COMPANY RESEARCH AND ANALYSIS REPORT

Japan Lifeline Co., Ltd.

7575

Tokyo Stock Exchange First Section

13-Aug.-2019

FISCO Ltd. Analyst
Kimiteru Miyata

FISCO Ltd.
http://www.fisco.co.jp

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https://www.japanlifeline.com/investors/

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Summary

Likely to sustain strong growth over the medium-term

Japan Lifeline Co., Ltd. <7575> (hereafter, also “the Company”) is an import trading company, as well as a manufacturer, of cardiovascular 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. It has also developed its own products to meet specific frontline healthcare needs. Besides these sales and manufacturing operations, the Company has also strengthened its regulatory platform to obtain regulatory approvals necessary to introduce medical devices. Furthermore, as an independent company, Japan Lifeline serves as a trusted sales partner for overseas manufacturers that do not possess sales channels in Japan. Purchased products often utilize exclusive sales contracts, and these arrangements support considerably higher gross margin than at trading company peers. The Company generates top-class profitability in the medical devices industry, including manufacturers, because of its sales, manufacturing, and regulatory capabilities with high added value.

The Company has four product categories: Cardiac Rhythm Management, EP/Ablation, Cardiovascular Surgery and Transvascular Intervention. The Cardiac Rhythm Management category handles devices used to treat cardiac arrhythmia, but is currently in a transition phase of switching the main supplier from MicroPort to Boston Scientific Corporation (BSX), a global medical devices manufacturer. The EP/Ablation category handles disposable electrode-equipped catheters used for diagnosis and treatment of arrhythmia, and other products. In FY3/19, the number of cases of atrial fibrillation treatment with ablation rose 17% YoY. Cases have been rapidly increasing in recent years. The Cardiovascular Surgery category handles artificial vessels to replace blood vessels that no longer function. The Transvascular Intervention category mainly handles medical devices to treat conditions, such as myocardial infarction and angina pectoris. The Company has recently been entering other medical fields besides cardiovascular, such as the digestive system.

In FY3/19, the Company reported ¥45,525mn in net sales (+7.6% YoY) and ¥10,526mn in operating profit (-1.4%). While profit fell on higher sales, this can be attributed to non-recurrence of a one-time boost to gross profit in FY3/18 thanks to an unrealized profit adjustment (¥1,170mn) accompanying a subsidiary merger. Operating profit on a real basis excluding the impact of unrealized profit rose by a healthy 10.8% YoY. Nevertheless, the Company lowered guidance during the period because of weak results with Orsiro, a much-anticipated major new product. The Company’s FY3/20 guidance calls for ¥54,059mn in net sales (+18.7% YoY) and ¥10,465mn in operating profit (-0.6%). A key factor in the outlook is the change in its supplier of Cardiac Rhythm Management devices. The Company switches from previous MicroPort products to Boston Scientific products and plans to begin full-fledged sales activities in September 2019. It does not expect much income growth in 1H due to anticipated buying restraint at medical entities through the end of August 2019, but targets substantially higher sales (YoY) from September.

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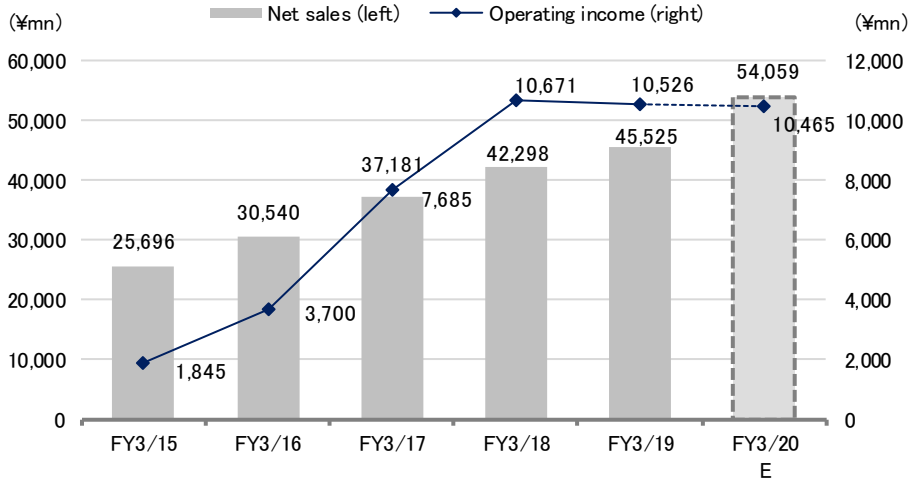
Summary

The Company changed multiple important contracts from past years in 2018-19, making revisions to the longer-term growth strategy. While it still wants high-margin operations by bolstering its own products, the outlook anticipates declines in the in-house product sales ratio and gross margin because of larger sales of procured products with the release of a major new product and arrangement of an exclusive contract with Boston Scientific. Nevertheless, the Company expects a substantial rise in sales per person and other sales efficiency due to selling Boston Scientific products through its nationwide sales network, and as a result, it can be expected that there will be an improvement in the SG&A expenses ratio. Therefore, although the Company lowered gross margin in the updated rolling mid-term business plan, it factored in sales expansion and a lower SG&A expenses ratio and set goals of ¥89.4bn in net sales and 23% operating margin (¥20.5bn in operating profit) in FY3/24. We expect the Company to retain its existing growth potential even if the scenario changes.

