COMPANY RESEARCH AND ANALYSIS REPORT

Japan Lifeline Co., Ltd.

7575

Tokyo Stock Exchange First Section

30-Jan.-2018

FISCO Ltd. Analyst
Kimiteru Miyata

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

Japan Lifeline Co., Ltd.
7575 Tokyo Stock Exchange First Section

30-Jan.-2018
http://www.japanlifeline.com/investors/

Index

This report is a translation of the Japanese report published on December 29, 2017.

Summary

An import trading company and manufacturer that is driving the medical devices industry and accelerating growth through its own products

Japan Lifeline Co., Ltd. <7575> (hereafter, also "the Company") is both an import trading company and a manufacturer, and it is an independent, hybrid trading company specializing in medical devices. Japan's medical devices market is gradually expanding against the backdrop of the aging population. Within it, the cardiovascular field has shown higher growth than other fields due to the expansion of indicated cases resulting from the advancements being made in medical devices, in addition to the aging of the population. In this sort of market environment, the Company is expanding its business by increasing the overseas products it handles as an import trading company specializing in medical devices, while also strengthening the development of its in-house products as a manufacturer.

In Japan's medical devices market, except for some diagnostic equipment such as magnetic resonance imaging (MRI) and endoscopes, the level of dependence on import goods, particularly from manufacturers in the United States and Europe, is high for advanced medical devices, including cardiac pacemakers used for direct treatment. Since its establishment, Japan Lifeline has built a network of domestic medical sites by concluding exclusive sales agreements with overseas manufacturers and introducing cutting-edge medical devices into these sites in Japan. It also reflects the needs of Japan's medical sites when it strengthens development and manufacturing of products in-house, and there is growing awareness of the Company as a manufacturer. Currently, as a specialist in the cardiovascular field with a unique business form from handling both highly original purchased products and in-house manufactured products, it can be counted among the companies that are driving the industry.

The Company handles medical devices used to treat a wide range of cardiovascular conditions, including arrhythmia, myocardial infarction and angina pectoris, heart valve disease, and aortic aneurysms. In principle, for the purchased products it concludes exclusive sales agreements with overseas manufacturers, mainly in Europe and the United States. But in addition to this, the Company handles processes other than manufacturing within Japan, including regulatory application, marketing, education, and sales promotions, in an integrated manner. In this way, it does not simply buy and sell products, it also plays a role close to that of a manufacturer, so one of its features is high profitability even for purchased products. The products it manufacturers in-house are also naturally highly profitable, and moreover, it has an excellent reputation as a manufacturer with high market shares in Japan for many products, including for vascular grafts and catheters for use in internal atrial cardioversion systems.

In the FY3/18 1H results, net sales were ¥20,267mn (up 13.4% year on year (YoY)) and operating income was ¥4,858mn (up 42.1%). Sales were driven by the strong performances of various products, including cardiac pacemakers compliant with MRI testing and products related to the treatment of atrial fibrillation. In profits, in addition to the growth of highly profitable items among both purchased products and in-house manufactured products, factors behind the higher operating income included an adjustment of an unrealized gain following the absorption merger of a consolidated subsidiary and a delay in the recording of one part of SG&A expenses. Therefore, the 1H results greatly exceeded their plan, net sales by ¥659mn and operating income by ¥961mn.

Japan Lifeline Co., Ltd.

7575 Tokyo Stock Exchange First Section | 30-Jan.-2018
http://www.japanlifeline.com/investors/

Summary

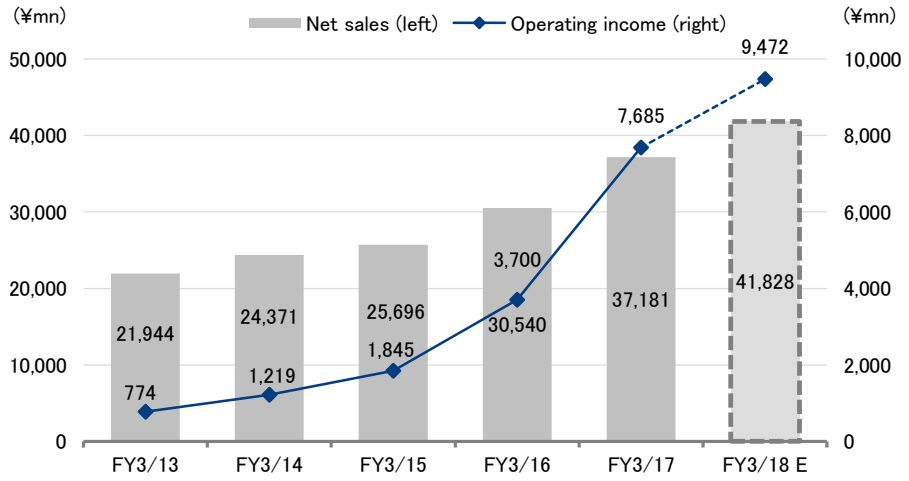
For the FY3/18 full-year results, the Company is forecasting net sales of ¥41,828mn (up 12.5% YoY) and operating income of ¥9,472mn (up 23.3%). The forecast is for a double-digit increase in sales, as although it seems that the market launches of some new products scheduled for 2H have been postponed, their values incorporated into the forecasts were small, while in addition, existing products are expected to maintain their strong sales. In profits, on the one hand, the gross profit margin is expected to improve from the rise in the composition ratio of highly profitable manufactured products, while on the other hand, SG&A expenses pushed back to 2H are scheduled to be recorded. Therefore, the Company has not changed its initial results forecasts. However, on considering the sales momentum and the gross profit margin trend in 1H and that SG&A expenses are being kept down, it seems highly likely that sales and profits will exceed their forecasts in 2H also.

In its medium-term management plan, the Company is aiming for net sales of ¥66.2bn and an operating income margin of 25% in FY3/22. On considering factors such as the aging of the population in Japan, the advancements being made in medical devices, and the Company's sales and regulatory structures and its production system, these targets would seem to be fully within an achievable range. In addition, it is considering expanding its domains, such as by entering into new business fields other than the cardiovascular field and strengthening exports supported by the construction of factories overseas. Its profits at the current time are also a strength that will further support its medium- to long-term growth.

