

# CYBERDYNE, INC. Financial Results for the Fiscal Year Ended March 31, 2018

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# **Consolidated net sales**

4.7% increase year on year. (30% increase, excluding the increase due to a special factor in the previous FY)



\*Ministry of Health, Labour and Welfare

### Consolidated financial results - year-on-year comparison for the fiscal year ended March 31, 2018

#### Net sale: +77M due to an increase in operating number of Medical HAL etc. (Improved by 4.7%) Gross profit: +126M due to an increase of sales and a decrease of cost of sales (gross profit margin improved by 4.4%)

#### Net income: Improvement of 198M (Improved by 25.1%)

[Consolidated income statement of the fiscal year ended March 31, 2018]

Unit: Millions of Yen

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ltem	FY2017				EV2017	EV2016		
	Q1 (Apr.1-Jun.30)	Q2 (Jul.1-Sep.30)	<b>Q3</b> (Oct.1-Dec.31)	<b>Q4</b> (Jan.1-Mar.31)	[Apr.1-March 31]	[Apr.1-March 31]	+/-	Comment
Net Sales	353	408	402	563	1,727	1,650	77	<ul> <li>+: Sales of Medical HAL and HAL Lumbar Type +423M</li> <li>- : Sales of HAL Lumbar Type covered by subsidy program of MHLW in the previous FY -332M</li> </ul>
Cost of sales	111	125	112	174	522	571	-49	
Gross profit	242	283	290	390	1,205	1,079	126	Gross margin improvement (65.4%→69.8%)
R&D expense	199	195	233	216	843	903	-60	Acceleration of new product development and clinical research (continued from the previous fiscal year)
Other SG&A expense	354	334	326	367	1,380	1,348	32	Taxes and dues +43M, cost related to shareholders meeting +10M, Other -21M
Operating loss	-310	-246	-269	-193	-1,018	-1,172	154	
Non-operating income	54	68	132	121	376	1,242	-867	Subsidy and consigned research -116M Reduction of subsidy for non-current assets (related to the production facility in Fukushima) -742M
Non-operating expense	1	5	19	21	47	853	-806	Non-recurring share issuance cost related to convertible bonds in the previous fiscal year -96M Decrease of loss on reduction of non-current assets (related to the production facility in Fukushima) -742M Share of loss of entities accounted for using equity method +42M
Ordinary loss	-257	-183	-155	-94	-689	-783	94	
Net income attributable to CYBERDYNE.INC.	-258	-184	-56	-93	-591	-789	198	Gain on sales of investment securities +100M
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# **Business highlights**



Medical HAL etc.	<ul> <li>Japan : Medical HAL: On going investigator initiated clinical trial to expand application of the device to stroke (2016/9~) HAL Single Joint Type: Making preparation to launch investigator initiated clinical trial for stroke</li> <li>USA : Obtained FDA marketing clearances for Medical HAL (2017/12) Commenced business with one of the busiest rehabilitation hospital groups, "Brooks Rehabilitation"(2018/03)</li> <li>Europe : Proceeding steps to obtain public health insurance coverage in Germany. Obtained private insurance coverage in Poland (2017/7)</li> <li>Other : Started treatment with Medical HAL in Saudi Arabia</li> </ul>
New product (New model)	<ul> <li>HAL Lumbar Type for Well-being: Commenced sales of a model to maintain/improve physical function in the body trunk and lower limb for users such as elderly people (2017/10)</li> <li>HAL Lumbar Type for Labor Support: Commenced sales of a new model with waterproof/dust proof function (2017/12) → Started distributing to factories of Daiwa House etc.</li> <li>Cleaning Robot: Commenced sales of an upgraded model (2018/3) → Started distributing to a shopping center (Mitsui Fudosan) and office buildings (Sumitomo Corporation)</li> <li>Cyin (Cybernic Interface): Daido Life donated to patients association → Preparing to commence general sales</li> <li>HAL for Well-being Lower Limb Type: Commenced sales as the successor model of HAL for Living Support Lower Limb Type (2018/4)</li> </ul>
Product development	<ul> <li>Medical HAL(2S Size): Expanding the range of applicable height (lowering the minimum height requirement to 100cm)</li> <li>Vital Sensor: Entering the process to obtain medical device approval → business on prevention of lifestyle-related diseases</li> <li>Other: Medical Care Pit etc.</li> </ul>
Business development	<ul> <li>Private Insurers: Collaborating with Daido Life Insurance (HAL Plus rider), AIG Japan (training program to improve walking function) and Sompo Japan Nipponkoa (comprehensive business alliance)</li> <li>IoH/IoT: Established a joint venture company "Cyberdyne Omni Networks" for telecommunication and devices (2017/8)</li> <li>Business collaboration: Establishing CEJ Fund to support and nurture venture companies and create Cybernic Industry</li> </ul>