Key Points

- Manufacturer and trading company for cardiovascular medical devices, moving into other fields in recent years
- Achieves high profitability in imported product business by using a sales format based on exclusive contracts
- Targeting renewed growth after a plateau driven by the long-term exclusive distribution agreement with Boston Scientific

Results trends



Source: Prepared by FISCO form he Company's financial results

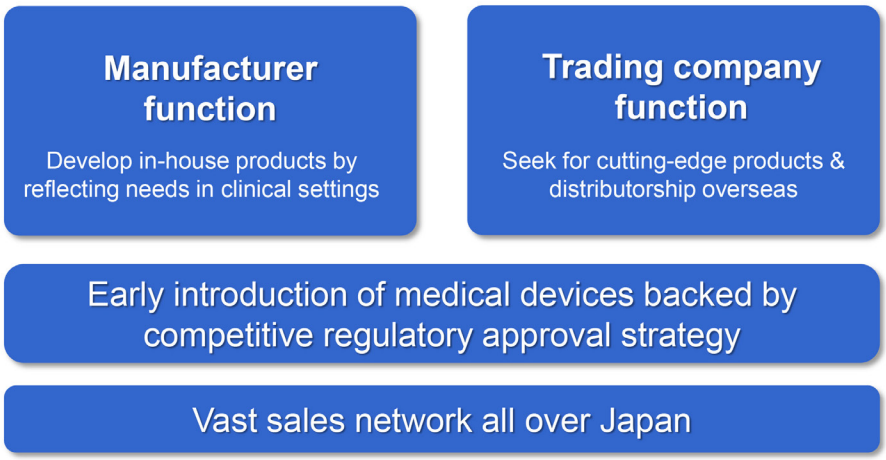
Business overview

Medical devices manufacturer and specialty trading company

1. Business description

Since it started sales of imported cardiac pacemakers in 1981, the Company has introduced cutting-edge overseas medical devices in Japan and expanded sales locations nationwide. It launched manufacturing of medical devices too. As a specialist trading company in medical devices, it communicates closely with doctors using advanced specialty knowledge and has cultivated excellent product discernment. Furthermore, as a manufacturer of medical devices, it utilizes a network of doctors who are active on the medical frontline to develop its own medical products precisely tailored to meet the needs of medical sites. Regulatory approval is required to release medical devices, and the Company is strengthening its regulatory operations based on experience introducing devices over many years. It moves smoothly through the process that includes acquisition of data showing product safety and effectiveness and negotiations with government officials. The Company's advantages are a nationwide sales structure, domestic introduction of cutting-edge products, its own products that meet specific needs, and robust regulatory operations. Furthermore, as an independent company, Japan Lifeline serves as a trusted sales partner for overseas manufacturers that do not possess sales channels in Japan. In fact, the Company has concluded many exclusive sales contracts with overseas firms.

The Company's growth foundation



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

Sales operations with nationwide coverage and robust R&D and manufacturing sites

2. Unique business model as a manufacturer and trading company

As its sales structure, the Company has 47 sales bases throughout Japan, from Hokkaido to Okinawa, and two logistics centers in Haneda and Kansai (as of the end of March 2019), 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 of the Company 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.

The Company is a manufacturer as well. 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 the end of March 2019). The products that the Company develops and manufactures in-house to meet needs in healthcare fields are guide wires, EP catheters, and ablation catheters. 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. JUNKEN MEDICAL merged with the Company in April 2017 through an absorption-type merger toward realizing synergies and improved efficiency in development and manufacturing products.

Unique products are the source of high profitability

3. Income structure

For purchased products, the Company concludes exclusive sales contracts with overseas manufacturers, mainly in Europe and the United States. It ties up with a single partner for each product category, in principle. The Company manages to arrange exclusive sales contracts because its role as a manufacturer too reassures overseas firms that they can trust it to do what is necessary as a manufacturer in Japan. In other words, it can handle tasks as a manufacturer on behalf of overseas firms, including acquisition of regulatory approval in Japan, marketing to smoothly promote use of medical devices via academic societies and other related organizations, and education for medical institutions. There is also 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, and involves an inventory burden not covered by sales distributors. Thanks to its exclusive sales contracts, the Company's gross margin on purchased products averages 40-50%, a high level compared to margins of sales agencies conducting secondary distribution that handle products of multiple companies and have gross margins of about 20%. The Company's gross margin on its own products, including unique products, is even higher in the 70-80% range. The Company hence generates very high operating margin in the medical devices industry.

Industry profitability comparison (latest fiscal year)

(¥mn, %)

Business category	Code	Company name	Net sales	Operating income	Operating margin	Market cap	Characteristics (* cardiovascular specialty trading company)
Manufacturer Trading company	7575	Japan Lifeline Co., Ltd.	45,525	10,526	23.1	148,118	* strength in cardiovascular business Procurement with exclusive sales and manufacturing of its own products
Trading company	3360	Ship Healthcare Holdings	444,048	17,952	4.0	234,856	Diversification from medical devices wholesale business into such areas as hospital support and pharmacies
Trading company	7476	AS ONE Corporation	66,733	7,562	11.3	201,709	Mainly handles scientific equipment Covers semiconductors and care equipment
Trading company	7600	Japan Medical Dynamic Marketing (MDM), INC.	16,728	2,234	13.4	38,125	Imports osteosynthesis materials and supplies in-house artificial joints
Trading company	3183	WIN-Partners Co., Ltd.	69,775	3,261	4.7	32,028	*Specializes in cardiac catheters and other cardiovascular products
Trading company	3154	MEDIUS HOLDINGS Co., Ltd.	168,135	960	0.6	15,689	Wide lineup from cutting-edge medical devices to consumables.
Trading company	2689	Kawanishi Holdings, Inc.	107,663	1,230	1.1	9,031	Medical devices wholesale business mainly in Setouchi areas including Okayama
Trading company	3079	DVx Inc.	40,380	1,237	3.1	8,945	*Specializes in cardiac pacemakers and other cardiovascular products
Trading company	9265	YAMASHITA HEALTH CARE HOLDINGS, INC.	58,692	373	0.6	3,074	Medical devices wholesale business mainly in Kyushu
Manufacturer	4543	Terumo Corporation	599,481	106,637	17.8	2,345,401	Major firm with large global market shares in catheters and other products
Manufacturer	7733	Olympus Corporation	793,862	28,281	3.6	1,761,547	Top global supplier of endoscopes, concentrating management resources in endoscope business
Manufacturer	6849	NIHON KOHDEN CORPORATION	178,799	15,044	8.4	277,284	EEGs, ECGs, patient information monitors, etc.
Manufacturer	6960	Fukuda Denshi Co., Ltd.	129,775	12,645	9.7	137,312	Top ECG firm, manufactures and sells medical electronic equipment

