

# Japan Lifeline Co., Ltd.

**7575**

Tokyo Stock Exchange First Section

5-Feb.-2019

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<http://www.fisco.co.jp>

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## Summary

### Continuing to build a base for growth, despite stagnant operating results in latest period

Japan Lifeline Co., Ltd. <7575> (hereafter, also “the Company”) is an import trading company, as well as a manufacturer, of cardiovascular system medical devices. Since its founding, the Company has introduced cutting-edge medical devices to the Japanese market from overseas and expanded its sales bases nationwide, and has also developed its own products to meet the specific needs in the healthcare field. In addition to its sales and manufacturing platforms, the Company has also strengthened its regulatory platform to obtain the regulatory approvals necessary to introduce medical devices. Furthermore, being an independent company, Japan Lifeline is a trusted and attractive sales partner for overseas manufacturers that do not possess sales channels in Japan.

The Company has four product categories: Cardiac Rhythm Management, EP/Ablation, Cardiovascular Surgery, and Transvascular Intervention. In FY3/19 1H, the Cardiac Rhythm Management category accounted for 14.4% of sales, the EP/Ablation category accounted for 50.5% of sales, while the Cardiovascular Surgery and Transvascular Intervention categories accounted for 25.1% and 10.1% of sales, respectively. The Cardiac Rhythm Management category handles devices used to treat cardiac arrhythmia, including cardiac pacemakers. The EP/Ablation category handles disposable electrode-equipped catheters used for diagnosis and treatment of arrhythmia, and other products. In FY3/19 1H, the number of cases of atrial fibrillation treatment with ablation was 20% higher than in the same period of the previous year, and the number of cases has been rapidly increasing in recent years. The Cardiovascular Surgery category handles prosthetic devices to replace blood vessels and heart valves that have lost their ability to function. The Transvascular Intervention category mainly handles medical devices to treat conditions such as myocardial infarction and angina pectoris.

In FY3/19 1H, the Company reported net sales of ¥22,265mn (up 9.9% year-on-year (YOY)), and operating income of ¥4,860mn (up 0.0%). However, operating income rose 11.6% in real terms, excluding the impact of the ¥502mn positive effect on gross profit due to the adjustment of unrealized gain in conjunction with the subsidiary merger in the same period of the previous fiscal year. The Company has downwardly revised its full-year forecast for FY3/19 net sales by 5.4%, and has lowered its operating income forecast by 7.3%. The outlook for SG&A expenses seems a bit conservative, but one reason for this is that net sales of Orsiro, which was expected to be a major product, fell short of the forecast. On a year-on-year basis, the Company expects net sales of ¥46,762mn (up 10.6%) and operating income of ¥10,383mn (down 2.7%). On a real term basis eliminating the impact due to the adjustment of unrealized gain, full-year operating income is expected to increase 9.3% YoY.

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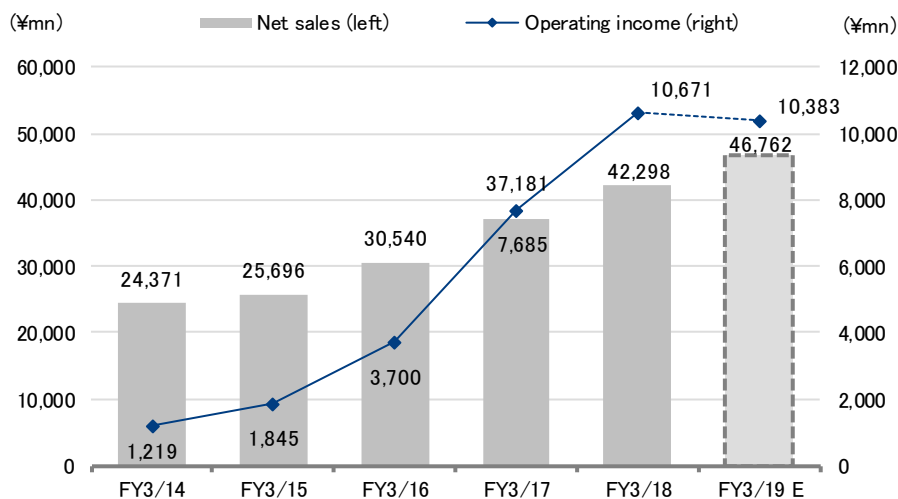
Summary

Sales of Orsiro fell short of the Company’s forecast, and this was one reason for the downward revision to the forecast, but the Company plans to strengthen its sales platform and expand the size lineup to achieve an increase in sales. Also, in 2018 there were a number of changes with respect to agreements with business partners and progress was made on the medium- to long-term growth strategy. In the field of arrhythmia treatment, the Company’s base business, the Company announced that in Cardiac Rhythm Management devices it would change its supplier of cardiac pacemakers and other products from MicroPort to Boston Scientific Japan in September 2019. In addition, in the Cardiovascular Surgery category, the Company announced that it would stop handling artificial valves. The short-term impact of this was negative (downward revision to forecasts). But in the arrhythmia treatment field, over the medium term, we view the aforementioned change to mean that the foundation for growth has been bolstered. The short-term impacts of this were negative (downward revision to forecasts), but over the medium term, we view this to mean that the foundation for growth has been bolstered in the arrhythmia treatment field. With respect to the Company’s in-house manufactured products, the number of cases of EP/Ablation continues to increase, and the outlook that this will drive the Company’s growth going forward remains unchanged, so the Company’s growth story is not likely to change significantly. In any case, the Company is planning to announce a new medium-term management plan in May 2019.