Key Points

- A hybrid import trading company and manufacturer specializing in medical devices. It is benefitting from the external environment, including the aging of the population and the advancements being made in medical devices
- Its features include its sales and regulatory structures, purchased products with exclusive sales agreements, and in-house manufactured products that meet the needs of medical sites. It has a highly profitable structure
- Highly likely to achieve the FY3/18 forecasts. The targets in the medium-term management plan may also be further raised from the expansion of domains, supported by strong results at the present time

Results trends



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

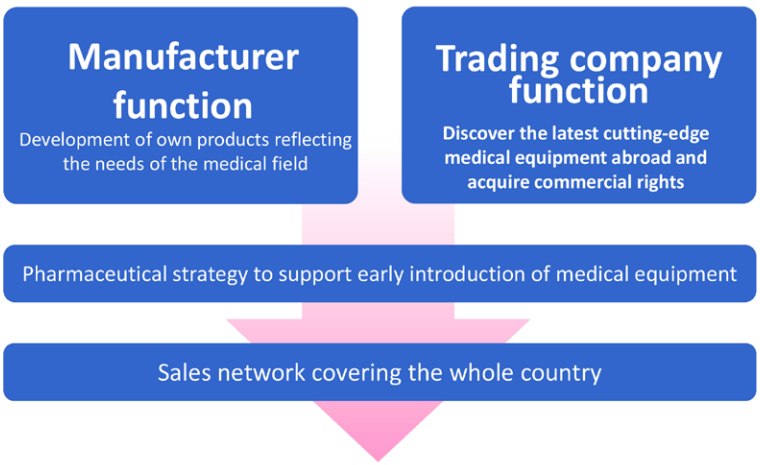
Business overview

A nationwide sales structure, an enhanced regulatory structure, and in-house manufactured products that do not compete with those of overseas manufacturers

1. Business description

From the time it was founded for the sales of imported cardiac pacemakers 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 in medical devices and communicates closely with doctors to cultivate the power of discernment for products as a specialist trading company. 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, and a product development system, 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



Source: The Company's results briefing materials

As a specialist trading company and manufacturer, it plays many roles in the cardiovascular medical devices industry

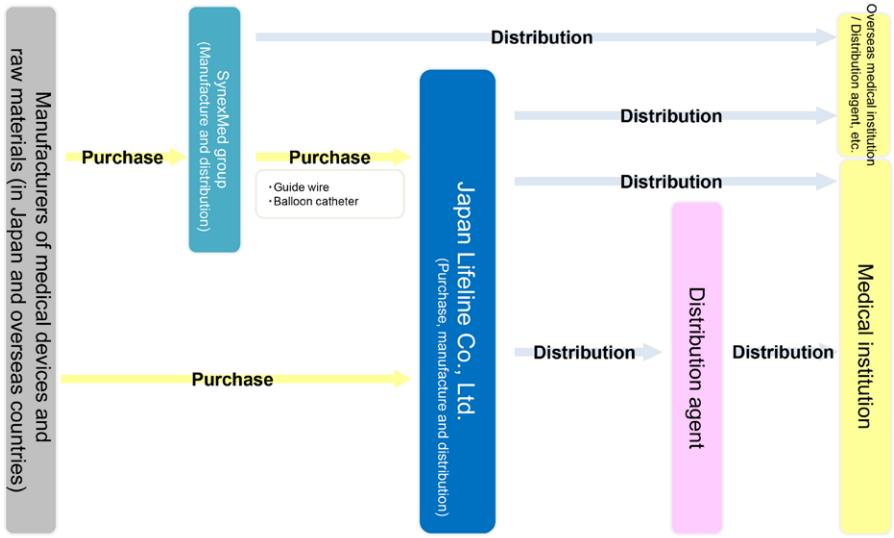
2. Distribution structure

As its sales structure, the Company has 44 sales bases (as of the end of FY3/18 1H) throughout Japan, from Hokkaido to Okinawa, 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, and it handles the product of only one company for the same category of medical device. Also, it takes the same position as that of manufacturers for aspects such as the acquisition of regulatory approval within Japan, marketing to smoothly 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, in return for bearing this burden, the Company's gross profit margin on its purchased products averages from 40-45%, which is extremely high compared to the margins of general wholesale and trading companies. Sales agencies conducting secondary distribution in Japan are able to 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 between the business structures of both companies.

The Company develops and manufactures in-house products as a manufacturer. It currently has one R&D base (the Research Center) and three manufacturing bases (the Toda Factory, Oyama Factory, and Ichihara Factory) in Japan. The products that the Company develops and manufactures in-house are guide wires, EP catheters, and ablation catheters, while 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.

Schematic diagram of the business



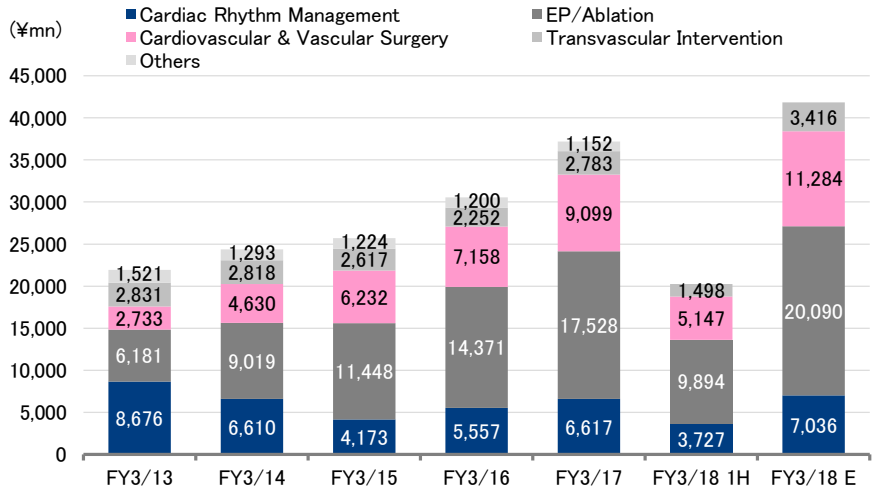
Source: The Company's results briefing materials

A product lineup specializing in cardiovascular diseases

3. Condition by product category

The Company has four product categories: Cardiac Rhythm Management, EP/Ablation, Cardiovascular & Vascular Surgery, and Transvascular Intervention.