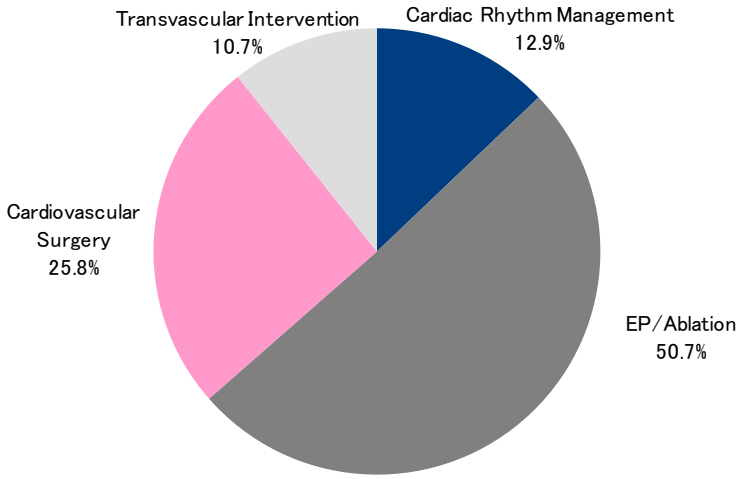
*Sales and operating profit values from latest fiscal years. Fiscal years end in June for Medius and Kawanishi, May for Yamashita, and March for others. Market caps as of 31 May 2019.
*Olympus' operating margin was lower in FY3/19 because of settlement and plea bargain outlays; normally about 10%
Source: Prepared by FISCO from each company's financial results

Review of product categories

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, Cardiac Rhythm Management contributed 12.9%, EP/Ablation 50.7%, Cardiovascular Surgery 25.8%, and Transvascular Intervention 10.7%.

Review of product categories

Percentages of net sales by product (FY3/19)



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

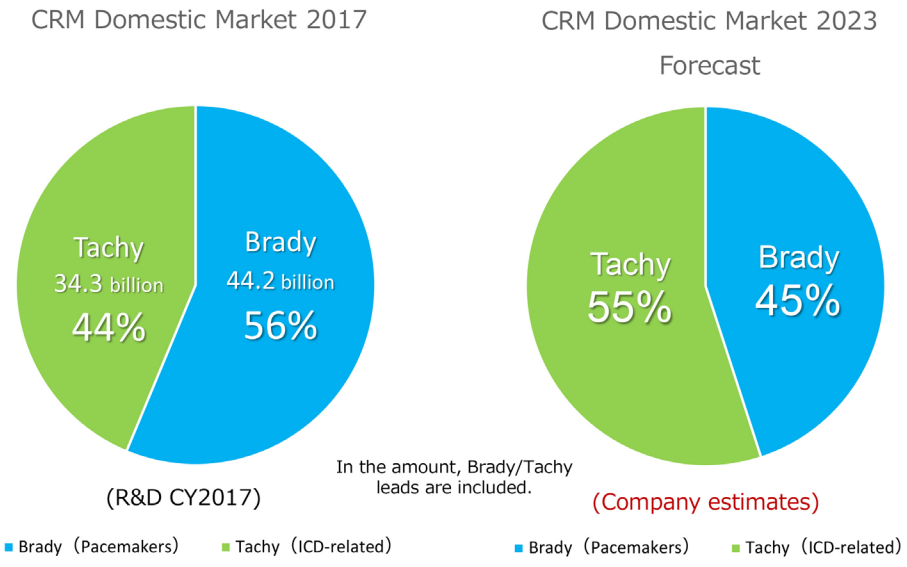
Shifting to better supply operations

1. Cardiac Rhythm Management

Cardiac Rhythm Management handles implantable medical devices that treat cardiac arrhythmia. The main products 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 Company obtains cardiac pacemakers and related products from MicroPort, with which it has an exclusive sales contract. MicroPort has superior expertise in cardiac pacemakers used to treat bradycardia (when the heart beats slower than usual) but also provides devices for tachycardia (when the heart beats quicker than usual). However, MicroPort faced issues in product development capabilities, such as delay in MRI-compatible products in tachycardia area and supply-capacity shortage for remote monitoring equipment. Demand for ICDs for tachycardia treatment has been growing recently in the cardiac rhythm management (CRM) market. The Company hence decided to end its relationship with MicroPort when the exclusive sales contract expired on 31 August 2019 and concluded a long-term exclusive sales contact for CRM-related products made by Boston Scientific (US). It plans to begin sales of all kinds of CRM-related products in September 2019.

Review of product categories

CRM market shifting from bradycardia to tachycardia treatment



* Brady: bradycardia, Tachy: tachycardia
Source: The Company's medium-term business plan briefing materials

Boston Scientific is a top-class global medical equipment manufacturer that has excellent medical devices especially in the tachycardia treatment field which had been an issue for the Company for many years. Since the new contract enables the Company to sufficiently cover the full CRM field, we expect larger sales and a more advanced sales strategy. Boston Scientific already had business sites in Japan and a close network with domestic medical personnel. However, it opted to unify CRM-related sales operations at the Company from September 2019 in order to achieve integrated sales strategy formulation and execution. As part of this reshuffling, the Company is absorbing salespeople from Boston Scientific Japan involved in handling CRM products in Japan. The Company aims to promptly build sales operations and provide stable, continuous follow-up support for patients and medical staff by receiving sustained sales assistance for products in the tachycardia treatment field, which requires higher-level expert knowledge than bradycardia treatment, from highly experienced personnel with in-depth knowledge cultivated through work at Boston Scientific Japan. We also expect sustainable growth in CRM business over medium- to long-term by gaining access to the Boston Scientific product pipeline. In FY3/20, however, the Company forecasts flat income due to likely buying restraint from medical entities through August 2019 during the transition from MicroPort to Boston Scientific.

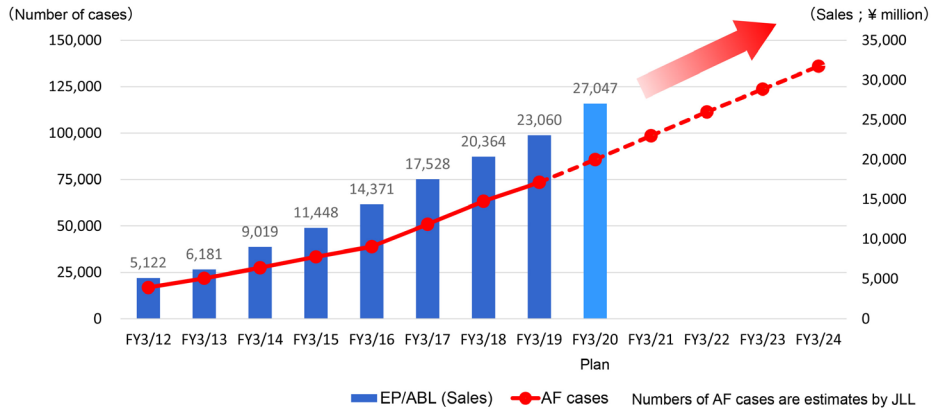
Continuation of high growth in AF case volume

2. EP/Ablation

In EP/Ablation, the Company handles disposable electrode-equipped catheter for diagnosis and treatment of arrhythmia. In FY3/19, the number of cases increased 17% 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.

