**

Wearable Cyborg

Can be worn in 10 sec

Waterproof/dustproof (IEC reg, IP54)

- Can be worn for long hours lacksquare
- Can be used with safety belts (full-body type) lacksquareand air conditioning suits!
- Can be moved smoothly on site lacksquare
- Respond with assistance in a variety of practical tasks!
- Visualize workload analysis and operation status!  $\bullet$ Integrated production management
- It moves according to the wearer's intention lacksquare
- Easy to put on and take off, share with multiple people!
- Can be worn outdoors, even in the rain! ullet

![](_page_55_Figure_18.jpeg)

![](_page_55_Picture_21.jpeg)

![](_page_55_Picture_22.jpeg)

![](_page_55_Picture_23.jpeg)

# [Workplace] Disinfection/Cleaning Robot CL02

## Operationalizing next-generation technologies in a post-coronary society

Extensive Cleaning ability	•	High speed autonomous navigation (Can safely clean at 4kr Massive cleaning area (Detects wall that is 30m away and co High vacuum performance (one of the best in the industry)
Can be used for multiple tasks such as disinfection	•	<b>Disinfection agent sprayer</b> (Disinfects handrails and benches <b>UV Ray Disinfector</b> (set on the bottom of the robot to disinfect
Visualizes its work	•	<b>Dust distribution map</b> (visualizes result of the task) <b>Navigated route</b> (to create efficient and effective cleaning plar
Automatically rides on the elevator	•	Elevator interface unit developed inhouse (Can connect to elevators developed by multiple vendors) Can work on multiple floors (Expands the space that can be
Cloud linkage	•	"CYCLES" designed for the Robot (realizes high usability and Integration with the base system

m/h to cover massive space in short time over max 3,000m<sup>2</sup> with full charge battery)

![](_page_56_Figure_4.jpeg)

![](_page_56_Picture_5.jpeg)

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SDGs for Society 5.0/5.1

![](_page_57_Picture_3.jpeg)

# Four projects that contributes to achieving SDGs

![](_page_58_Picture_1.jpeg)

#### **Develop Cybernics Technology to** support people with reduced physical function

#### Main initiatives

- Disseminate Cybernics Treatment that promotes functional improvement and regeneration of the brain, nervous system, and muscular system using a Wearable Cyborg HAL, as a global standard treatment
- Disseminate Wearable Cyborg HAL to improve the level of care required by the elderly and prevent severe illness and prevent frailty and maintain independence as physical functions decline with age
- Develop Cyin for Living Support for people with severe disabilities who cannot speak or write as they wish due to the progression of intractable diseases to communicate and operate machines without speech or physical movement

![](_page_58_Picture_7.jpeg)

#### Health Risk Management with **Cyberdyne Cloud**

#### Main initiatives

- Develop Cyberdyne Cloud to accumulate, analyze, and perform AI processing of big data on people and things (IoH/IoT big data) obtained through all Cybernics Technologies equipped with communication functions
- Realize personalized healthcare through Cyberdyne Cloud
- · Develop sensing technology to monitor vital information daily
- Develop HAL at Home as a new service that can share user's information on their training sessions conducted at home using HAL with medical and care facilities

![](_page_58_Picture_14.jpeg)

#### Main initiatives

CYBERNICS DIGITAL INDUSTRY

- Establish a system to support companies and human resources that develop and deploy technologies and services that solve social problems
- Construct Cybernics Innovation Base to promote innovation in the medical and biotechnology fields
- Continue the projects at the Next-generation multi-purpose robotized production facility to induce innovation in the production field

![](_page_58_Picture_19.jpeg)

#### Realize Society 5.0/5.1, a future society that accelerates innovation

#### Main initiatives

- Develop mobility technologies that are safe, affordable, and ready for use by all people
- Develop a future city where all people, including the elderly and disabled, can easily access public spaces.
- Establish educational institutions that develop knowledge and skills to help people.
- Create shared spaces that promote innovation and scientific research and areas for field testing