Net sales trend by product category

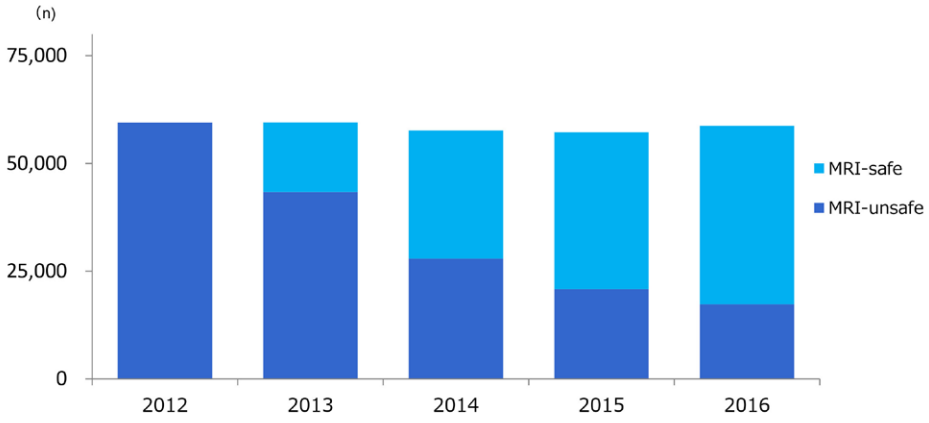


Note: In line with the subsidiary merger, the product category "Others" has been reclassified as "Cardiovascular & Vascular Surgery" starting from FY3/18.
Source: Prepared by FISCO from the Company's results briefing materials

Business overview

Cardiac Rhythm Management handles implantable devices used 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). In the cardiac pacemaker market, MRI-compliant pacemakers have become the mainstream product, so the Company has also launched the KORA 250 and other MRI-compliant products. All of the items in this segment are purchased products.

Change in sales volume in pacemaker market



*Prepared based on statistical values from Japan Arrhythmia Device Industry Association
*Sales volume of single/dual chamber. Indicated as MRI-unsafe for all in 2012.

Source: The Company's results briefing materials

Cardiac Rhythm Management

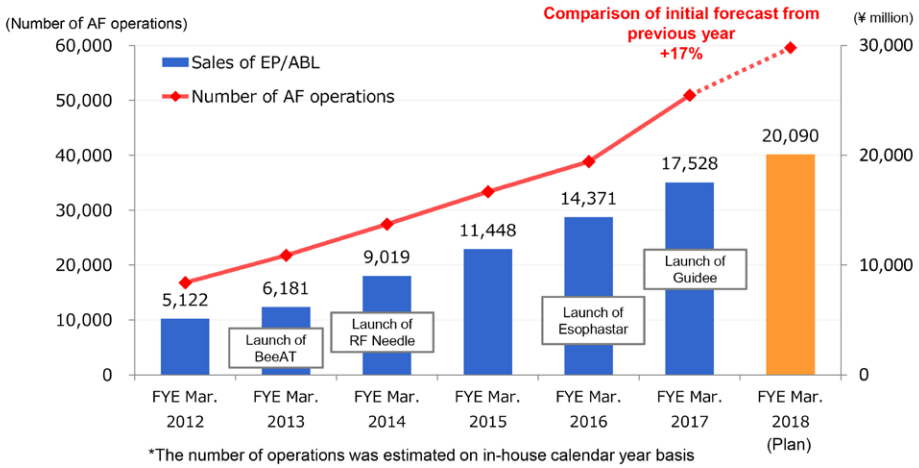
Cardiac pacemakers
(manufactured by LivaNova)

ICD (implantable cardioverter defibrillator)
(manufactured by LivaNova)

Source: The Company's results briefing materials

EP/Ablation handles disposable-type electrode catheters used for arrhythmia testing and treatment. Main in-house manufactured products include EP catheters that measure the electric potential in the heart, ablation catheters that terminate abnormal electrical stimulation pathways, the only-one product of intracardiac defibrillation catheters, and esophageal temperature monitoring catheters. Purchased products include the only-one product of transseptal needles. In FY3/18 1H, the number of indicated cases rose 20% YoY, and the number of ablation procedures for atrial fibrillation has been growing rapidly in recent years. Catheters broadly refer to medical devices made of hollow, soft, and thin tubes that are inserted into blood vessels from the skin surface to provide medical treatment.

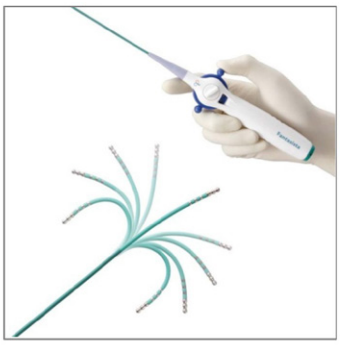
Change in the number of operations for atrial fibrillation



Source: The Company's results briefing materials

EP/Ablation

Ablation catheters
(in-house manufactured product)



EP (Electrophysiology) catheters
(in-house manufactured product)

Source: The Company's results briefing materials

Cardiovascular & Vascular Surgery handles medical devices used for surgical treatments to replace with artificial organs those blood vessels or heart valves that have lost their functioning. Main in-house manufactured products are vascular grafts and open stent grafts, both of which had been manufactured by JUNKEN MEDICAL, which the Company merged with and absorbed in April 2017. Main purchased products include thoracic and abdominal stent grafts, prosthetic heart valves, and annuloplasty rings. The AFX Stent Graft System for the abdomen has proven popular, and it has acquired over 10% market share in just a year since its launch. Stent grafts are medical devices used to treat aortic aneurysms, the same as vascular grafts. In contrast to a vascular graft requiring open-chest surgery, 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 until inserted at the treatment site, at which point the force of the springs press against the blood vessel to fix it in place.

Business overview

Products for Cardiovascular & Vascular Surgery

Open surgery		Percutaneous treatment	
In-house product		Purchased product	
Vascular graft	Open stent graft	Thoracic stent graft	Abdominal stent graft
J-Graft	J-Graft FROZENIX	RELAY Plus	AFX
Japan Lifeline Co., Ltd.		Bolton Medical	Endologix

Launched in Jul. 2014

ONLY ONE

Launched in May 2013

Launched in Jan. 2016

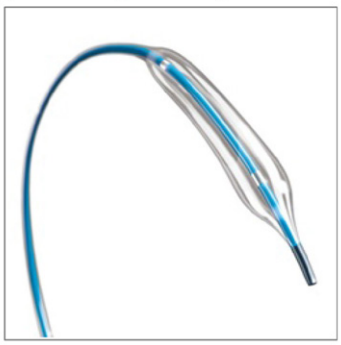
New model of AFX will be full-released in December this year

Source: The Company's results briefing materials

Transvascular Intervention mainly handles medical devices to treat conditions such as myocardial infarction and angina pectoris. Main in-house manufactured products are guide wires and balloon catheters used to treat blood vessels (coronary arteries) in cases of myocardial infarction and related conditions. Main purchased products include penetration catheters that are used in the same way when treating myocardial infarction and related conditions, 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.