**Key Points**

- A medical device company hybrid of import trading company and manufacturer specializing in cardiovascular field
- The Company’s main products are in-house manufactured products and imported products which are distributed exclusively, and it has a highly-profitable structure
- The Company has concluded medium- to long-term exclusive distribution agreements, and is expected to revise its medium-term management plan in May 2019

**Results trends**



Source: Prepared by FISCO from the Company’s financial results

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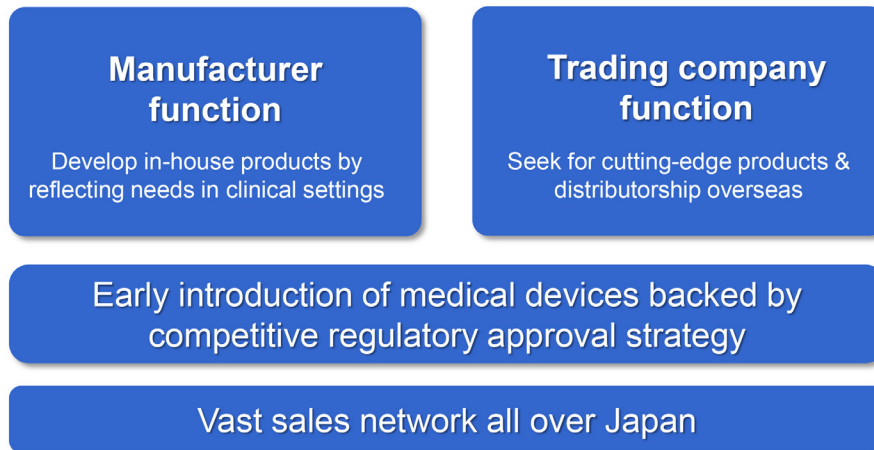
## ■ Business overview

**Features include a sales platform, regulatory platform, domestic launches of cutting-edge overseas products, and an in-house manufactured development platform**

### 1. Business description

From the time it was founded for the sales of imported cardiac pacemakers in 1981 up to the present day, the Company has expanded its sales bases nationwide, while importing into Japan the latest medical devices from overseas. It has advanced expertise as a specialist trading company in medical devices and communicates closely with doctors to cultivate the power of discernment for products. Furthermore, it is utilizing its network of doctors who are active on the medical frontline to develop medical products precisely tailored to meet the needs of medical sites. Also, regulatory approval is required to introduce a medical device, and the Company is strengthening its regulatory department structure based on its experience of introducing devices over many years, and it is able to smoothly progress this process, including for the acquisition of data showing a product's safety and effectiveness and negotiations with the administration. In addition to its features of having a nationwide sales structure, an enhanced regulatory structure, domestic introduction of advanced product and a development system for products meeting needs, it is independent. Therefore, for overseas manufacturers that do not have sales channels in Japan, the Company can be said to be extremely trustworthy and appealing as a sales partner.

#### The Company's growth foundation



**Will expand business scale and increase profitability to achieve high growth**

Source: The Company's medium-term management plan briefing materials

## Plays many roles in the cardiovascular medical devices industry

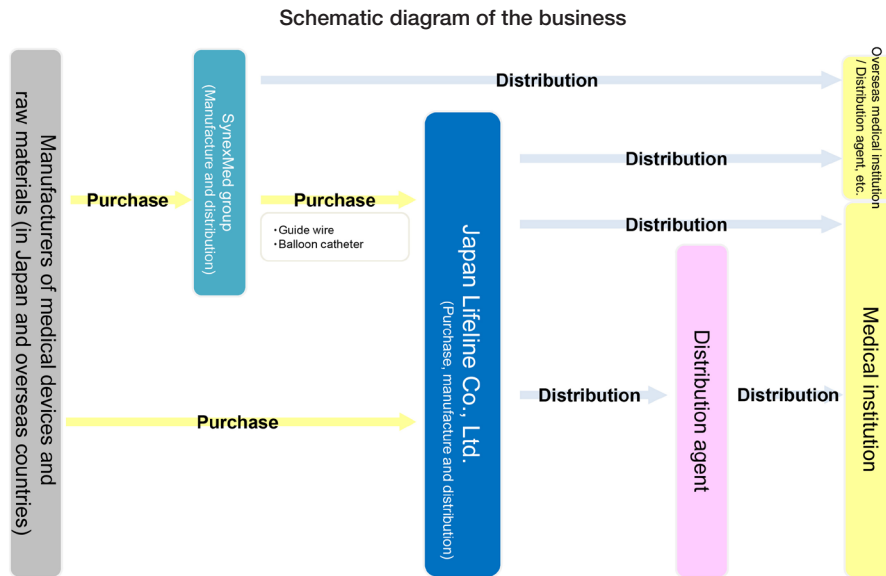
### 2. Distribution structure

As its sales structure, the Company has 47 sales bases throughout Japan, from Hokkaido to Okinawa, and Haneda and Kansai logistics centers (as of September 2018), with staff who possess high-level specialist knowledge and who support medical practitioners. Its customers include medical institutions and sales agencies, although it sells few devices directly to medical institutions and most are sold via sales agencies. Sales representative focus on specialist operations, including providing product information to medical institutions, and the cooperation they obtain from sales agencies, such as for supplementing product inventory and for sales, enables them to conduct sales efficiently.

For purchased products, the Company concludes exclusive sales agreements with overseas manufacturers, mainly in Europe and the United States. It ties up with a single partner in a particular product category, in principle. Also, it takes the same position as that of manufacturers for aspects such as the acquisition of regulatory approval in Japan, marketing smoothly to spread the use of medical devices through academic societies and related, and education for medical institutions. Further, as there is a commercial practice unique to the medical devices industry of deposit sales, which entails depositing a product at a medical facility and recording it as sales when it is used, manufacturers have to bear the inventory burden instead of sales agencies. However, as a result of handling products with an exclusive sales contract, the Company's gross profit margin on its purchased products averages from 40-50%, which is extremely high compared to the margins of other typical sales agencies. In general, sales agencies conducting secondary distribution in Japan handle the products of multiple companies, and although their stock burden is light, many of these companies have a gross profit margin of below 20%. Based on this, there is a clear differentiation among the business structures of the Company and other sales agencies.

The Company develops and manufactures in-house products as a manufacturer. It has one R&D base (the Research Center) and three manufacturing bases (the Toda Factory, Oyama Factory, and Ichihara Factory) in Japan (as of September 2018). The products that the Company develops and manufactures in-house are guide wires, EP catheters, and ablation catheters. The gross margin of the Company's in-house products is relatively high, and of the Company's in-house products, those that are one-of-a-kind products have an even higher gross margin. Meanwhile, it has also expanded its portfolio through M&A. In 2009, it acquired Ube Junken Co., Ltd. (name subsequently changed to JUNKEN MEDICAL Co. Ltd.), which at that time was the only manufacturer of vascular grafts in Japan, and it incorporated these vascular grafts into its lineup of in-house manufactured products. Also, in 2010, it made subsidiaries of the SYNEXMED Group (companies in Hong Kong and Shenzhen), which manufactured guide wires and balloon catheters, and newly added balloon catheters to its lineup of in-house manufactured products. JUNKEN MEDICAL merged with the Company in April 2017 through an absorption-type merger toward realizing synergies and improved efficiency.