![](_page_58_Picture_26.jpeg)

![](_page_58_Picture_27.jpeg)

![](_page_58_Picture_28.jpeg)

![](_page_58_Picture_29.jpeg)

![](_page_58_Picture_30.jpeg)

![](_page_58_Picture_31.jpeg)

![](_page_58_Picture_32.jpeg)

![](_page_58_Picture_33.jpeg)

![](_page_58_Picture_34.jpeg)

## **Develop Cybernic Technology to support people with** reduced physical function

![](_page_59_Picture_1.jpeg)

#### Main target

**10.2** by 2030 empower and promote the social, economic and political inclusion of all irrespective of age, sex, disability, race, ethnicity, origin, religion or economic or other status

### **Our contribution**

By developing the Wearable Cyborg HAL for medical and welfare fields, and Cyin for Well-being to support severely disabled to communicate their intentions, we are supporting the elderly and disabled person by maintaining and improving their functions. We also help them express what they have in mind.

We also develop another type of HAL to support people engaged in heavy work.

This project promotes the empowerment of these people and their social, economic, and political inclusion.

![](_page_59_Picture_8.jpeg)

Cybernics Treatment Center and Medical HAL

![](_page_59_Picture_10.jpeg)

Cyin for Living Support to support severely disabled person on their communication

![](_page_59_Picture_12.jpeg)

HAL Lumbar Type to support various heavy work

#### **Disseminating Medical HAL as a** global standard treatment

As of the end of September 2022, HAL for Medical Use is available in 20 countries and regions, including Southeast Asia and South Asia, as a treatment technology for stroke, spinal cord injury, and intractable neuromuscular diseases.

In addition, in order to contribute to solving the needs of developing countries, we have been selected by the Japan International Cooperation Agency (JICA) to conduct a research project in Brazil.

We will continue to disseminate the technology.

#### Post-discharge care at the **Robocare Center**

For those who want to keep improving their physical functions after they get discharged from the hospital, we offer Neuro HALFIT at self-funded rehabilitation facilities called RoboCare Center. As of the end of September 2022, they are 17 centers around Japan. A user can also access similar programs at selffunded rehabilitation facilities with which we have cooperative relationships.

In addition, we have formed alliances with private insurance companies such as Daido Life, AIG Insurance, and Sompo Japan to cover the cost of such programs for their policyholders.

We will continue our efforts to improve physical and economic access.

#### Improving the working environment

Job turnover due to the onset of back pain and the deterioration of performance caused by frequent heavy lifting is becoming a significant issue in nursing care, construction, and logistics.

The Company develops HAL Lumbar Type to reduce the risk of developing back pain by reducing the load applied to the lower back. The technology empowers people engaged in heavy lifting and enables the worker to continue working longer and safer.

As of the end of September 2022, 1,598 units of HAL Lumbar Type were in operation.

This product is currently available in Japan and the UK. We will continue to disseminate the technology to more countries and regions.

#### Supporting communication for the severely disabled

We develop Cyin for Living Support, which enables people with severe disabilities who cannot speak or move their bodies due to the progression of intractable diseases to communicate and operate devices.

The product is available on the market. Daido Life Insurance donated the product to several patient groups and patient support groups to promote this endeavor.

We will continue to work on additional functions and offer the product outside of Japan once it is ready.

![](_page_59_Picture_32.jpeg)

![](_page_59_Figure_33.jpeg)

![](_page_59_Figure_34.jpeg)

![](_page_59_Figure_35.jpeg)

![](_page_59_Picture_36.jpeg)

![](_page_59_Picture_37.jpeg)

![](_page_59_Picture_38.jpeg)

![](_page_59_Picture_39.jpeg)

![](_page_59_Picture_40.jpeg)

# Health Risk Management with Cyberdyne Cloud

![](_page_60_Picture_1.jpeg)

#### Main target

**3.d** Strengthen the capacity of all countries, in particular developing countries, for early warning, risk reduction and management of national and global health risks

## **Our contribution**

Cybernics Technology deployed in various fields such as medicine, nursingcare, production, and other workplaces with households, integrally connects people's internal information (brain nerve information, physiological information, etc.), people's external information (behavioral information, lifestyle information, etc.), and environmental information with a supercomputer.