Transvascular Intervention

Balloon catheters
(manufactured by SYNEXMED)



Guide wires
(in-house manufactured product)

Source: The Company's results briefing materials

Learned a lot from major decreases in sales due to the loss of sales rights in the past

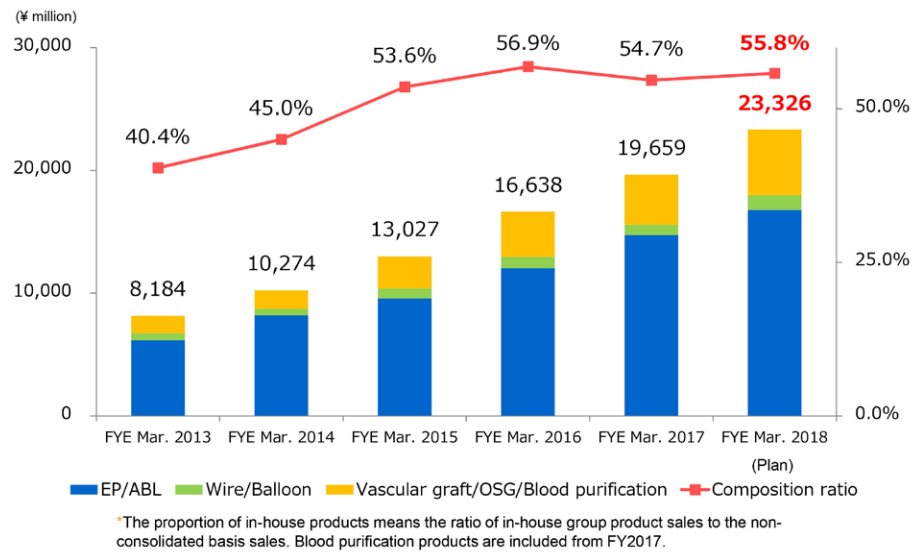
4. The turning point

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 the acquisition by a competitor of Arterial Vascular Engineering Inc., which up to that time had supplied the Company with coronary bare metal stents. This meant that it lost the sales rights to this product within Japan and its sales fell significantly in FY3/00. The Company 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 developed in-house manufactured products.

In 2001, it launched guide wires as its first in-house manufactured product, and subsequently expanded its lineup to include EP catheters and ablation catheters. Furthermore, 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 launching in-house manufactured products, such as the J-Graft series of vascular grafts and only-one product, open stent grafts.

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 this condition, contributing greatly to improvement in 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.

Sales of in-house group products



*The proportion of in-house products means the ratio of in-house group product sales to the non-consolidated basis sales. Blood purification products are included from FY2017.

Source: The Company's results briefing materials

Performance trends

The profit margin improved significantly and operating income increased by 42.1% in FY3/18 1H

1. Trends in FY3/18 1H

The FY3/18 1H results were strong, consisting of net sales of ¥20,267mn (up 13.4% YoY), operating income of ¥4,858mn (up 42.1%), ordinary income of ¥5,027mn (up 47.2%), and net income attributable to owners of the parent of ¥3,386mn (up 42.7%).

FY3/18 1H results

(¥mn, %)

	FY3/17 1H			FY3/18 1H			
	Actual	% of sales	Progress rate	Actual	% of sales	Change rate	Progress rate
Net sales	17,871	100.0	48.1	20,267	100.0	13.4	48.5
Gross profit	10,380	58.1	47.2	12,529	61.8	20.7	48.5
SG&A expenses	6,960	38.9	48.6	7,671	37.8	10.2	46.9
Operating income	3,419	19.1	44.5	4,858	24.0	42.1	51.3
Ordinary income	3,415	19.1	42.6	5,027	24.8	47.2	52.3
Net income attributable to owners of the parent	2,372	13.3	44.3	3,386	16.7	42.7	50.7

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

In Cardiac Rhythm Management, sales of MRI-compliant cardiac pacemakers grew, while in EP/Ablation, sales increased of products relating to the treatment of atrial fibrillation, including of only-one products, against the backdrop of the continuing rise in the number of cases of atrial fibrillation treated with ablation. In Cardiovascular & Vascular Surgery, the abdominal stent graft newly launched in January 2016 and the open stent graft, an only-one product, continued to maintain high levels of growth, while in Transvascular Intervention, sales of penetration catheters and atrial septal defect closure devices trended steadily. Major academic society meetings relating to the Company's business fields were concentrated in FY3/18 2Q, and although there were concerns about the impact of this on sales, in contrast sales trended strongly. In April 2017, the Company began the construction of a new research center building.

Operating income greatly increased at a rate above the growth in net sales. The reasons for this include growth in net sales above the forecast, improvement in the gross profit margin, and postponement of some SG&A expenses. The gross profit margin improved 3.7 percentage points YoY, due to continuing reduction in costs for in-house manufactured products, improvement in the product mix from growth in in-house manufactured products and highly profitable items, and an adjustment to an unrealized gain on the inventories of JUNKEN MEDICAL, which was previously acquired through an absorption merger. The increase in SG&A expenses was kept down to 10.2% YoY because although there were increases in land rent and travel expenses related to the opening of new sales bases, advertising and other expenses were pushed back to 2H. Non-operating income improved, including due to an increase in interest income and the recording of a foreign exchange gain, while extraordinary profit/loss worsened from expenses associated with the transfer of a subsidiary's factory.

The Company published three press releases of interest in FY3/18 2Q: 1) “Announcement of Execution of the Exclusive Distribution Agreement for RELAY Plus Thoracic Stent-Graft with Terumo Corporation” on August 21, 2017, 2) “Announcement of Execution of the Joint Research and Development Agreement and Exclusive Distribution Agreement on Stent Grafts for Thoracic Aortic Disease Treatment” on September 11, and 3) “Regarding the Press Release from LivaNova PLC” on September 15, 2017.

The content of the first press release above regarded the exclusive sale agency agreement that the Company has concluded with Terumo Corporation <4543>, which is a rival manufacturer, for stent grafts for the treatment of thoracic aortic aneurysms. These two companies are competitors so this agreement may seem a little strange, but the reasoning is that the Company has an exclusive sales agreement for RELAY Plus, a stent graft for the treatment of thoracic aortic aneurysms and one of its main products, with Bolton Medical Inc., which became a subsidiary of Terumo. The agreement with Bolton Medical will be effective up to April 30, 2018, and for the period after that of up to March 31, 2019, the Company has concluded an exclusive sales agreement with Terumo to extend the sales period by one year. However, at the current point in time, there is no guarantee that the agreement will be extended beyond this period, and there is the risk for the Company that it will be unable to maintain its exclusive agreement if the other party to the agreement is acquired by another company.