Review of product categories

EP/ABL Forecast of AF ablation cases



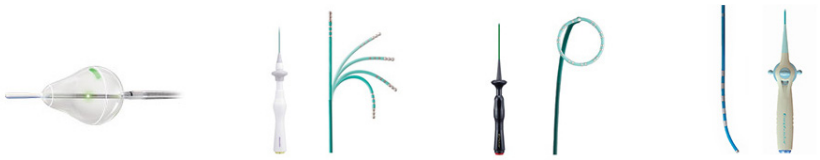
Source: The Company's medium-term management plan briefing materials

EP catheters (Japan Lifeline) are a thin catheter with an electrode used to measure electric potential in the heart and to identify the part causing the arrhythmia. To inspect the various parts within the heart, it comes in many types, including a curve-shaped tip, number and positions of electrodes, and catheter diameters. There is also the single-directional type (turns to one side) that curves the tip using a grip lever for the hand and the bi-directional type (turns to both sides). These products come with a variety of curves. Ablation catheters (Japan Lifeline) are an electrode catheter that locally cauterizes and treats the stimulus conduction pathway that causes local arrhythmia (tachycardia) with a high-frequency current. Similar to EP catheters, it comes in many types to support cauterization of various parts inside the heart. Irrigation catheters are a type of ablation catheter with a hole at the tip to spray normal saline solutions. It has a function to reduce 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 occurs 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). Ablation treatment for atrial fibrillation has a higher incidence rate of complications such as esophageal fistula (hole between the left atrium and esophagus) and other esophageal esophagitis and esophageal ulcers, than other ablation procedures. The esophageal temperature monitoring system (Japan Lifeline) prevents these complications by continuously monitoring the temperature of the esophagus during ablation treatment. The HeartLight endoscope ablation catheter released in July 2018 is a balloon-type ablation catheter for eradication treatment of arrhythmia (atrial fibrillation) with a built-in endoscope that fits a balloon in the myocardium near pulmonary veins that require treatment and shines a laser with adjustable output while looking at the spot via the endoscope to cauterize the abnormal electric path. While this was a revolutionary technique, it faced a bottleneck from requiring a longer procedure than rival products and did not gain as much traction as anticipated. Despite the slow start, the Company plans to increase sales by securing enough doctors capable of teaching the technique and expanding facilities using the system. It also intends to release HeartLight X3, which substantially shortens procedure length by FY3/22 and expects a large contribution to higher sales after launching this next-generation model.

Review of product categories

EP/Ablation catheter



Note: (From the left) HeartLight (CardioFocus), ablation catheter (JLL), EP catheter (JLL), and esophageal temperature monitoring system (JLL)
Source: The Company's website

Healthy momentum for in-house artificial vessels

3. Cardiovascular Surgery

In Cardiovascular Surgery category, the Company handles medical devices used for surgical treatments, such as aorta artificial blood vessels and stent grafts. Main in-house manufactured products are artificial blood vessels and open stent grafts manufactured by JUNKEN MEDICAL, which the Company absorbed and merged with in April 2017. Purchased products, meanwhile, include thoracic stent grafts, abdominal stent grafts, artificial heart valves, and annuloplasty rings. Artificial blood vessels (Japan Lifeline) are a medical device used in treatment of aortic aneurysm in the chest and abdomen. They replace aneurysms in the vessels and provide bypass of blocked vessels. Open stent grafts (Japan Lifeline) are medical devices used to treat thoracic aorta disease. In replacement of the thoracic aorta over a wide range, two open-chest surgeries were necessary for treatment with conventional artificial blood vessels. The open stent graft, meanwhile, enables complete treatment with just a single open-chest surgery thanks to use of a unique stent structure. This product shortens the surgery time and alleviates physical burden on the patient. It is an in-house and unique product in Japan. The Company sees robust competitiveness in other countries too and hopes to leverage it in pursuit of overseas business.

Similar to artificial blood vessels, stent grafts are medical devices used to treat aortic aneurysms. However, unlike the former, which requires surgery to open the chest or abdomen, a stent graft does not require a surgical procedure and uses spring-like metal tubes called stents, which remain in a contracted state within a catheter and are delivered to the treatment location via the catheter inserted into the blood vessel from the groin. At the location, the spring force presses the released stent against the blood vessel to fix it in place. There are two types depending on the part of aorta being treated: thoracic stent graft and abdominal stent graft. The AFX2 Stent Graft System for the abdomen (Endologix), the Company's first entry into a non-cardiovascular area, fared well. However, the joint development contract on a stent graft system for the chest (Endologix) ended in September 2018, and the contract for artificial cardiac valve products with a declining number of cases due to low-invasive treatment with catheters finished at the end of May 2019. The Company hence stopped handling these products. It also delayed the release timing of the abdominal aorta stent graft Nellix carrying high expectations. We think Cardiovascular Surgery business has moved into a flatter phase as well. The Company is currently preparing for future releases of abdominal stent graft Ovation (Endologix) and thoracic stent graft NEXUS (Endospan).

Review of product categories

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

Still expecting Orsiro to drive growth

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 location. It is inserted into a blood vessel, such as via the thigh, and passes through the constriction in the coronary arteries or peripheral arteries, and a balloon catheter or other 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. Treatment involves inflating a balloon on the catheter (thin tube) from inside the blood vessel to expand the blood vessel. The penetration catheter (Teleflex) is a medical device used to support the passage of guide wires through the affected area in coronary arteries or 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. This method does not require a surgery and is 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.