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# HAL for Medical Use Lower Limb Type Obtained marketing clearance from the US FDA (2017/12/17)



- HAL became the only device with the combination of these two category. Neurological Devices & Physical Medicine Devices\*
- Temporarily help improve ambulation upon completion of the HAL gait training intervention. It is NOT designed for support of gait when its worn
- →As product like HAL did not exist, FDA reviewed the definitions of the product classification
- The results of HAL gait training intervention suggest a statistically significant improvement in the gait related outcome measures collected without wearing HAL, and clinical significance was acknowledged

\*21 CFR 882.5050 21 CFR 890.3480

# FDA 510k summary clearly indicated that HAL is for improvement of Gait function and acknowledged the therapeutic effect of HAL

reference ) FDA 510(k) Summary : https://www.accessdata.fda.gov/cdrh\_docs/pdf17/K171909.pdf

# **Business Development in USA**



#### Joint venture established with one of the busiest rehabilitation hospital groups, "Brooks Rehabilitation" and commenced joint operation (2018/3)





### **Brooks Rehabilitation**

First Cybernics Treatment Center in the U.S.

- Admits 45,000 patients p.a. with the entire group one of the busiest inpatient rehab hospitals in USA
- 32 outpatient clinics admitting over 30,000 patients p.a
- clinical research centers for stroke, spinal cord injury, etc.



Reference) CYBERDYNE | Helping Spinal Cord Injury Patients Walk : https://www.youtube.com/watch?time continue=4&v=t e11u4dO3k

## **Business development in Europe (Poland)**

#### Started Cybernic Treatment with Medical HAL covered by private insurance (2017/7)

\*Constance Care, a medical institution located in Warsaw contracts with WARTA, a major private insurance company. Constance Care will accept patients of spinal cord injury who hold insurance policy of WARTA. Alike the insurance coverage by German public workers' compensation insurance, each patients will be covered with approximately 30,000 euro (approximately 500 euro x 60 times) by WARTA.



# **Development in other areas (Saudi Arabia)**

#### Medical HAL approved as a medical device by SFDA<sup>\*1</sup> (2017/8) Exported Medical HAL to ALJ hospital for the first time (2017/10) patients suffering from after-effects of spinal injuries in Saudi Arabia : 13,000 per year<sup>\*2</sup> (double of Japan)



Quoted from the facebook page of ALJ Hospital

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\*3 From the left Mohamed Jameel CEO and Chairman of ALJ, Adel Fakeih, Minister of Economy and Planning of Saudi Arabia and CEO Sankai
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### Walking speed multiplies after treatment with HAL

#### Comparison of walking speed before and after HAL Treatment (10 Meter Walking Test)



Journal) JNS Neurosurgical Focus: "Against the odds: what to expect in rehabilitation of chronic spinal cord injury with a neurologically controlled Hybrid Assistive Limb exoskeleton. A subgroup analysis of 55 patients according to age and lesion level "

## (Reference) stroke clinical research



### Treatment with HAL improved the patients ability to walk by 5 times when compared to traditional rehabilitation

Comparison of improvement of walking speed between HAL

Treatment and traditional rehabilitation

(Comparison using 10M Walking Test on maximum walking speed)



Journal) JNeuroRehabilitation : "Gait training with Hybrid Assistive Limb enhances the gait functions in subacute stroke patients: A pilot study"

# Number of units in operation



-HAL for Medical Use Lower Limb Type



# Number of units in operation



-HAL for Living Support Lower Limb Type etc.