Business overview

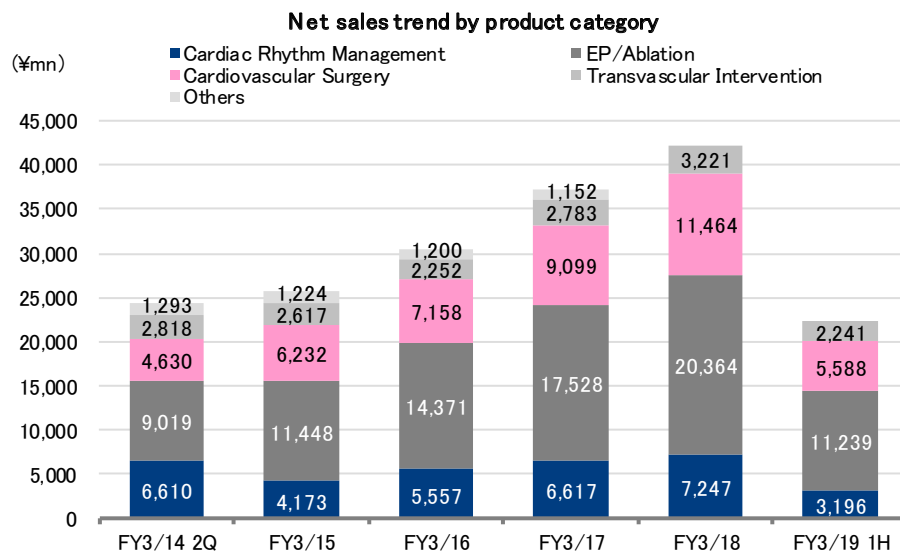


Source: The Company's results briefing materials

## An abundant product lineup specializing in cardiovascular diseases

### 3. Sales highlight by product category

The Company has four product categories; Cardiac Rhythm Management, EP/Ablation, Cardiovascular Surgery, and Transvascular Intervention. In terms of the percentages of sales, in FY3/19 1H, Cardiac Rhythm Management contributed 14.4%, EP/Ablation 50.5%, Cardiovascular Surgery 25.1%, and Transvascular Intervention 10.1%.



Note: In line with the subsidiary merger, the product category "Others" has been reclassified as "Cardiovascular Surgery" starting from FY3/18.

Source: Prepared by FISCO from the Company's results briefing materials

## Business overview

**(1) Cardiac Rhythm Management**

Cardiac Rhythm Management handles for treating cardiac arrhythmia. The main products are implantable devices that use electrical stimulation to ensure that the heart beats normally, including cardiac pacemakers, ICDs (implantable cardioverter defibrillators), and CRT-Ds (cardiac resynchronization therapy defibrillators). It also handles AEDs (automated external defibrillators). Most of the items in this segment are purchased products. The supplier (MicroPort) has expertise in cardiac pacemakers, which are implantable medical devices used when the heart beats too slowly. A pacemaker constantly monitors a person's heartbeat, and when it senses that the pulse has been interrupted, it sends out an electrical stimulus and returns the heart beat to normal. In the cardiac pacemaker market, MRI-compatible pacemakers have rapidly become mainstream in recent years, so the Company has also launched the KORA250 and other MRI-compatible cardiac pacemakers.

An ICD (implantable cardioverter defibrillator, MicroPort), automatically senses high-risk arrhythmias, such as sudden ventricular fibrillation and ventricular tachycardia, and recovers the heart's contractions to normal using electrical therapy. In the event of severe heart failure, the CRT-D (cardiac resynchronization therapy defibrillator, MicroPort) prepares for ventricular dyssynchrony and improves the heart's pumping function by electrically stimulating both the left and right ventricles of the heart, while it also has a defibrillation function similar to an ICD. The pacemaker lead (MicroPort) is a conducting wire used to transmit an electrical stimulation to the myocardium, and is connected to the cardiac pacemaker. The ICD lead (MicroPort) used for transmitting the electrical stimulation emitted by the ICD to the myocardium is equipped with a coil to provide treatment by electric shock. The event recorder (MicroPort) is an extracorporeal electrocardiograph that detects and records cardiac events. It can confirm changes in an electrocardiogram and its uses include the analysis of arrhythmia. The AED (automated external defibrillator, NANOOMTECH) automatically examines the status of the heart, and when it senses that it is in a convulsive state, such as ventricular fibrillation, it delivers an electric shock or defibrillation, thereby recovering it to the normal state.

The Company is currently supplied with cardiac pacemakers and related products by MicroPort. The number of units sold had declined due to a delay in the launching of MRI-compatible pacemakers, but in FY3/18, its market share recovered to 15%. However, the Company is expecting a year-on-year decline in sales volume in FY3/19. The reason for this is short supply of remote monitoring devices. In April 2018, the reimbursement price for remote medical treatment has been revised up, and this led to add up medical facilities' demand for remote monitoring. However, MicroPort has not been able to supply enough remote monitoring devices and the Company has therefore been unable to meet the market's needs. Also, the demand for ICDs and other devices to treat tachycardia (higher than normal heart rate) has grown, but MicroPort products have some issues, including not yet being able to supply MRI-compatible products, so the Company changed its supplier to Boston Scientific Japan with which it has concluded an exclusive distribution agreement. From September 2019 onward, the Company will sell CRM products of Boston Scientific exclusively. We view this as a positive development.