The second press release describes the response to this risk. The Company already has an exclusive sales agreement with Endologix, Inc., for the AFX Stent Graft System for treating abdominal aortic disease, and they have newly concluded a joint research and development agreement and an exclusive sales agreement for Japan for a stent graft for the treatment of thoracic aortic disease. Through this collaboration, the Company will be involved in the development of the stent graft, and the intention is to commercialize the jointly developed product at an early stage toward a market launch in Japan in around five years. Also, as the exclusive sales period for the jointly developed product is 15 years from its inclusion in insured products, it will result in a long-term collaborative relationship that goes beyond the relationship between a trading company and a manufacturer. Therefore, the Company will aim to enhance its product lineup in the aortic treatment area over the long term.

The third press release describes the LivaNova press release that stated it was conducting strategic reviews of the exclusive sales agreements for its cardiac pacemakers and other products in order to concentrate management resources. The release did not clarify the specific details, but the worst-case scenario is that the exclusive sales agreement is ended through the acquisition of LivaNova’s Cardiac Rhythm Management business by a major, existing pacemaker company. However, LivaNova’s products somewhat lag behind those of other manufacturers that have gone ahead of it, so it seems the possibility of an acquisition by such a company is low and it highly likely that the acquiring side will not be a company that already handles pacemakers. Moreover, a large percentage of LivaNova’s Cardiac Rhythm Management business is for the Japanese market, so in order to secure sales of a certain scale, it is considered that it will be necessary to maintain the agreement with the Company.
*Subsequently on November 20, 2017, LivaNova disclosed that it had reached a basic agreement with MicroPort Scientific Corporation (China) for the sale of this business. At the current point in time, MicroPort Scientific Corporation does not have a sales network in Japan in the cardiovascular field.

2. Sales trends by product in FY3/18 1H

Sales trends by product are as described below, but it seems that each exceeded their initial forecasts.

Net sales by product

(¥mn, %)

	FY3/17 1H		FY3/18 1H		
	Actual	% of sales	Actual	% of sales	Change rate
Pacemaker-related	2,781	15.6	3,355	16.6	20.6
ICD related	371	2.1	281	1.4	-24.3
Others	103	0.6	91	0.4	-12.1
Cardiac Rhythm Management total	3,256	18.2	3,727	18.4	14.5
EP catheter	6,513	36.4	7,446	36.7	14.3
ABL catheter	664	3.7	586	2.9	-11.7
Others	1,495	8.4	1,860	9.2	24.4
EP/ABL total	8,673	48.5	9,894	48.8	14.1
Heart valve related	879	4.9	840	4.1	-4.4
Cardiopulmonary related	57	0.3	49	0.2	-13.1
Vascular graft related	3,206	17.9	3,781	18.7	17.9
Blood purification	463	2.6	474	2.3	2.3
Cardiovascular Surgery related total	4,607	25.8	5,147	25.4	11.7
Balloon catheter	393	2.2	462	2.3	17.6
Guide wire	190	1.1	191	0.9	0.2
Others	749	4.2	845	4.2	12.8
Transvascular Intervention total	1,333	7.5	1,498	7.4	12.4
Total	17,871	100.0	20,267	100.0	13.4

Note: In line with the subsidiary merger, the product category “Others” has been re-classified as “Cardiovascular & Vascular Surgery” starting from FY3/18.
Source: Prepared by FISCO from the Company’s results briefing materials

In Cardiac Rhythm Management, net sales were ¥3,727mn (up 14.5% YoY). The sales volume of the KORA250 pacemaker, which was launched in March 2016 and which conditionally is compliant with MRI testing, continues to increase. A factor behind this is that in addition to allowing MRI to be taken, it has features that have been highly evaluated, of having the smallest class of unit size in the world and a long battery life. Also, in June 2017, the Company launched VEGA, which is a MRI compliant pacemaker lead compliant with the KORA250 and the number of cases in which it is indicated are increasing, and this also contributed to the favorable performance of cardiac pacemakers. This has enabled the Company to restore the market share it lost when its products were not MRI compliant, back up to 15%. In ICD-related, it launched the new products of the PLATINIUM series, which feature small unit sizes and a long battery lives, but they struggled due to the impact of competitors’ MRI-compliant products.

In EP/Ablation, net sales were ¥9,894mn (up 14.1% YoY). The number of cases of treatment of atrial fibrillation by ablation rose 20%, and the growth is accelerating. Sales volume increased of both the RF Needle, which is a radio frequency transseptal needle that is used in 90% of cases and a purchased product for which the Company has an exclusive sales agreement, and BeeAT, which is an internal atrial cardioversion catheter and an only-one product used in 80% of cases. The market share of the esophageal temperature monitoring system fell in 2Q due to the improved performance of a competitor’s product, but the Company is planning to launch an improved version of the current model, so is likely to recover the lost share in 4Q. On the other hand, the sales volume of ablation catheters is trending downward due to the spread of competitor products, of balloon catheters for use in cyroablation. To respond to this, the Company is preparing to launch HeartLight, which will be the first combination laser and endoscopic system in Japan.

In Cardiovascular & Vascular Surgery, net sales were ¥5,147mn (up 11.7% YoY). In vascular graft-related, J-Graft FROZENIX, which is an open stent graft and an only-one product, was highly evaluated and sales were strong, while the AFX Stent Graft System for the abdomen, which is a stent graft used for the percutaneous treatment of aortic disease that was newly launched in January 2016, also performed well. In prosthetic heart valves-related, due to the spread in the use of TAVI (transcatheter aortic valve implantation), which does not required a surgical procedure, for the treatment of heart valve disease, sales of the Company's bioprosthetic valve, which does require a surgical procedure, struggled somewhat. In response, it is advancing preparations for the launch of PERCEVAL, which is a sutureless bioprosthetic valve that places less of a burden on the patient as sutures are not required, so the procedure time is shortened.

In Transvascular Intervention, net sales were ¥1,498mn (up 12.4% YoY). In balloon catheters, sales of balloon catheters for coronary arteries were steady, while Mastuly, which a balloon catheter used in the peripheries of the lower limbs launched in June 2017, also performed well. Among the other items, sales increased by double digits of GuideLiner, a penetration catheter that supports the passage of the treatment device through the narrow parts of the coronary artery, and FigullaFlex II, an atrial septal defect closure device launched in February 2016.