The Company works on the system that accumulates, analyzes, and AI processes all the IoH/IoT Big Data obtained through this process, contributing to personalized medicine, early warning of health risks, and enhancing risk mitigation and risk management capabilities.

![](_page_60_Figure_7.jpeg)

**Release of Cyberdyne Cloud** 

The Company develops Cyberdyne Cloud to connect different fields and provide feedback on health risks based on IoH/IoT Big Data. In Japan, a system that allows users to send information on their training sessions from home to a facility and receive timely support from the facility is already in operation from November 2020.

We will continue to expand this system to other fields according to the development of products and services. We will also offer the system outside Japan to contribute to health management in all countries, including developing countries.

#### **Realizing personalized** healthcare

By accumulating, analyzing, and Alprocessing IoH/IoT Big Data related to a single user across different fields, we will realize personalized healthcare that will maximize the effect and safety of that user.

This initiative is being carried out simultaneously with the formation of IoH/IoT Big Data for all users. We will continue to expand this system to other fields according to the development of products and services. We will also offer the system outside Japan to contribute to health management in all countries, including developing countries.

#### **Developing vital sensing** technology

In addition to developing the Wearable Cyborg HAL and autonomous navigation technology, we are developing sensing technology to prevent and detect diseases.

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For example, commercialization of Cyvis, an ultra small-sized vital sensor to detect arteriosclerosis and arrhythmia at an early stage, and a photoacoustic imaging device to enable real-time analysis of capillary information.

By promoting these products, we will accumulate important vital information that will lead to the prevention and early detection of diseases, thereby contributing to the enhancement of capabilities for health risk management.

#### New service: HAL at Home

HAL at Home is a new service that enables safe and effective training at home. HAL at Home also realized the visualization of exercise information and remote online support by professional staff through HAL's builtin communication functions.

The Company is also working to expand home visiting services so that seniors who have concerns about handling digital devices can also engage in the program.

![](_page_60_Figure_21.jpeg)

![](_page_60_Picture_22.jpeg)

## Form social infrastructure to create the Cybernic Industry

![](_page_61_Picture_1.jpeg)

#### Main target

9.2 Promote inclusive and sustainable industrialization and, by 2030, significantly raise industry's share of employment and gross domestic product, in line with national circumstances, and double its share in least developed countries

## **Our contribution**

We are working to create an inclusive and sustainable industry called Cybernics Industry by building an innovation ecosystem called C-Startup and facilities to accelerate innovation in medicine/biotechnology and production.

#### C-Startup, the foundation for the creation of new industries

C-Startup is an innovation ecosystem to create a new industry for solving problems of people and society: Cybernics Industry. We work together with startups and entrepreneurs with similar visions, regardless of their nationalities.

We accelerate creating the Cybernics Industry by providing technical advice by Yoshiyuki Sankai (CEO of CYBERDYNE/Professor of Tsukuba University) and financial support by CYBERDYNE and its related Fund.

As part of this initiative, we have formed partnerships with a total of 21 startups and are managing a 10 billion yen fund to support this endeavor.

![](_page_61_Figure_10.jpeg)

#### **Promoting the vision of the Cybernics** Industry

The Company promotes the vision of the Cybernics Industry, a new industry that fuses Human and Cyber/Physical Space, both domestically and internationally. With this initiative, we are leading the efforts to form Cybernics Industry together with industry, academia, and government.

![](_page_61_Picture_16.jpeg)

G20 delegates visit CYBERDYNE HQ (2019)

For example, in 2019, we communicated this vision to various countries at the G20 Trade and Digital Economic Ministerial Meeting held in Tsukuba City, Ibaraki Prefecture.

We will continue to share our vision of the Cybernics Industry as a foundation for industrial and technological innovation.