Business overview

Cardiac Rhythm Management (MicroPort)

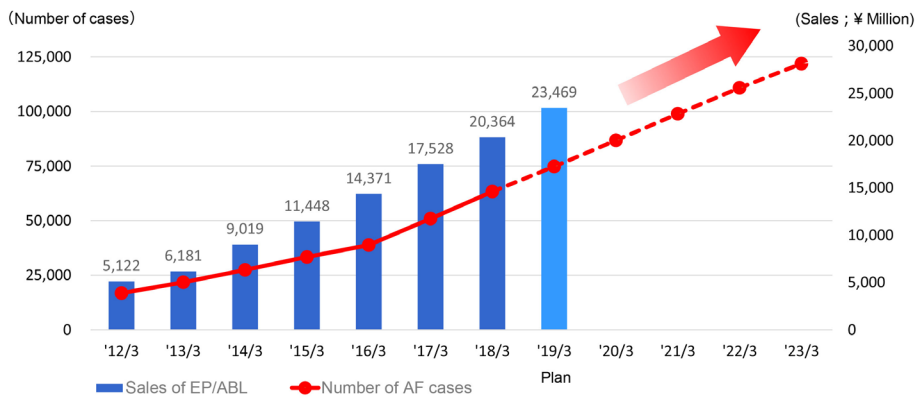


Source: The Company's website

(2) EP/Ablation

In EP/Ablation, the Company handles disposable electrode-equipped catheter for diagnosis and treatment of arrhythmia. In FY3/19 1H, the number of cases increased 20% YoY, and in recent years, the number of cases of atrial fibrillation treated with ablation has been rapidly increasing. A catheter broadly refers to a medical device that is a hollow, soft, and thin tube that is inserted into a blood vessel from the surface of the skin to provide treatment.

Forecast number of cases of EP/ABL ablation



※Number of cases are based on JLL's estimate

Source: The Company's medium-term management plan briefing materials

The EP catheter (Japan Lifeline) is a thin catheter with an electrode used to measure the electric potential in the heart and to identify the part causing the arrhythmia. To inspect the various parts precisely within the heart, it comes in an abundance of types, including with a curve-shaped tip, and also in terms of number and positions of electrodes and also catheter diameters. There is also a single-directional type (turns to one side), in which the tip is curved and there is a grip lever for the hand, and a bi-directional type (turns to both sides), and the lineups of both types come with a variety of curves.

Business overview

The ablation catheter (Japan Lifeline) is an electrode catheter that locally cauterizes and treats the stimulation conduction pathway causing local arrhythmia (tachycardia) with a high frequency current. The same as the EP catheter, it comes in an abundance of types that physicians can choose from to make an optimal treatment in accordance with various patients' anatomy. In addition, the irrigation catheter is one type of ablation catheter, and at the tip of the catheter, there is a hole from which physiological saline solution sprays. It has a function to reduce the occurrence of thrombus in the body by performing cauterization, while cooling the tip electrode.

The internal atrial cardioversion system (Japan Lifeline) is a system that performs defibrillation within the heart, such as for atrial fibrillation that can occur during ablation treatment. Since it conducts defibrillation with much lower output compared to defibrillation from outside of the body, it can be performed less invasively (reducing the physical burden on the patient). Compared to other ablation procedures, ablation procedures for atrial fibrillation have a high rate of incidence of complications of esophageal esophagitis and esophageal ulcers, especially in the left atrium with a high mortality rate and the esophageal fistula, through which the esophagus penetrates. The esophageal temperature monitoring system (Japan Lifeline) prevents these complications by continuously monitoring the temperature of the esophagus during ablation treatment.

EP/Ablation catheter



From left: Ablation catheter, EP catheter, esophageal temperature monitoring system  
Source: The Company's website

**(3) Cardiovascular Surgery**

In Cardiovascular Surgery category, the Company handles medical devices used for surgical treatments to provide treatment by replacing blood vessels or heart valves that have lost their functions with prosthetic devices. The main in-house manufactured products are vascular grafts and open stent grafts, both of which were manufactured by JUNKEN MEDICAL, which the Company absorbed and merged with in April 2017. The main purchased products include thoracic stent grafts, abdominal stent grafts, prosthetic heart valves, and annuloplasty rings. The AFX Stent Graft System for the abdomen (Endologix) has proven to be popular, and in FY3/18 it acquired a market share above 15%. Similar to vascular grafts, stent grafts are medical devices used to treat aortic aneurysms. However, unlike a vascular graft, which require surgery to open the chest or abdomen, a stent graft is a medical device made up of spring-like metal tubes called stents, which remain in a contracted state within the catheter. The catheter enclosing a stent graft is inserted into the blood vessel from the groin and then delivered to the target lesion where the stent graft is released and the force of the springs press against the blood vessel to fix it in place. Depending on which part of aorta to be treated, there are two types of product: thoracic stent graft and abdominal stent graft. The company handles thoracic stent grafts manufactured by Bolton Medical. The Company will stop handling artificial heart valve-related products in May 2019, when its agreement with supplier LivaNova terminates.

Business overview

Vascular grafts (Japan Lifeline) are medical devices for treating aortic aneurysms, and they are used to replace blood vessels and to bypass blocked blood vessels. The open stent graft (Japan Lifeline) is a medical device to treat thoracic aortic disease. When replacing thoracic aorta with vascular grafts over a wide range, in the case of treatment only using conventional vascular grafts, two open-chest surgeries are required. But by using the open stent grafts, the treatment can be completed with just one open-chest surgery, which shortens the surgery time and reduces the physical burden on the patient.

Products for Cardiovascular Surgery



From left: Vascular graft (JLL), open stent grafts (JLL), thoracic stent graft (Bolton Medical), abdominal stent graft (Endologix)  
Source: The Company's website

**(4) Transvascular Intervention**

Transvascular Intervention mainly handles medical devices to treat conditions such as myocardial infarction and angina pectoris. The Company's main in-house manufactured products are guide wires and balloon catheters that are used to treat blood vessels (coronary arteries) in cases of myocardial infarction and related conditions. Its main purchased products include penetration catheters that are used in the same way when treating myocardial infarction, especially balloon catheters used in treatment of cases of complete closure, and atrial septal defect closing devices that are used when treating congenital structural heart disease. The percutaneous transluminal angioplasty balloon catheters market for peripheral blood vessels is growing, and it seems that the Company is working to capture this growth by meeting needs in this expanding field.

The guide wire (Japan Lifeline) is a wire-like medical device used to guide a balloon catheter, stent, or other devices through the blood vessels to the target lesion. It is inserted into a blood vessel, such as via the thigh, and passes through the target lesion in the coronary arteries and peripheral arteries, and a treating device is carried along this wire. The balloon catheter (Japan Lifeline) is a medical device for treating myocardial infarction and angina caused by the narrowing or blocking of the coronary arteries. They are treated by inflating the balloon on the catheter (thin tube) from inside the blood vessel and thereby expanding the blood vessel. The penetration catheter (Teleflex) is a medical device used to support the passage of guide wires through lesions in coronary arteries and peripheral arteries.