Drug-eluting coronary stent Orsiro (BIOTRONIK), which had been expected as a major product, disappointed with just a 7% market share a year after its release. However, the Company addressed various issues in the line-up and sales capabilities, and market share has been trending upward. While share is unlikely to reach the initial goal of 15%, profit contributions from this product are steadily rising.

Review of product categories

Transvascular Intervention

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

Performance trends

Realized double-digit operating profit growth in real terms and healthy expansion of business scope in FY3/19

1. Trends in FY3/19

In FY3/19, the Company reported ¥45,525mn in net sales (+7.6% YoY), ¥10,526mn in operating profit (-1.4%), ¥10,808mn in ordinary profit (+0.7%), and ¥7,723mn in net profit attributable to parent shareholders (+3.3%). Robust demand exists for medical devices with low invasiveness amid rapid advances in aging because they alleviate physical burden on patients and can reduce medical costs. The national government, meanwhile, is steadily lowering insurance reimbursement prices and sales prices are trending lower mainly for existing medical devices. Medical device manufacturers and wholesale firms are competing fiercely in this environment. The Company continues to introduce products from overseas cutting-edge medical device manufacturers to Japan and also develops and manufactures its own products that reflect specific needs of frontline medical sites, thereby strengthening competitiveness.

In Cardiac Rhythm Management, sales of existing products weakened due to the impact of reductions in insurance reimbursement prices from April 2018 and the disclosure of a planned change in the procurement source in August 2018. In EP/Ablation, sales benefited from gains in related products for atrial fibrillation treatments, such as the Company's unique internal atrial cardioversion system, thanks to increase in cases of atrial fibrillation ablation treatment and contributions from endoscope laser ablation catheter Heartlight. In Cardiovascular Surgery, the Company posted upbeat sales of artificial blood vessel-related products. In Transvascular Intervention, which was affected by insurance reimbursement price reductions, the release of drug-eluting coronary stent Orsiro contributed.

In profits, gross margin improved at the parent level, despite unchanged sales share for in-house products, because of an increase in sales of in-house products with high profitability. In consolidated results, however, gross margin dropped by 1.7 percentage points (YoY) due to non-recurrence in FY3/19 of ¥1,170mn booked as an unrealized profit adjustment (addition to gross profit) related to a subsidiary merger in FY3/18. SG&A expenses were higher because of additional personnel costs accompanying reinforcement of sales operations and increases in advertising and promotional costs to expand new product sales and travel and transportation costs. These trends resulted in a decline in operating profit. Meanwhile, operating profit rose 10.8% on a real basis that takes into account the ¥1,170mn unrealized profit adjustment.

The Company concluded an exclusive distribution agreement for CRM-related products with Boston Scientific Japan, which is highly competitive worldwide, in November 2018 in the Cardiac Rhythm Management business. This arrangement provides coverage of the tachycardia therapy field that had been an issue and solidifies a business foundation for long-term growth along with the Company's EP/ablation strength. In manufacturing, the Company is building a plant in Malaysia to secure supply capacity for in-house products and has started construction of a second-phase building at the Oyama factory aimed at expansion of catheter-related technology. Furthermore, it plans to enter other fields, such as colonic stents and liver cancer treatment devices, as applications of accumulated technologies and knowhow.

F3/19 results

			Values after revision of one-time income					Revised
	FY3/18 (¥mn)	% of sales (%)	FY3/18 (¥mn)	% of sales (%)	FY3/19 (¥mn)	% of sales (%)	Change rate (%)	Change rate (%)
Net sales	42,298	100.0	42,298	100.0	45,525	100.0	7.6	7.6
Gross profit	26,576	62.8	25,406	60.1	27,822	61.1	4.7	9.5
SG&A expenses	15,904	37.6	15,904	37.6	17,295	38.0	8.7	8.7
Operating income	10,671	25.2	9,501	22.5	10,526	23.1	-1.4	10.8
Ordinary income	10,730	25.4	9,560	22.6	10,808	23.7	0.7	13.1
Net income attributable to owners of the parent	7,478	17.7	6,308	14.9	7,723	17.0	3.3	22.4

* Partly estimated by FISCO
Source: Prepared by FISCO from the Company's financial results and result briefing materials

Offsetting delay in ramp-up of major new products and impact from completing sales of some products

2. Sales trends by product in FY3/19

Cardiac Rhythm Management sales dropped 19.1% YoY to ¥5,862mn. The main setback other than insurance reimbursement reductions from April 2018 was curtailed buying of cardiac pacemakers and ICD-related current products following disclosure of the planned change in the supplier in August 2018. In light of this situation, the Company has been working with Boston Scientific Japan, the new supplier of CRM devices, to prepare for full-fledged sales of Boston Scientific products from September 2019. It also began sales in April 2019 at all certified sites ahead of other products of Boston Scientific's unique product in the tachycardia treatment field – the subcutaneous implantable cardioverter defibrillator EMBLEM MRI S-ICD System. By starting sales of products in the tachycardia treatment field that it emphasizes, the Company aims to make progress in building operations ahead of the full-fledged launch of Boston Scientific's CRM-related products and to lay the groundwork for prompt expansion of CRM business.

EP/Ablation sales rose 13.2% YoY to ¥23,060mn. In EP catheters, the Company expanded sales of unique products BeeAT, an internal atrial cardioversion system, and RF needle, a high-frequency atrial septum needle, against a backdrop of increase in ablation for atrial fibrillation cases. In ablation catheters, sales volume fell for conventional ablation catheters that use high frequency. Despite slightly disappointing progress, the endoscope laser ablation catheter HeartLight released in July 2018 is gradually making inroads at medical entities. Ablation therapy for atrial fibrillation using balloon technology could expand further through simplification of the technique. It is taking hold at medical sites because the combination of the endoscope and laser supports in-depth treatment of individual cases.

Cardiovascular Surgery sales were up 2.3% to ¥11,730mn. In artificial blood vessels, the Company increased sales of the AFX2 Stent Graft System, a product that targets the abdominal field, in stent grafts that percutaneously treat aortic disease. Meanwhile, sales volume declined for thoracic products due to completion of the exclusive sales contract in March 2019. For in-house products, sales of open stent graft J-Graft FROZENIX, which is a unique product and contributes to low invasiveness in chest-opening surgery for thoracic aortic disease, were healthy, and artificial blood vessel sales climbed too. In artificial cardiac valve-related products, sales weakened because of inroads by low-invasive therapy using a catheter and the Company finished handling these products through expiration of the current exclusive sales contract as of end-May 2019.