Successor model (HAL for Well-being Lower Limb Type) will be introduced to the market



### **Number of units in operation** -HAL for Well-being Single Joint Type



Preparing investigator initiated clinical trial towards obtaining medical device approval



## Effect of HAL for Care Support Lumbar Type

My work was very tiring and I used to go straight to bed afterwards. Since I started wearing HAL, care task got much easier. My **burden was reduced to 1/5** of what it used to be\*. I wear HAL at work everyday. I can now do some house work once I go home!



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Comment of the worker who returned to work from treatment of cancer (multiple myeloma)

\*This is a comment from a individual

#### **Reported effect of adopting HAL**

- There is significant difference of fatigue around the lumbar region upon performing care task with HAL or without HAL
- It used to require 2 female workers in night shift for certain tasks. With HAL, it only requires 1 worker to do the same tasks
- Time required for transferring aid was reduced and work efficiency was improved
- Workers feel less tiring and they no longer require too many absence from work

Above are excerpts from documents reported by Kanjinkai in "domestic gathering of users of HAL Lumbar Type for Care Support 2018" Reference Challenge of Medical Corporation Kanjinkai (METI "Project to Promote the Development and Introduction of Robotic Devices for Nursing Care") https://www.youtube.com/watch?v=WMwRr2gvYeE&feature=youtu.be

## New model of HAL Labor Support



### dust proof/water proof function to expand its uses to all outdoor/indoor sites





- Dust proof/water proof function • →Can use in rain or dusty outdoor construction site  $\rightarrow$ Can use in humid indoor sites
- Reinforced communication function (covering all indoor/ outdoor areas)
  - $\rightarrow$  Promotes network with IoH/IoT\* and utilization of Big Data





### **Announcement by Daiwa House Industry** (2018/3)

### Adopted 30 units of HAL Lumbar for all of their 9 factories in Japan



4/10 NHK

## Launch of HAL Lumbar Type for Well-being (2017/10)

Maintains and improves the weakened bodily functions of the user in the core and lower body, supporting both care givers and care receivers





- Alike other HAL products, the Product reads "bio-electrical signal" to realize intended movements of the wearer
- Compact/ light weighted (approx.3kg) model, easy to wear and control
- Repeat body core movements, standing up, sitting down etc with the devices on
  - $\rightarrow$  Improves the function of the body it self
  - $\rightarrow$  Promotes independence of the user without HAL strapped on



### Improves ability to stand/sit to promote independence

### Supporting the care givers and care receivers alike



2017/10/2 TV Tokyo



### **Released the third generation of the Lumbar Type**



### Number of units in operation -HAL Lumbar Type





### Release of upgraded Cleaning Robot (CL02) (2018/3)



#### Cleaning route can be set easily (less work for operator)

CL02 is capable of cleaning without guidance of magnetic tapes or markers. The Operator can select options for CL02 to generate the cleaning route on its own.

#### Fast autonomous navigation (extensive cleaning efficiency)

CL02 is capable of very fast autonomous navigation. One battery charge will make CL02 clean a wide area.

#### 3D obstacle detection (high safety)

CL02 is capable of detecting obstacles in its pathways using its 3D cameras and it can stop safely.

#### Feedback of cleaning results (improvement of cleaning quality)

CL02 is capable of generating map of dust distribution when it finishes its duty.

# Adoption by shopping facilities and office buildings

Large shopping facilities

#### Mitsui Fudosan adopts CL02 for Diversity Tokyo Plaza (2018/3)

#### Office buildings

#### Jointly promoting automation of cleaning in office building with Sumitomo Corporation (2018/3)



The Nikkei https://www.youtube.com/watch?v=Tl6onRoF37w





### Utilization of sensing technology developed through HAL

Uses the bio-electric signal so patients can

- Communicate with others
- Control other devices eg. nurse calls
- Do above without moving or speaking



2018/3 Daido Life Insurance donated Cyin to 11 of the patients association/ supporting association

**Commencing general sales soon!** 

### Communication/device business related to IoH/IoT\* where all "humans" and "things" will be connected by internet

\*Internet of Humans / Internet of Things

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## **Towards creation of CEJ Fund**



Nurturing/Supporting venture to create Cybernic Industry and accelerate realization of Society 5.1 Forming a spiral where all the "seeds" of innovation around the world would gather to Japan





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