Business outlook

The impression is that the FY3/18 full-year results forecasts are conservative

1. FY3/18 outlook

For its FY3/18 full-year results, the Company is forecasting net sales of ¥41,828mn (up 12.5% YoY), operating income of ¥9,472mn (up 23.3%), ordinary income of ¥9,604mn (up 19.9%), and net income attributable to owners of the parent of ¥6,684mn (up 24.9%).

FY3/18 outlook

(¥mn, %)

	FY3/17		FY3/18		
	Actual	% of sales	Forecast	% of sales	Change rate
Net sales	37,181	100.0	41,828	100.0	12.5
Gross profit	21,998	59.2	25,835	61.8	17.4
SG&A expenses	14,313	38.5	16,362	39.1	14.3
Operating income	7,685	20.7	9,472	22.6	23.3
Ordinary income	8,010	21.5	9,604	23.0	19.9
Net income attributable to owners of the parent	5,350	14.4	6,684	16.0	24.9

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

According to the Company's initial estimations, in FY3/18 the insurance reimbursement price would not be revised and the number of cases would continue to increase, so it forecast an increase in sales. But compared to FY3/17, fewer new products will be released during the fiscal period, so the sales-increase rate is expected to be slightly slower than in the previous fiscal year. In profits, there will be no downward pressure on the gross profit margin as there will be no revisions to the insurance reimbursement price, while the other factors are the improvement to the product mix from the rise in the percentage of profitable products; other improvements such as from the decline in cost prices in manufactured and purchased products; and the deterioration of the SG&A expenses ratio due to increases in expenses, including personnel expenses and advertising expenses on the market launches of new products. By taking into consideration these factors, the increase in gross profit will absorb the rise in SG&A expenses, and operating income is forecast to increase 23.3%.

However, when considering the sales momentum of each item up to 1H, the improvement trend in the gross profit margin from the strong performances of profitable items, that SG&A expenses were kept down in 1H, that in 2H there will be no meetings of the academic societies relating to the Company's business, and that expenses will decrease because the market launches of two products have been postponed until FY3/19, we cannot help but think that the forecasts for net sales and operating income are conservative.

Lineup of new products for FY3/19 and beyond

2. Outlook of net sales by product in FY3/18

In 1H, Company-wide net sales continued to be strong, and each product exceeded their respective net sales forecasts. But when looking as far as individual product items, the differences with the poorly performing ones are noticeable. The Company is taking measures in response to this, but it would seem that this trend will continue in 2H also. In addition, of the three items scheduled to be launched in FY3/18, the launches of two items have been postponed until FY3/19. The Company's forecasts remain based on the initial assumptions.

Outlook of net sales by product in FY3/18

(¥mn, %)

	FY3/17		FY3/18		
	Actual	% of sales	Actual	% of sales	Change rate
Pacemaker-related	5,674	15.3	6,017	14.4	6.1
ICD related	724	1.9	742	1.8	2.5
Others	218	0.6	276	0.7	26.4
Cardiac Rhythm Management total	6,617	17.8	7,036	16.8	6.3
EP catheter	13,160	35.4	15,089	36.1	14.7
ABL catheter	1,258	3.4	1,245	3.0	-1.0
Others	3,109	8.4	3,755	9.0	20.8
EP/ABL total	17,528	47.1	20,090	48.0	14.6
Heart valve related	1,755	4.7	1,979	4.7	12.8
Cardiopulmonary related	113	0.3	76	0.2	-32.7
Vascular graft related	7,229	19.4	7,955	19.0	10.0
Blood purification	1,152	3.1	1,272	3.0	10.5
Cardiovascular Surgery related total	10,251	27.6	11,284	27.0	10.1
Balloon catheter	814	2.2	1,087	2.6	33.6
Guide wire	373	1.0	415	1.0	11.3
Others	1,596	4.3	1,913	4.6	19.9
Transvascular Intervention total	2,783	7.5	3,416	8.2	22.7
Total	37,181	100.0	41,828	100.0	12.5

Note: In line with the subsidiary merger, the product category "Others" has been re-classified as "Cardiovascular & Vascular Surgery" starting from FY3/18.
Source: Prepared by FISCO from the Company's results briefing materials

In Cardiac Rhythm Management, the forecast is for net sales of ¥7,036mn (up 6.3% YoY). Breaking this down, sales of pacemaker-related will be ¥6,017mn (up 6.1%), ICD-related will be ¥742mn (up 2.5%), and others will be ¥276mn (up 26.4%). The reason for the low growth rate compared to the previous fiscal year is that it is forecast that the recovery of market share will be moderate, as some time has passed since the launch of the MRI testing-compliant pacemaker KORA250 in FY3/17. However, conditions will be severe for ICD-related products that are not MRI compliant, but in pacemakers, KORA250 is not expected to lose its momentum. So for the full fiscal year, Cardiac Rhythm Management net sales are forecast to be stronger than expected.

In EP/Ablation, the forecast is for net sales of ¥20,090mn (up 14.6% YoY). Breaking this down, sales of EP catheters will be ¥15,089mn (up 14.7%), ablation catheters will be ¥1,245mn (down 1.0%), and others will be ¥3,755mn (up 20.8%). In EP catheters, the trend of the rise in the number of ablation treatments indicated for cases of atrial fibrillation is expected to continue. The Company had assumed the number of cases would increase by 17%, but in 1H, the increase was higher than expected, up 20%, and this strong growth is expected to continue in 2H also. Conversely, the endoscopic ablation system HeartLight, which uses balloon technology to enable precise laser ablation while observing the endoscopic images, was scheduled to be launched in FY3/18 to compete in the same business. But even though regulatory approval was obtained in July 2017, the launch of sales is expected to be postponed until FY3/19 1H, as it is a highly novel product and therefore it will take some time for it to be included in the scope of insurance. The effects of this on the FY3/18 results will be negligible. Whatever the case, it is likely that results in 2H will continue to be driven by riding on the wave of the rises in the number of cases for BeeAT and RF Needle.

In Cardiovascular & Vascular Surgery, the forecast is for net sales of ¥11,284mn (up 10.1% YoY). Breaking this down, sales of prosthetic heart valve-related will be ¥1,979mn (up 12.8%), cardiopulmonary related will be ¥76mn (down 32.7%), vascular graft-related will be ¥7,955mn (up 10.0%), and blood purification-related will be ¥1,272mn (up 10.5%). While growth of other items, such as prosthetic heart valves, is not expected, sales of vascular graft-related are set to continue to be strong in 2H also. However, PERCEVAL, which is the first sutureless bioprosthetic valve in Japan, was scheduled to be market launch in FY3/18 4Q, but as some time will be required for it to be included in the scope of insurance, it is not expected to contribute to profits until FY3/19 1H.