The atrial septal defect closing device (Occlutech) is a medical device for treating atrial septal defect, which is a congenital disease in which a hole called a septal defect hole is found in the atrial septal, which is the wall separating the left and right atria of the heart. It does not require a surgery and it is said to be extremely minimally invasive because catheter treatment can be applied to close and treat the septal defect hole with a disk-shaped device called a closing plug.

Business overview

Transvascular Intervention



From left: PTCA guide wire (JLL), balloon catheter (JLL), penetration catheter (Vascular Solutions), atrial septal defect closure device (Occlutech)  
 Source: The Company's website

## Performance trends

### In-house manufactured products are making up for the shortfall in purchased products

#### 1. The turning point

Many Japanese medical device-related companies are either manufacturers or specialist trading companies. However, while the Company started as a trading company, it subsequently added manufacturing functions. Currently, it has two business forms, import and sales of products manufactured overseas and sales of products manufactured in-house, and it has established a hybrid business model. The trigger for its incorporation of manufacturing functions was a major decline in sales in FY3/00. At that time, Arterial Vascular Engineering Inc., which up to then had supplied the Company with coronary bare metal stents, was acquired by a competitor, which meant that the Company lost the sales rights to this product within Japan. It has experienced similar cases on several occasions in the past, and so as a means of preparing for the risk of losing sales rights, it launched the Research Center in 1999 and started to develop in-house manufactured products.

In 2001, it launched guide wires as its first in-house manufactured products, and subsequently expanded its lineup to include EP catheters and ablation catheters. In FY3/09, the Company acquired Ube Junken, which was a subsidiary of Ube Industries, Ltd. <4208> and the only manufacturer of vascular grafts in Japan. Manufacturing capabilities were also triggered by the fact that, at that time, Vascutek Ltd. was acquired by a competitor, and this acquisition subsequently led to the Company to launch in-house manufactured products, such as the J-Graft series of vascular grafts and “only-one” product, open stent grafts.

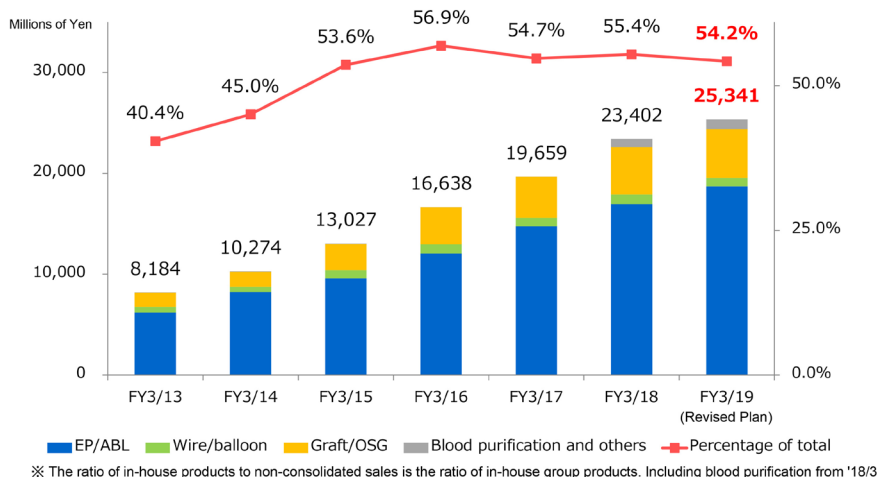
| \* Ube Junken was subsequently renamed JUNKEN MEDICAL and absorbed by the Company in April 2017. |

Performance trends

The product that spurred the growth of in-house manufactured products, lineup of which has expanded in this way, was BeeAT, which is an “only-one” catheter product with an internal atrial cardioversion system that was launched in October 2012. This product is used in approximately 80% of ablation treatments of atrial fibrillation, and its sales volume has grown rapidly along with the increase in the number of cases of atrial fibrillation, contributing greatly to improve the Company’s profit level. The development of in-house manufactured products started as a means of hedging against the risk of losing sales rights to purchased products, but today, their sales scale has grown to exceed that of purchased products. However, for the time being from FY3/19, the ratio of in-house products is forecast to decrease slightly due to multiple launches of large-scale purchased products. Details will follow later, but there seemed to have been some hurdles in the initial period of these new products during FY3/19 1H, but results had underlying support from the stable gross margin of the Company’s in-house products.

Sales of in-house group products

Continuing growth in in-house products, but decreased in ratio due to growth in third party’s products



Source: The Company's results briefing materials

Although FY3/19 1H sales fell short of expectations, SG&A expenses from up-front investment were held below the forecast

2. Trends in FY3/19 1H

In the FY3/19 1H results, net sales were ¥22,265mn (up 9.9% YoY), operating income was ¥4,860mn (up 0.0%), ordinary income was ¥5,089mn (up 1.2%), and net income attributable to owners of the parent was ¥3,638mn (up 7.4%). These results were a bit disappointing, as the Company was expected to achieve a high growth. However, in the same period of the previous fiscal year, adjustment of unrealized gain, which amounted to as much as ¥502mn, in conjunction with the subsidiary merger boosted profits, and the operating profit growth in real term excluding this impact grew by 11.6%, thereby maintaining the double-digit growth. Meanwhile, net sales were ¥637mn lower than the initial forecast, but operating income, ordinary income, and net income attributable to owners of parent exceeded the initial forecasts by ¥243mn, ¥343mn, and ¥421mn, respectively.

Performance trends

Despite the impact from downward revisions of reimbursement prices on all handled products in April 2018, the increase in sales volumes stemming from the increase in cases in the cardiovascular field and the launch of new products contributed to a near double-digit growth in profits. However, profits fell short of the initial forecast due to the weak sales of Cardiac Rhythm Management products resulting from the slow start for new products and the supply shortage for remote monitoring devices. The gross profit margin declined 0.8 percentage points due to the revision of insurance reimbursement prices and the non-recurrence of the adjustment for unrealized gains that were recorded in the previous period, but the gross profit margin was 1.1 percentage points higher than the forecast due to the fact that the ratio of in-house manufactured products was higher than expected and many of these were highly-profitable products. SG&A expenses rose 13.7% YoY, and grew more than net sales, due to the increase in personnel and advertising expenses as a part of efforts to strengthen the sales platform ahead of the launch of new products, as well as development expenses for in-house manufactured products and outsourcing costs related to the logistics base, which started operation in Kansai from this year. In addition, there was an improvement in non-operating income due to factors including the increase in foreign exchange gains and interest received, while extraordinary income/loss also improved due to the non-recurrence of factory transfer expenses. Operating income and all subsequent profit lines exceeded initial expectations. This was due to the fact that the shortfall in net sales was made up for by the improvement in the gross profit margin and the efforts to keep SG&A expenses (including advertising costs) down.

