COMPANY RESEARCH AND ANALYSIS REPORT

Japan Lifeline Co., Ltd.

7575

Tokyo Stock Exchange First Section

5-Jul.-2018

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Summary

Stable, high growth of 20% in FY3/18 and the same forecast for FY3/19 also, based on actual capabilities

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 foreign manufacturers, particularly from the United States and Europe, is high for advanced medical devices, including cardiac pacemakers used for direct treatment. Since its establishment, the Company 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. Moreover, on behalf of these overseas manufacturers, it engages in all of the processes other than manufacturing, such as domestic regulatory applications, marketing, education, and sales promotions.

On the other hand, the Company's in-house manufactured products include many with high market shares domestically, including vascular grafts and catheters for use in internal atrial cardioversion systems, and it has an excellent reputation as a manufacturer. In this way, it does not simply buy and sell products, it also plays the role of a manufacturer or close to that of a manufacturer, so one of its features is high profitability. 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 FY3/18 results were positive, with net sales of ¥42,298mn (up 13.8% year-on-year (YoY)) and operating income of ¥10,671mn (up 38.9%). In the cardiovascular field, in addition to the increase in the number of cases of disease due to the aging of the population, through the advancement of medical devices, it has become possible to treat cases that were previously difficult to treat. In particular, the number of cases of atrial fibrillation treatment continues to increase at a high level, and alongside this, sales have especially grown of the highly profitable "only-one" products, which was a factor behind the positive results. Also, following the absorption merger of the consolidated subsidiary JUNKEN MEDICAL Co., Ltd., the adjustment of an unrealized gain for inventory purchased before the merger became a temporary factor pushing-up operating income.

The forecasts for the FY3/19 results are for net sales of ¥49,411mn (up 16.8% YoY) and operating income of ¥11,202mn (up 5.0%). Continuing from before, the number of cases of atrial fibrillation treatment is expected to increase, and in addition, the Company will launch highly anticipated large-scale products, so net sales are forecast to grow significantly. However, in addition to the end of the temporary profits that were recorded in FY3/18 following the merger with the subsidiary, profits seem to be slowing, including due to the revisions to the insurance reimbursement prices, promotions costs for new large-scale products, and development costs for in-house manufactured products. However, even when deducting temporary profits and converting the results to on an actual-capabilities basis, we find that in FY3/18, operating income was still ¥9,201mn and that operating income is continuing to grow at the high rate of around 20% for 2 consecutive years, of 19.7% in FY3/18 and 21.7% in FY3/19.

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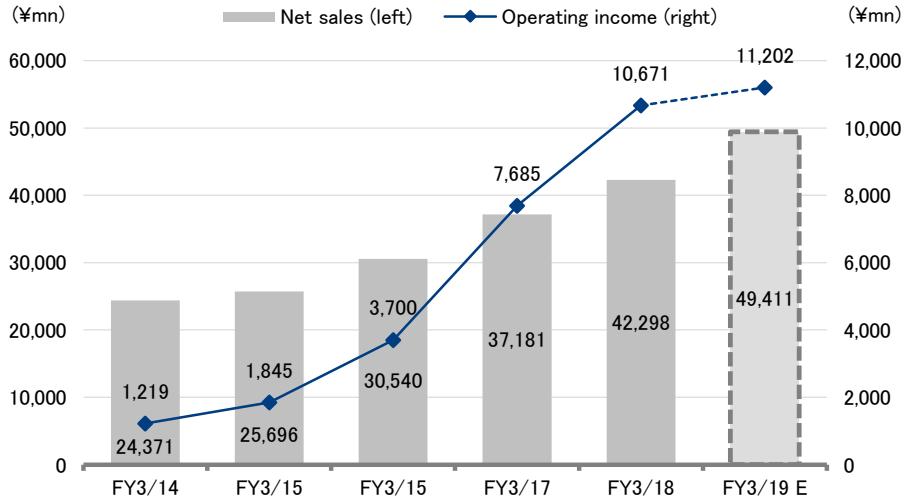
Summary

On May 29, 2018, the Company updated its medium-term management plan released in 2017, and the Company is now aiming for net sales of ¥77.7bn and an operating income margin of 25% in FY3/23. 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 working on expanding its business 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 we can expect a further medium-term growth above the forecast.