Transvascular Intervention sales rose 51.2% YoY to ¥4,872mn. Balloon catheter sales fell mainly on the impact of insurance reimbursement reductions, while guide wire sales strengthened with contributions from the Amati product ramped up from October 2018. In other products, pressure from rival products weighed on sales of atrial septal defect closing device Figulla Flex II and penetration catheter Guideliner. Drug-eluting coronary stent Orsiro, which the Company released in March 2018, meanwhile, missed the initial outlook on slower ramp-up than initially expected, but sales volume gradually improved in 2H with support from an expanded size lineup. In the ischemic heart disease (IHD) treatment field, the Company released OptoWire, a guide wire equipped with a sensor that measures pressure inside blood vessels, in October 2018 as a product that supports proper PCI (percutaneous coronary intervention) treatment, albeit without exclusive sales.

Sales situation by product categories in FY3/19

(¥mn, %)

	FY3/18 result	% of sales	FY3/19 result	% of sales	YoY	FY3/19 revised forecast	vs. revised forecast
Pacemaker-related	6,463	15.3	5,169	11.4	-20.0	5,390	-4.1
ICD-related	584	1.4	496	1.1	-15.1	495	0.2
Others	200	0.5	196	0.4	-1.7	285	-31.0
Cardiac Rhythm Management	7,247	17.1	5,862	12.9	-19.1	6,170	-5.0
EP catheter	15,354	36.3	17,028	37.4	10.9	17,201	-1.0
ABL catheter	1,161	2.7	1,369	3.0	17.9	1,748	-21.7
Others	3,848	9.1	4,662	10.2	21.2	4,520	3.2
EP/Ablation	20,364	48.1	23,060	50.7	13.2	23,469	-1.7
Heart valve-related	1,742	4.1	1,448	3.2	-16.9	1,535	-5.6
Vascular graft-related	8,482	20.1	9,133	20.1	7.7	9,028	1.2
Blood purification	1,131	2.7	1,070	2.4	-5.4	1,157	-7.5
Others	106	0.3	77	0.2	-27.7	68	12.8
Cardiovascular Surgery	11,464	27.1	11,730	25.8	2.3	11,790	-0.5
Balloon catheter	950	2.2	565	1.2	-40.5	625	-9.6
Guide wire	371	0.9	403	0.9	8.4	406	-0.9
Others	1,899	4.5	3,903	8.6	105.5	4,299	-9.2
Transvascular Intervention	3,221	7.6	4,872	10.7	51.2	5,332	-8.6
Total	42,298	100.0	45,525	100.0	7.6	46,762	-2.6

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

Likely to move off the plateau in 2H FY3/20

3. FY3/20 outlook

For the FY3/20 results, the Company is expecting net sales of ¥54,059mn (up 18.7% YoY), operating income of ¥10,465mn (down 0.6%), ordinary income of ¥11,167mn (up 3.4%), and net income attributable to owners of the parent of ¥7,747mn (up 0.3%).

Performance trends

In sales, the Company ended sales of thoracic stent grafts, except in some regions, accompanying expiration of the contract with the transaction partner in March 2019. It also finished sales of artificial cardiac valve-related products at the end of May 2019. Furthermore, official prices will be revised in October 2019 to reflect the consumption tax hike. Impact from price reductions is likely to reduce 2H sales by about 2-3% and substantially weaken sales of some items. Nevertheless, the Company plans full-fledged launch of Boston Scientific's CRM-related products in Cardiac Rhythm Management business in September 2019. It expects a sharp rise in sales, including Boston Scientific's existing commercial flow, mainly led by products in the tachycardia treatment field as it expands its product lineup. Furthermore, it factors in continued rapid growth in case volume for ablation treatment of atrial fibrillation and anticipates advances in related products, including its own products.

In profits, the Company forecasts decline in gross margin due to reimbursement price reduction pressure on gross profit and change in mix with a higher sales share of purchased products that have lower gross margin than in-house products. In SG&A expenses, it is likely to incur a few hundred million yen annually from sales assistance for Boston Scientific Japan related to building sales operations for CRM-related products (cost of operating activities for its business) and depreciation costs for monopoly sales rights. Furthermore, it expects increase in trial costs for acquisition of regulatory approval of new products. Growth should flatten in FY3/20, including these costs. The bottom, meanwhile, should be FY3/19 1H. The Company expects substantial improvement of sales growth with the ramp-up of Boston Scientific products and restoration of profit gains in FY3/20 2H.

FY3/20 outlook

Full-year forecast	FY3/19 (¥mn)	% of sales (%)	FY3/20 E (¥mn)	% of sales (%)	Change rate (%)
Net sales	45,525	100.0	54,059	100.0	18.7
Gross profit	27,822	61.1	30,600	56.6	10.0
SG&A expenses	17,295	38.0	20,134	37.2	16.4
Operating income	10,526	23.1	10,465	19.4	-0.6
Ordinary income	10,808	23.7	11,167	20.7	3.3
Net income attributable to owners of the parent	7,723	17.0	7,747	14.3	0.3

1H forecast	FY3/19 (¥mn)	% of sales (%)	FY3/20 E (¥mn)	% of sales (%)	Change rate (%)
Net sales	22,265	100.0	24,955	100.0	12.1
Gross profit	13,579	61.0			
SG&A expenses	8,719	39.2			
Operating income	4,860	21.8	4,571	18.3	-5.9
Ordinary income	5,089	22.9	4,980	20.0	-2.2
Net income attributable to owners of the parent	3,638	16.3	3,424	13.7	-5.9

2H forecast	FY3/19 (¥mn)	% of sales (%)	FY3/20 E (¥mn)	% of sales (%)	Change rate (%)
Net sales	23,260	100.0	29,104	100.0	25.1
Gross profit	14,243	61.2			
SG&A expenses	8,576	36.9			
Operating income	5,666	24.4	5,894	20.3	4.0
Ordinary income	5,719	24.6	6,187	21.3	8.2
Net income attributable to owners of the parent	4,085	17.6	4,323	14.9	5.8

* Partly estimated by FISCO
Source: Prepared by FISCO from the Company's financial results and result briefing materials