In Transvascular Intervention, the forecast is for net sales of ¥3,416mn (up 22.7% YoY). Breaking this down, sales of balloon catheters will be ¥1,087mn (up 33.6%), guide wires will be ¥415mn (up 11.3%), and others will be ¥1,913mn (up 19.9%). Sales of Mastuly, a peripheral balloon catheter launched in June 2017, and GuideLiner, a penetration catheter, are expected to continue to be strong in 2H. In FY3/18 4Q, the Company plans to launch the large-scale new product Orsiro, which is a drug-eluting coronary stent for coronary artery disease for which it concluded an exclusive sales agreement with Biotronik in February 2017. This is the first product that has been shown to be statistically superior in clinical trials to a competitor's product that has the leading market share, and it will be launched as a competitive product in the DES market.

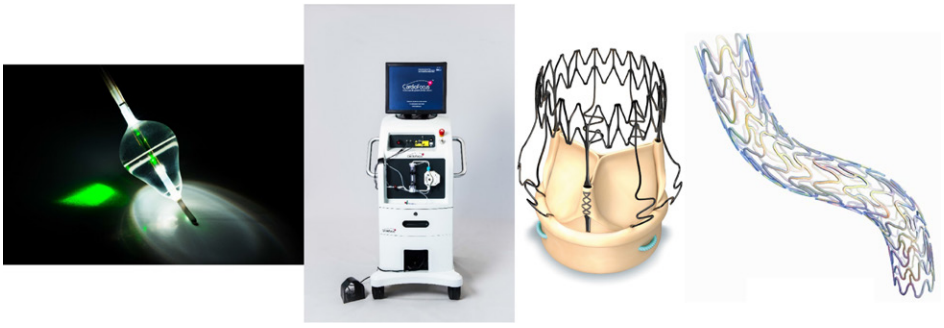
Reflecting the current strong performance and large scale new products, the targets in the next medium-term management plan after it is rolled are set to be upwardly revised

3. The medium-term management plan

Against the backdrop of the aging of the Japanese population and the advancement of medical devices, the heart disease medical devices market continues to expand. In this sort of environment, there is no other company within Japan that can provide sales and regulatory structures at the same levels as those of the Company, which means that collaborations with it are the best possible choice for overseas manufacturers. As a result, the Company will have an abundance of products in the pipeline in the future. Moreover, it is considering expanding its R&D bases and constructing overseas factories, and it is thought to be advancing joint development not only for in-house manufactured products, but for purchased products also. Both the external and internal environments are in place, and it seems it will continue to grow as in the past. The Company is aiming for net sales of ¥66.2bn and an operating income margin of 25% in FY3/22.

In fact, it is expected to market launch three large-scale products in the near future. The endoscopic ablation system HeartLight is a product that uses a new laser technology and also balloon technology to make possible accurate ablation with a laser while observing the endoscopic images. After its launch, the Company will also progress the launch of a next-generation model with even more advanced functions. The sutureless bioprosthetic valve PERCEVAL is expected to reduce the burden on the patient by shortening the time required for the surgical procedure, as sutures are not required. Due to its stentless structure, it features include superior hemodynamics and that it is optimal for complex surgery and minimally invasive cardiac surgery, and it is a product that can be expected to create a new market for surgeons. For Orsiro, which is a drug-eluting coronary artery stent used for the main devices to treat arterial disease, as it is a new entry into the market, preparing consignment stock for hospitals of a certain size seems to be a burdensome task. But its features include that it has the world's thinnest strut to inhibit restenosis and prevention of thrombus, its use of nano-coating to prevent elution of metallic ions, and that it is extremely durable. Previously, the target for market share in its first fiscal year (FY3/19) was 10%, but due to its excellent performance in clinical study, this has been raised to 15%. There are considerable needs for all of these products in medical treatment sites, and we think these products will drive the Company's growth in the medium term.

The large-scale new products for which there are major expectations (from the left; HeartLight, PERCEVAL, Orsiro)

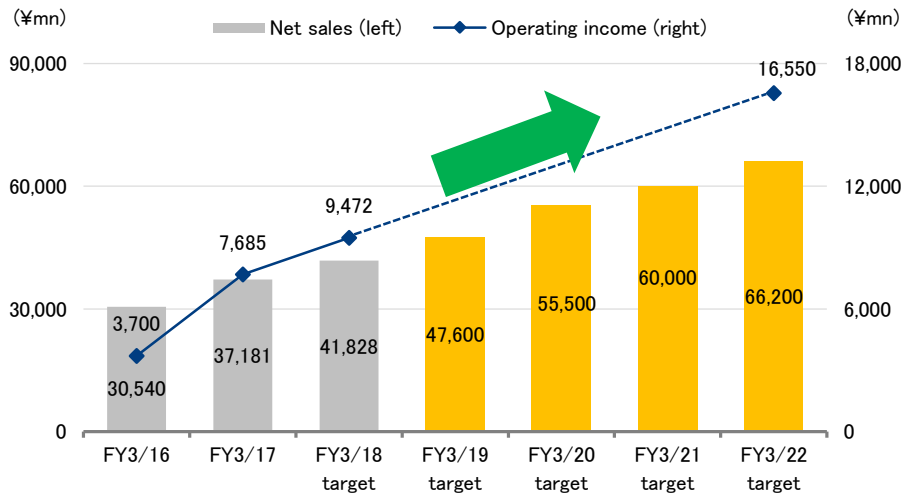


Source: The Company's results briefing materials

On the other hand, the possibility has arisen that due to the continuous market launches of large-scale new products, the percentage of all products that are manufactured in-house, which is currently around 55%, may fall to around 50% in the medium term. This is expected to cause deterioration in the product mix that has been contributing to the improvement of the Company's profitability. As the Company is a hybrid (a manufacturer and a trading company), it is inevitable that its product mix will change, depending on the timing of manufactured or purchased products and the needs of medical sites. However, in many cases, purchased products target larger and more advanced categories, and moreover do not have any development costs. Therefore, as their operating income amount is not considered to be greatly different to that of in-house manufactured products, the strong profit growth can be expected to continue. Of course, the Company will not change its policy of strengthening its manufacturer functions, and from a long-term perspective, it intends to conduct development in fields closer to basic research. So its image for the medium to long term is an approach of strengthening both purchased products and in-house manufactured products.