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
- Profits may seem to slow in FY3/19, but this will be due to the recording of temporary profits in FY3/18. On an actual-capabilities basis, operating income will grow by around 20% for the second consecutive year.

Results trends



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

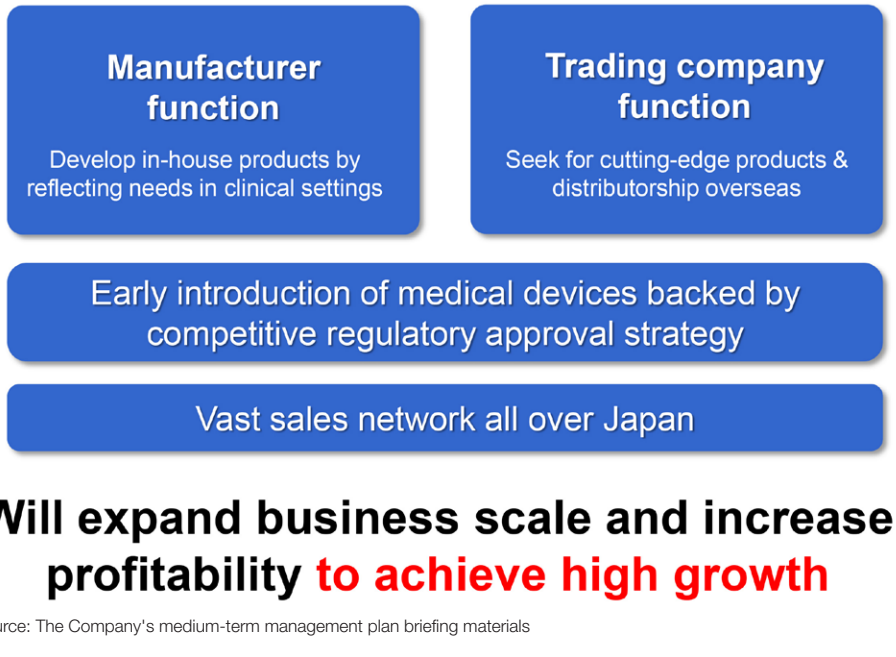
Business overview

Features include a sales system, a regulatory system, the domestic launches of advanced products, and products developed according to needs