![](_page_61_Picture_20.jpeg)

Exterior image

#### **Construction of Cybernics Medical Innovation Base**

We plan to construct the Cybernics Innovation Base in Kawasaki City, Kanagawa Prefecture, as a faci accelerate innovation in the medical and biotechn fields. The facility will house a cluster of medica biotechnology ventures. The Company, universities resident companies can conduct a clinical trial facility on their own and through collaboration.

The facility is planned to start operation within the fiscal year ending March 2022.

#### **Activities at the Next-Generation** Multipurpose Robotic Manufacturing Base

In Koriyama City, Fukushima Prefecture, we have constructed a next-generation production base to produce robots and devices with Cybernics Technology. In this facility, the Company embedded the skills of experienced workers into the robots so the robots and human workers can work in harmony.

The Company constructed the facility in 2016 and completed a registration to manufacture medical devices in 2020.

![](_page_61_Picture_29.jpeg)

Exterior of the facility

![](_page_61_Picture_31.jpeg)

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in	the

![](_page_61_Picture_35.jpeg)

## Realize Society 5.0/5.1, a future society that accelerates innovation

![](_page_62_Picture_1.jpeg)

#### Main target

11.2 by 2030, provide access to safe, affordable, accessible and sustainable transport systems for all, improving road safety, notably by expanding public transport, with special attention to the needs of those in vulnerable situations, women, children, persons with disabilities and older persons

11.7 by 2030, provide universal access to safe, inclusive and accessible, green and public spaces, particularly for women and children, older persons and persons with disabilities

### **Our contribution**

Using innovative Cybernics Technology, we promote the fusion of Human and Cyber/Physical Space to create Society 5.0/5.1. We envision this future society as a techno-peer-supported society where technology and human support each other as partners.

#### Creation of Society 5.0/5.1

Society 5.0 is a concept first proposed in Japan's Fifth Science and Technology Basic Plan as the ideal future society. In this society, science and technology connect all people and things, sharing various knowledge and information to create new values never seen before.

We contribute to the creation of Society 5.0 by implementing Cybernics Technology in the various business fields to integrate internal information (brain nerve information, physiological information, etc.), people's external information (behavioral information, lifestyle information, etc.), and environmental information with a supercomputer. As one of the leaders in this challenge, we work to explore the society beyond Society 5.0/5.1.

![](_page_62_Picture_10.jpeg)

perspective drawing of the future city

#### **Mobility Infrastructure**

We are working on personal mobility and drones for transportation that is safe, inexpensive, and easy to use, taking into consideration the needs of the elderly and disabled living in the community.

We are also planning cities based on the premise of introducing mobility, which will shorten travel time and create new connections and added value between functions and facilities.

While developing mobility infrastructure in-house, we are also collaborating with startups that are developing related technologies.

#### **Shared Economy**

We plan to shift from the conventional model of occupying information, people, goods, space, and time to a new form of a city where we can share and help each other.

We will work to achieve success with the allies formed in C-Startup. We will also continue to gather people and companies with seeds related to Cybernics and accelerate the creation of innovation through sharing and mutual aid of information, people, goods, space, and time.

#### **Futuristic housing**

Through daily health management and lifestyle support infrastructure based on Cybernics Technology, we will develop housing where all people, including the elderly and disabled, can live in harmony with technology and mutually support each other to ensure peace of mind.

Specifically, various Cybernics Technologies, such as the Wearable Cyborg HAL, autonomous navigation robots, and vital sensors, will be introduced into every space, including residences. Personal health information will be accumulated, analyzed, and processed by AI to be linked to medical facilities to manage each person's health and safety better.

#### An educational institution that nurtures the next generation of human resources

Through collaboration between industry, academia, and government, we are planning an educational institution to foster the next generation of innovators.

We will nurture the next generation of innovators with educational institutions ranging from graduate school to elementary school, taught by instructors from various companies.

![](_page_62_Picture_27.jpeg)

# Disclaimer

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![](_page_63_Picture_3.jpeg)