Changes in sales shares for individual products

4. Outlook of net sales by product in FY3/20

The Company expects continued healthy momentum for in-house products, mainly in atrial fibrillation-related products and open stent grafts and other EP/ABL catheters, based on an assumption of ongoing strong growth in AF cases (+17% YoY). Meanwhile, the balance of sales shares for individual products is changing due to a number of major changes in commercial flow. The Company anticipates decline (YoY) in Cardiac Rhythm Management sales in 1H because of buying restraint at some medical entities following the announcement of its plan to end the exclusive sales contract with MicroPort, which had issues in product development capabilities for the tachycardia field. However, it expects substantially higher sales in FY3/20 2H thanks to the start of contributions by Boston Scientific products, which possesses strength in not just the bradycardia field but particularly in the tachycardia field, from September 2019. Furthermore, completion of contract periods in thoracic stent grafts (end-March 2019; though business continues in some areas) and artificial valve-related products (end-May 2019) with exclusive contracts fundamentally ends sales of these products. Planned reduction of insurance reimbursement prices in October 2019 is likely to impact sales results for individual products too.

Outlook of net sales by product in FY3/20

	FY3/19 (¥mn)	% of sales (%)	FY3/20 E (¥mn)	% of sales (%)	Change rate (%)
Pacemaker-related	5,169	11.4	5,093	9.4	-1.5
ICD-related	496	1.1	5,856	10.8	1080.4
Others	196	0.4	328	0.6	66.7
Cardiac Rhythm Management	5,862	12.9	11,277	20.9	92.4
EP catheter	17,028	37.4	19,443	36.0	14.2
ABL catheter	1,369	3.0	2,174	4.0	58.8
Others	4,662	10.2	5,429	10.0	16.4
EP/Ablation	23,060	50.7	27,047	50.0	17.3
Heart valve-related	1,448	3.2	173	0.3	-88.0
Vascular graft-related	9,133	20.1	8,843	16.4	-3.2
Blood purification	1,070	2.4	1,228	2.3	14.7
Others	77	0.2	19	0.0	-74.9
Cardiovascular Surgery	11,730	25.8	10,265	19.0	-12.5
Balloon catheter	565	1.2	597	1.1	5.6
Guide wire	403	0.9	415	0.8	3.1
Others	3,903	8.6	4,455	8.2	14.1
Transvascular Intervention	4,872	10.7	5,468	10.1	12.2
Total	45,525	100.0	54,059	100.0	18.7

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

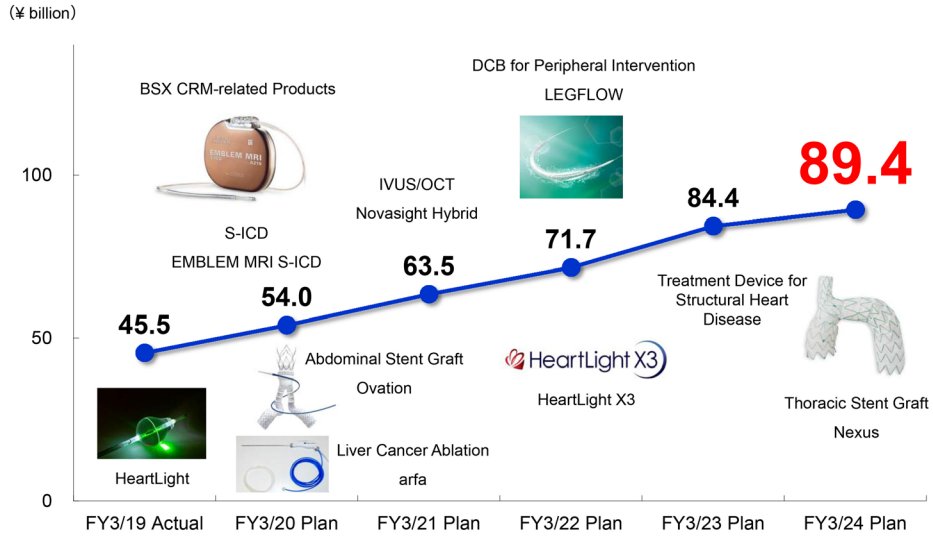
Medium-term management plan

Large impact on the income structure by the contract with Boston Scientific

1. Medium-term management plan assumption

Releases of two major products – drug-eluting coronary stent Orsiro and endoscope ablation catheter HeartLight – were important factors in FY3/19 results. While these products both missed expectations prior to releases, contributions to Transvascular Intervention and EP/Ablation businesses began. Healthy sales growth should continue in EP/Ablation business with ongoing increase in AF case volume. In contractual relationships with suppliers, meanwhile, the Company made a number of important decisions with medium- to long-term consequences, including a change in supplier for Cardiac Rhythm Management products and completion of artificial cardiac valve business in Cardiovascular Surgery. These impacts are showing up in the flat growth trend in FY3/20. Nevertheless, we expect the Company's pipeline in purchased products and conclusion of an exclusive distribution agreement in the CRM field with global firm Boston Scientific to reinforce the Company's income structure and strongly contribute to further growth over the medium- to long-term.

Product Pipeline (partial)



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

Expecting a growth phase fueled by the exclusive distribution agreement with Boston Scientific