From the point of medium- to long-term growth, there is also the issue of expanding domains. At the present time, the Company's growth capability in the cardiovascular field within Japan is expected to be strong in the future, while it plans to enter into new business fields and expand its domains to new business areas, and it is already quietly progressing measures for this. For the entry into new business fields, in June 2017 it market launched a colonic stent, which is an in-house manufactured product, and took its first step into the gastrointestinal field. Although it is still at the stage of trial operations as a new field, the Company's policy is to gradually increase its sales in the future. It also plans to build a new factory in Malaysia, which initially will manufacture balloon catheters as back-up to the Shenzhen factory. But in the future, the intention is for it to manufacture EP catheters and to expand the sales areas to overseas, including to Asia. The contribution to profits of these new business fields have not been incorporated into the current medium-term management plan. In the next medium-term management plan, which is scheduled to be a rolling plan from May 2018, in addition to the strong FY3/18 results and the large-scale products to be market launched in the near future, it is possible that the new business fields and new areas will be reflected in it in some way. Already, at the 2Q results briefing, the Company indicated guidance that it is aiming for ¥50bn for the FY3/19 net sales, which exceeds the target of ¥47.6bn in the current medium-term management plan. In the next medium-term management plan, after it has been rolled, we can expect a growth outlook that exceeds the pace of the current medium-term management plan.

Targets set in the medium-term management plan



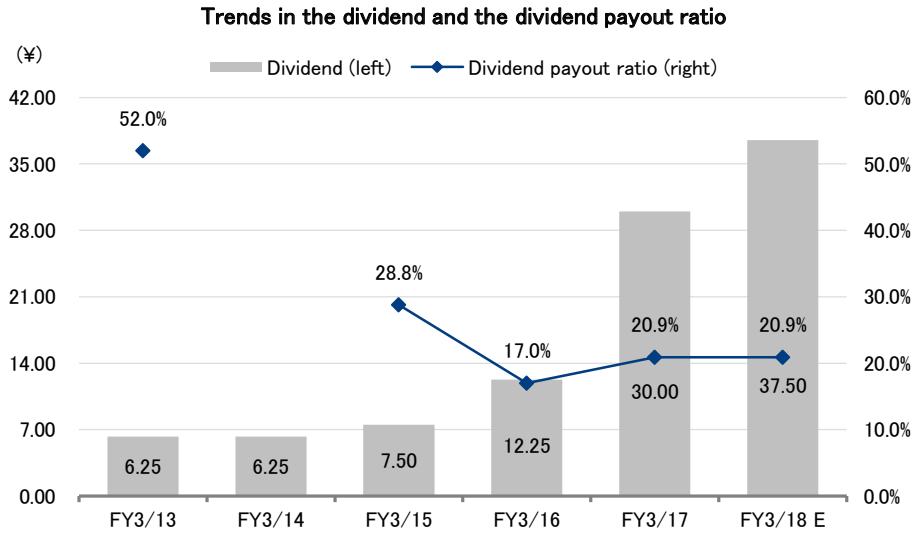
Source: Prepared by FISCO from the Company's results briefing materials

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 corporate 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.

On considering the Company's medium-term targets up to the present time, we estimate that free cash flow will continue to grow in the future. Accordingly, while maintaining a balance between returning profits to shareholders and securing internal reserves, the Company's investment and dividend capabilities have been improving and it can be said to have reached a stage where it can return profit growth to shareholders. Moreover, it is considered that it intends to utilize free cash flow, which is currently rapidly expanding, as the source of funds to invest in overseas factories and to expand its business into non-cardiovascular fields.



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

Announced funding through a third-party allocation and a stock split

The Company announced funding through a third-party allocation of share acquisition rights on November 30, 2017 (resolution on the November 30 issue, resolution on the December 6 conditional issue). The assignment date of the share acquisition rights was December 21, 2017, the amount of funds raised is estimated to be ¥17,484mn, and the exercise period of the share acquisition rights is January 2018 to December 2020. In terms of the specific uses of the funds, ¥5,900mn will be to secure the pipeline for new products, ¥5,300mn will be to further strengthen the development and production systems, ¥4,200mn will be for working funds for the sales of the large-scale new products, and ¥2,084mn will be to secure standby funds, such as for M&A, and to repay borrowings. The expenditure periods for all of these items are scheduled to be from January 2018 to December 2020. The Company also considered bank borrowing as the funding method, but it chose to raise funds through share acquisition rights in order to strengthen the management foundations in the medium term. For the Company, which is continuing to actively manage its business in the growth market of cardiovascular-related medical devices, it seems that the aim of this funding is to make its medium-term growth even more certain.

At the same time, the Company announced a stock split and a revision to the dividend forecast. The stock split was scheduled to be a two-for-one split of common stocks, with December 31, 2017, as the record date. In conjunction with this, it revised the FY3/18 dividend forecast from ¥37.50 to ¥18.75. In substantive terms the dividend will not change, but as a result of the stock split, the amount per investment unit will fall and the liquidity of shares will increase, which for investors will create an environment in which it is easier to invest. Of course, the funding and the setting of a stock split can be understood as expressing the Company's confidence in the outlook for its results in the future. On entering FY3/18, the Company's growth potential has become widely known and an increasing number of investors want to hold its shares, so the stock split can be said to be good news for these investors.

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.

FISCO

Disclaimer

FISCO Ltd. (the terms “FISCO”, “we”, mean FISCO Ltd.) has legal agreements with the Tokyo Stock Exchange, the Osaka Exchange,and Nikkei Inc. as to the usage of stock price and index information. The trademark and value of the “JASDAQ INDEX” are the intellectual properties of the Tokyo Stock Exchange, and therefore all rights to them belong to the Tokyo Stock Exchange.

This report is based on information that we believe to be reliable, but we do not confirm or guarantee its accuracy, timeliness,or completeness, or the value of the securities issued by companies cited in this report. Regardless of purpose,investors should decide how to use this report and take full responsibility for such use. We shall not be liable for any result of its use. We provide this report solely for the purpose of information, not to induce investment or any other action.

This report was prepared at the request of its subject company using information provided by the company in interviews, but the entire content of the report, including suppositions and conclusions, is the result of our analysis. The content of this report is based on information that was current at the time the report was produced, but this information and the content of this report are subject to change without prior notice.

The final selection of investments and determination of appropriate prices for investment transactions are decisions for the recipients of this report.

FISCO Ltd.