**FY3/19 1H results**

	(¥mn)					
	FY3/18 1H	FY3/19 1H initial forecast	FY3/19 1H revised forecast	% of sales	YoY	vs. initial forecast
Net sales	20,267	22,902	22,265	-	9.9%	-2.8%
Gross profit	12,529	13,719	13,579	61.0%	8.4%	-1.0%
SG&A expenses	7,671	9,102	8,719	39.2%	13.7%	-4.2%
Operating income	4,858	4,617	4,860	21.8%	0.0%	5.3%
Ordinary income	5,027	4,746	5,089	22.9%	1.2%	7.2%
Net income attributable to owners of the parent	3,386	3,217	3,638	16.3%	7.4%	13.1%

Source: Prepared by FISCO from the Company's financial results

## Major product Orsiro falls short of initial forecast

### 3. Sales trends by product in FY3/19 1H

In Cardiac Rhythm Management, sales of cardiac pacemakers declined due to the lowering of insurance reimbursement prices and the insufficient supply of remote monitoring devices. The Company launched sales of new product PLATINUM 4LV SonR CRT-D this July, but there was a decline in ICD-related sales. In EP/Ablation, there was a negative impact from the lowering of insurance reimbursement prices on some EP catheters, but the high growth trend in the number of cases of ablation treatment for atrial fibrillation, which increased by 20% YoY, contributed to the strong sales of products related to atrial fibrillation treatment, such as the one-of-a-kind BeeAT and RF needles. In July 2018, the Company launched sales of the endoscopic laser ablation system HeartLight, a new product for which the Company has high expectations.

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Performance trends

In the Cardiovascular Surgery category, sales of the abdominal stent graft AFX2 grew, partly due to support from VELA, an abdominal extension, while sales of vascular graft-related products like J-Graft FROZENIX, a one-of-a-kind open stent graft, were strong. Meanwhile, there has been a downward trend in artificial valves due to the spread of transcatheter aortic valve implantation (TAVI). In Transvascular Intervention, sales of penetration catheters, balloon catheters, guide wires, and other existing products struggled due to competition and insurance reimbursement price cuts. However, sales increased significantly due to the contribution by sales of Orsiro, the drug-eluting coronary stent launched in March 2018. However, while expected to be a hit product, sales of Orsiro fell short of the initial forecast.

Net sales by product in FY3/19 1H

	FY3/18 1H	FY3/19 1H initial forecast	FY3/19 1H result	% of sales	YoY	vs. initial forecast
						(¥mn)
Pacemaker-related	3,355	2,872	2,844	12.8%	-15.2%	-1.0%
ICD-related	281	280	241	1.1%	-14.0%	-13.7%
Others	91	106	110	0.5%	21.0%	3.3%
<b>Cardiac Rhythm Management</b>	<b>3,727</b>	<b>3,259</b>	<b>3,196</b>	<b>14.4%</b>	<b>-14.2%</b>	<b>-1.9%</b>
EP catheter	7,446	8,447	8,385	37.7%	12.6%	-0.7%
ABL catheter	586	584	638	2.9%	8.8%	9.2%
Others	1,860	2,179	2,215	9.9%	19.1%	1.6%
EP/Ablation	9,894	11,211	11,239	50.5%	13.6%	0.2%
Heart valve-related	840	872	764	3.4%	-9.1%	-12.4%
Vascular graft-related	3,781	3,836	4,305	19.3%	13.8%	12.2%
Blood purification	474	486	478	2.1%	0.8%	-1.7%
Others	49	30	40	0.2%	-19.8%	31.3%
<b>Cardiovascular Surgery</b>	<b>5,147</b>	<b>5,225</b>	<b>5,588</b>	<b>25.1%</b>	<b>8.6%</b>	<b>6.9%</b>
Balloon catheter	462	375	294	1.3%	-36.4%	-21.7%
Guide wire	191	179	179	0.8%	-6.3%	-0.2%
Others	845	2,650	1,768	7.9%	109.3%	-33.3%
<b>Transvascular Intervention</b>	<b>1,498</b>	<b>3,205</b>	<b>2,241</b>	<b>10.1%</b>	<b>49.6%</b>	<b>-30.1%</b>
<b>Total</b>	<b>20,267</b>	<b>22,902</b>	<b>22,265</b>	<b>100.0%</b>	<b>9.9%</b>	<b>-2.8%</b>

Source: Prepared by FISCO from the Company's results briefing materials

## Full-year results forecast revised downward due to Orsiro sales shortfall and other factors

### 4. FY3/19 outlook

For the FY3/19 results, the Company has revised its initial forecasts, and is now expecting net sales of ¥46,762mn (up 10.6% YoY), operating income of ¥10,383mn (down 2.7%), ordinary income of ¥10,745mn (up 0.1%), and net income attributable to owners of the parent of ¥7,530mn (up 0.7%). In FY3/18, the profit level was increased by the ¥1,170mn unrealized gain from the subsidiary mergers, so operating income is forecast to increase by 9.3% YoY on a real-term basis. However, compared to the initial plan, the Company reduced its forecasts for net sales by 5.4%, operating income by 7.3%, ordinary income by 6.4%, and net income attributable to owners of parent by 3.8%.

Performance trends

In FY3/19 1H, while net sales exceeded forecasts for EP/Ablation and Cardiovascular Surgery, net sales undercut forecasts in both Cardiac Rhythm Management and Transvascular Intervention. In particular, in the Transvascular Intervention category, net sales of Orsiro fell short of the forecast. However, by curbing advertising and other SG&A expenses, operating income and other profit lines ended up exceeding the initial forecasts. In the second half of FY3/19, although continued strong performance is expected in both EP/Ablation and Cardiovascular Surgery, the Company lowered its full-year sales assumption for Orsiro from ¥50mn to ¥27mn due to the difficult environment, and the Company also expects a decline in sales of MicroPort products prior to the change of suppliers from MicroPort to Boston Scientific Japan. As such, the Company lowered its full-year results forecasts. However, the Company has kept its full-year SG&A expenses outlook at roughly the same amount as in the initial forecast, which seems a bit conservative.