2. Envisaged medium-term growth

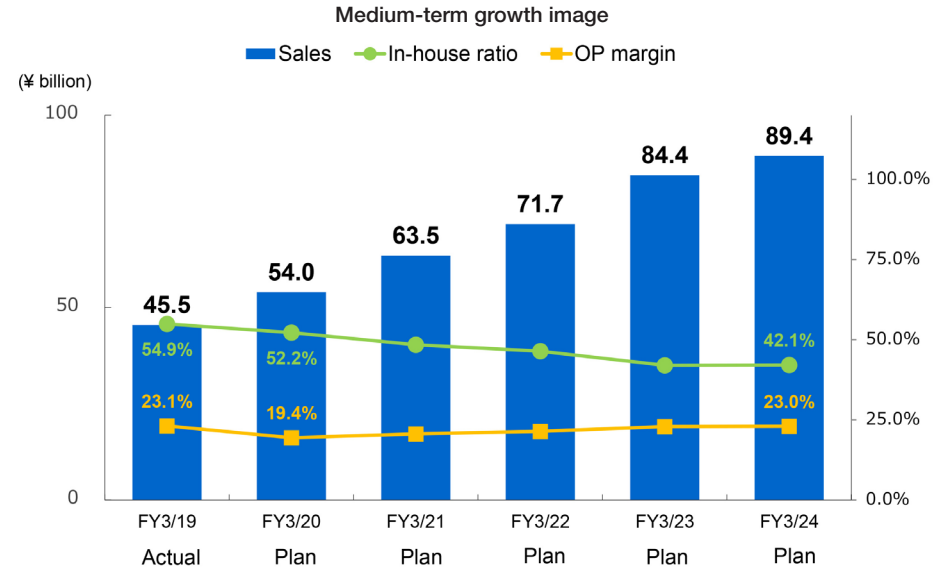
The Company's medium-term goals in the previous fiscal year were ¥77.7bn in net sales and 25% operating margin (¥19.4bn operating profit) in FY3/23, and its rolling updates set FY3/24 goals at ¥89.4bn in net sales and 23% operating margin (¥20.5bn in operating profit). The Company factored major changes in product mix, including the above-mentioned conclusion of an exclusive distribution agreement with Boston Scientific and exit from the artificial cardiac valve business, into the new five-year plan. It projects a decline in the in-house product sales ratio from 54.9% in FY3/19 to the 42% level in FY3/24 because of the prospect of a substantial rise in purchased product sales with the launch of Boston Scientific product business. However, the Company explains that this shift does not indicate diminished priority on in-house products and it envisions healthy growth for in-house product sales over the medium- to long-term. Furthermore, since the Company's medium-term plan contains almost no growth in overseas sales, we anticipate upside if overseas business performs well. While the Company previously aimed to raise gross margin by increasing the percentage of in-house product business, it switched this time to an outlook for declines in the in-house product sales ratio and gross margin because of arrangements of multiple exclusive sales contracts for major products.

Furthermore, even though change in sales mix for its own products and purchased products clearly implies decline in gross margin, we think the Company obtains relatively high gross margin from purchased products compared to other companies. Despite the presence of fixed costs in a portion or throughout the contract period, such as sales assistance fees and costs from amortizing the initial contract payment, in the exclusive distribution agreement with Boston Scientific, sales efficiency per person is likely to rise due to fully leveraging the Company's robust sales capabilities and this should steadily lower the SG&A expenses ratio. The Company hence offers a medium- to long-term scenario of substantial expansion of its presence in the CRM market and improved profitability.

We think this change has boosted the prospect of Cardiac Rhythm Management business, which the Company had not seen as a major growth opportunity up to now, becoming a longer-term growth driver. The Company also continues to place emphasis on strengthening in-house products and is likely to head toward a growth stage again after the anticipated plateau in FY3/20.

In other words, despite likely decline in gross margin over the medium term on stronger sales and a higher sales ratio for purchased products, operating margin should improve in medium-term term as increased sales and settling down of cost additions reduce the SG&A expenses ratio by even more. Furthermore, collaboration between a strong manufacturer (particularly in tachycardia product capabilities) and strong sales company might provide larger synergies than anticipated. At the very least, we think reinforcement of product offerings in the tachycardia field with market expansion potential lifted the outlook for Cardiac Rhythm Management, which had not been seen as a major growth source, to be a driver of medium- to long-term growth. This does not mean that the Company will stop focusing on in-house products. It remains strategically committed to the goal of bolstering in-house products and has also added a powerful array of purchased products. We think the Company is headed for a renewed growth phase after flatness in FY3/20.

Medium-term management plan



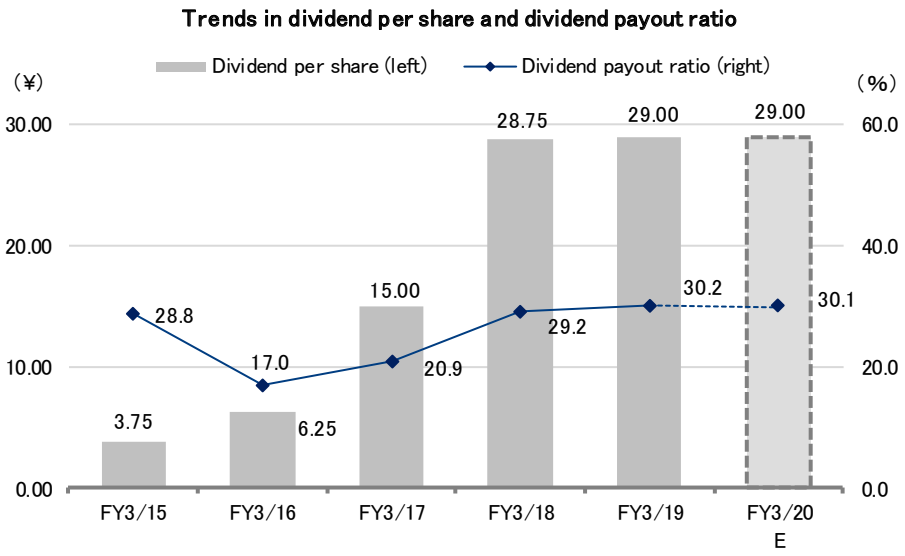
Source: The Company's medium-term management plan briefing materials

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 in FY3/18, 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: Values updated retroactively for stock splits from one to two ordinary shares each on 1 October 2015, 1 December 2016, and 1 January 2018
Source: Prepared by FISCO form he Company's financial results

The Company procured ¥13,856mn in funds with completion of the exercise of second share acquisition rights issued in December 2017 on 26 January 2018. It is using these funds for the exclusive distribution agreement for Boston Scientific products, loans to suppliers, initial inventories for new products, and plant construction (Malaysia, Oyama Factory No.2 Building). According to the Company, it finished raising funds for growth with this round and hence acquired and cancelled the third share acquisition rights issued in December 2017 without exercise based on the suspension designation and termination clause. The Company also retired 5mn of ordinary shares that it held on 31 May 2019.

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 way it is working to improve the information-security management level.

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■ For inquiry, please contact: ■
FISCO Ltd.
5-11-9 Minami Aoyama, Minato-ku, Tokyo, Japan 107-0062
Phone: 03-5774-2443 (Financial information Dept.)
Email: support@fisco.co.jp