**FY3/19 outlook**

	(¥mn)					
	FY3/18	FY3/19 initial forecast	FY3/19 revised forecast	% of sales	YoY	vs. initial forecast
Net sales	42,298	49,411	46,762	-	10.6%	-5.4%
Gross profit	26,576	29,455	28,194	60.3%	6.1%	-4.3%
SG&A expenses	15,904	18,252	17,811	38.1%	12.0%	-2.4%
Operating income	10,671	11,202	10,383	22.2%	-2.7%	-7.3%
Ordinary income	10,730	11,482	10,745	23.0%	0.1%	-6.4%
Net income attributable to owners of the parent	7,478	7,825	7,530	16.1%	0.7%	-3.8%

Source: Prepared by FISCO from the Company's results briefing materials

## Changes occurring in each business field

### 5. Outlook of net sales by product in FY3/19

In Cardiac Rhythm Management, the agreement with MicroPort will terminate in August 2019, so there is a possibility that customers will hold off on making purchases. Meanwhile, the exclusive distribution agreement with Boston Scientific Japan will start from September 2019, and the Company is planning to build a sales platform starting in the second half of FY3/19. There is thus a high likelihood that earnings will plateau from August 2019 until September 2019. The agreement with Boston Scientific Japan was expensive, as it included an upfront payment of ¥3.0bn (amortized over 10 years on a straight-line basis), but significant synergies are expected between the strong manufacturer (especially strong products in the tachycardia field) and strong distributor. At the very least, this relationship is expected to grow the Company's earnings over the medium to long term by enhancing the product lineup in the tachycardia field for which the market is forecast to expand going forward. With this, it is now more likely that the Cardiac Rhythm Management category, which was not expected to see much growth, will become a growth field over the medium term.



## Performance trends

**Outlook of net sales by product in FY3/19**

	FY3/18	FY3/19 initial forecast	FY3/19 revised forecast	% of sales	YoY	vs. initial forecast
Pacemaker-related	6,463	5,739	5,390	11.5%	-16.6%	-6.1%
ICD-related	584	680	495	1.1%	-15.2%	-27.2%
Others	200	305	285	0.6%	42.5%	-6.7%
<b>Cardiac Rhythm Management</b>	<b>7,247</b>	<b>6,725</b>	<b>6,170</b>	<b>13.2%</b>	<b>-14.9%</b>	<b>-8.2%</b>
EP catheter	15,354	17,225	17,201	36.8%	12.0%	-0.1%
ABL catheter	1,161	1,611	1,748	3.7%	50.5%	8.5%
Others	3,848	4,509	4,520	9.7%	17.4%	0.2%
<b>EP/Ablation</b>	<b>20,364</b>	<b>23,345</b>	<b>23,469</b>	<b>50.2%</b>	<b>15.2%</b>	<b>0.5%</b>
Heart valve-related	1,742	1,806	1,535	3.3%	-11.9%	-15.0%
Vascular graft-related	8,482	8,564	9,028	19.3%	6.4%	5.4%
Blood purification	1,131	1,176	1,157	2.5%	2.3%	-1.5%
Others	106	58	68	0.1%	-35.9%	16.2%
<b>Cardiovascular Surgery</b>	<b>11,464</b>	<b>11,606</b>	<b>11,790</b>	<b>25.2%</b>	<b>2.8%</b>	<b>1.6%</b>
Balloon catheter	950	781	625	1.3%	-34.2%	-19.9%
Guide wire	371	399	406	0.9%	9.4%	1.9%
Others	1,899	6,553	4,299	9.2%	126.4%	-34.4%
<b>Transvascular Intervention</b>	<b>3,221</b>	<b>7,734</b>	<b>5,332</b>	<b>11.4%</b>	<b>65.5%</b>	<b>-31.1%</b>
<b>Total</b>	<b>42,298</b>	<b>49,411</b>	<b>46,762</b>	<b>100.0%</b>	<b>10.6%</b>	<b>-5.4%</b>

Source: Prepared by FISCO from the Company's results briefing materials

In EP/Ablation, the number of atrial fibrillation cases is increasing rapidly, and the Company has revised its full-year assumption from an increase of 18% to 19%, and the Company expects further growth in BeeAT and RF needles. There are high expectations for HeartLight as a new treatment device to take the place of high-frequency (RF) catheters and other competing balloon type devices, as it delivers laser treatment while allowing direct viewing of pulmonary veins via an equipped endoscope. Currently, Post-Marketing Surveillance (PMS) has gotten off to a good start, with more progress than expected. The Company expects HeartLight to make a full-scale contribution from FY3/20, and plans to encourage sales in the treatment field (ablation catheters) which currently has a low market share by realizing early market penetration of HeartLight. The Company predicts that 45% of AF cases will use balloon catheters in FY3/23, and is aiming for HeartLight to capture 40% of the balloon ablation market.

In Cardiovascular Surgery, the Company is expecting a decline in sales of artificial valve-related products because the exclusive sales agreement for LivaNova's artificial valve-related products will end. In addition, overseas expansion has been delayed due to the outlook for a postponement in CE Mark acquisition in Europe for open stent grafts. However, abdominal stent grafts and other vascular graft-related products are expected to continue to drive an increase in sales. The Company plans to stop sales of LivaNova products related to artificial valves on May 31, 2019, including the suture-less valve PERCEVAL, the new product for which expectations was high. There is a possibility that the Company will re-enter the artificial valve-related business in the medium term, but in the near term the Company plans to focus on the lineup of vascular graft-related products. Meanwhile, the joint R&D agreement with Endologix <ELGX> (the supplier of abdominal stent grafts) for thoracic stent grafts was terminated. The Company will maintain its cooperative relationship with Endologix with respect to products in the abdominal area, and plans to expand the lineup to cover diverse cases. With respect to thoracic products, the Company entered into an exclusive distribution agreement with Endospan, an Israeli company, for the branched thoracic stent graft NEXUS. The Company has already submitted an application for CE mark (the first such application for an aortic arch device), and there are high hopes that this product will help reduce complications based on its unique design. The Company is aiming to launch the product in the market in 2023.

Performance trends

In Transvascular Intervention, the Company is expecting a slight increase in sales of guide wires, but a decline in sales of penetration catheters and balloon catheters for which the external environment is challenging. For Orsiro, which was a major factor behind the downward revision to the Company's forecast, the Company has significantly lowered its expectations, revising its target market share downward from 15% to 8%. While the product is superior to those of first-mover companies, the gap in sales experience and sales platforms between the Company and the first-mover companies was the reason for the downward revision. Going forward, the Company will handle long size variations and revise its sales strategy, aiming to acquire an 8% market share. Elsewhere, the Company has been steadily implementing measures to strengthen the Transvascular Intervention category. Such efforts include starting sales of an FFR (fractional flow reserve) measurement device and filing an application for regulatory approval for the IVUS-OCT hybrid system, an imaging system that integrates IVUS (intravascular ultrasound) and OCT (optical coherence tomography) in a single catheter.

Large-scale products for which there are high expectations



From left: endoscopic laser ablation system (HeartLight), thoracic stent graft (NEXUS), new concept and new generation stent graft (Nellix), drug-eluting coronary stent (Orsiro)  
 Source: The Company's results briefing materials

## Medium-term management plan

### Waiting for an update to the medium-term management plan based on changes in agreements with partners

#### 1. Medium-term management plan

By FY3/19 1H, the drug-eluting coronary stent Orsiro, and the endoscopic ablation system HeartLight, were brought to market. Both of these are major products. As mentioned above, sales of Orsiro fell short of expectations, but did contribute to the increase in sales in the Transvascular Intervention category, while sales of HeartLight exceeded the Company's forecast despite its first year of sales. With respect to existing products, there was steady growth in atrial fibrillation-related products in the EP/Ablation category. Moreover, the Company made some important decisions that would have implications over the medium to long-term. These included changing its suppliers in the Cardiac Rhythm Management category, and ending its artificial valve-related business in the Cardiovascular Surgery category. Given the major changes to the assumptions in the existing medium-term management plan, which aims for net sales of ¥77.7bn and operating margin of 25% in FY3/23, the Company has decided to update its medium-term management plan in May 2019.

## No significant changes expected in medium- to long-term growth story

### 2. Medium-term growth assumptions remain unchanged

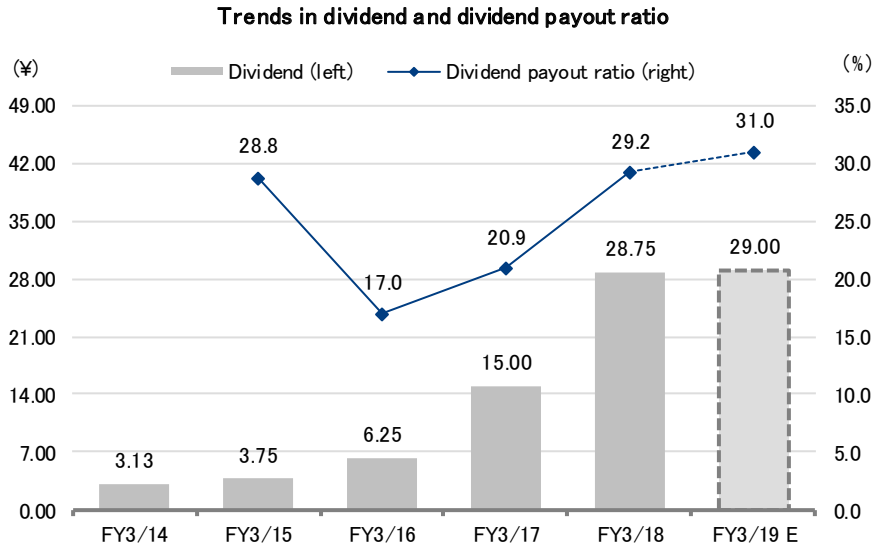
The heart disease medical devices market continues to expand against a backdrop of an aging population in Japan and thanks to the advancement of medical devices. In this sort of environment, there is no other company in Japan that can provide sales and regulatory work at the same level as the Company does, which means that collaborating with the Company is the best strategy for overseas manufacturers without sales channels in Japan. As a result, the Company will have an abundance of products in the pipeline going forward. Moreover, it is expanding its R&D bases and plans to grow its pipeline of in-house manufactured products. Furthermore, the Company is also expanding its business domains, including entering the gastrointestinal field. It also plans to build a new factory in Malaysia. This factory will initially manufacture balloon catheters for the Japan market, but in the future the Company intends for this plant to manufacture EP catheters and sell them in Asia and Europe. Considering the business environment both in Japan and overseas, it can be safe to assume that the Company's growth story will not change significantly. The Company plans to announce a new medium-term management plan in May 2019.

## Shareholder return policy

### Dividends are expected to continue to increase alongside the profit growth

The Company's basic policy for returning profits to shareholders is "to consider the various factors, such as the results and the demand for capital for business development in the future, and to implement appropriate measures to return profits to shareholders, mainly through continuously and stably paying a dividend, while retaining the necessary internal reserves." In addition, its policy for internal reserves is "to increase enterprise value by aiming to raise results and invest in developing and manufacturing products in-house that utilize our strengths," and going forward, it will raise the dividend in line with profit growth. It has carried out equity finance, but considering the Company's performance, we expect that its free cash flow will continue to expand in the future. Accordingly, while maintaining a balance between returning profits to shareholders and securing internal reserves, the Company's investment and dividend capabilities are expected to improve onward. Therefore it can be reasonable to say that the Company has reached a growth stage where it can return profit growth to shareholders.

Shareholder return policy



Note: The amounts have been retroactively adjusted in relation to the 2-for-1 share splits in 2015, 2016, and 2018.  
 Source: Prepared by FISCO from the Company's financial results

## Information security

The Company is implementing various information security measures, such as using remote servers, implementing encryption measures and measures to defend against malware, and conducting network monitoring to detect unauthorized access. Recently, it has started collaborating with a company specializing in security and it is regularly conducting operations evaluations and ascertaining points to improve on, and in such ways it is working to improve the information-security management level.



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