1. Business description

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

The Company's growth foundation



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

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

2. Distribution structure

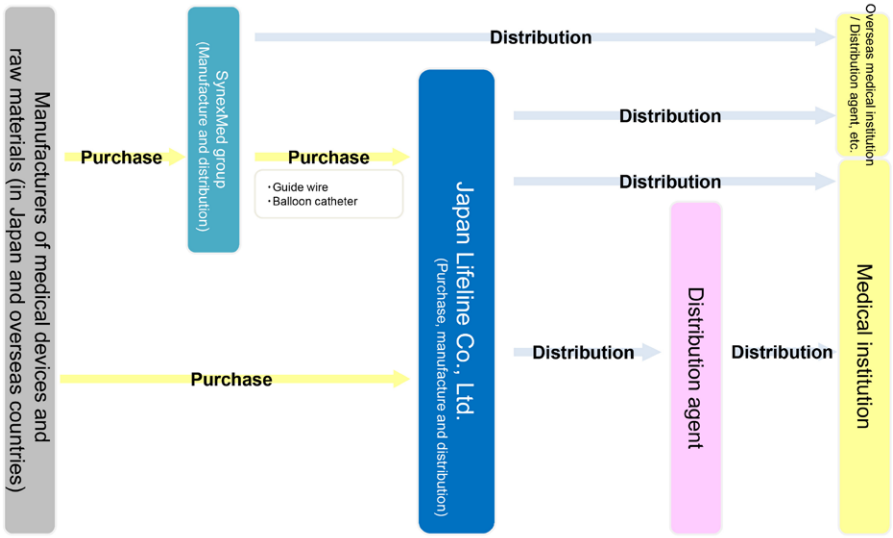
As its sales structure, the Company has 47 sales bases (as of April 2018) throughout Japan, from Hokkaido to Okinawa, with staff who possess high-level specialist knowledge and who support medical practitioners. Its customers include medical institutions and sales agencies, although it sells few devices 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, which means it ties up with a single partner in a particular product category. Also, it takes the same position as that of manufacturers for aspects such as the acquisition of regulatory approval within Japan, marketing smoothly to spread the use of medical devices through academic societies and related, and education for medical institutions. Further, as there is a commercial practice unique to the medical devices industry of deposit sales, which entails depositing a product at a medical facility and recording it as sales when it is used, manufacturers have to bear the inventory burden instead of sales agencies. However, as a result of handling products with an exclusive sales contract, the Company's gross profit margin on its purchased products averages from 40-45%, which is extremely high compared to the margins of trading companies. In general, sales agencies conducting secondary distribution in Japan handle the products of multiple companies, and although their stock burden is light, many of these companies have a gross profit margin of below 20%. Based on this, there is a clear differentiation between the business structures of the Company and general trading 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. The gross profit margin of the Company's in-house products is relatively high, and of the Company's in-house products, those that are one-of-a-kind products have an even higher gross profit margin. In 2009, it acquired Ube Junken Co., Ltd. (name subsequently changed to JUNKEN MEDICAL Co. Ltd.), which at that time was the only manufacturer of vascular grafts in Japan, and it incorporated these vascular grafts into its lineup of in-house manufactured products. Also, in 2010, it made subsidiaries of the SYNEXMED Group (companies in Hong Kong and Shenzhen), which manufactured guide wires and balloon catheters, and newly added balloon catheters to its lineup of in-house manufactured products. JUNKEN MEDICAL merged with the Company in April 2017 through an absorption-type merger toward realizing synergies and improved efficiency.

Business overview

Schematic diagram of the business



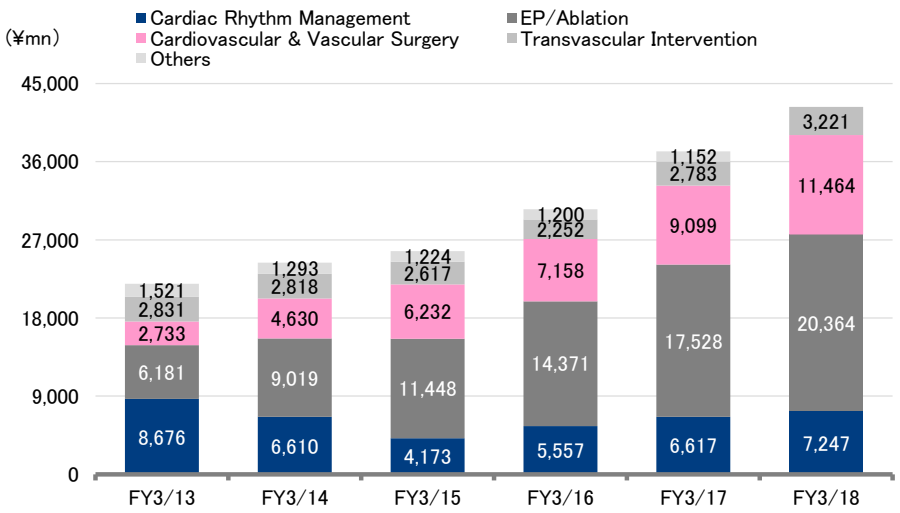
Source: The Company's results briefing materials

An abundant 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. In terms of the percentages of sales, in FY3/18, Cardiac Rhythm Management contributed 17.1%, EP/Ablation 48.1%, Cardiovascular & Vascular Surgery 27.1%, and Transvascular Intervention 7.6%.

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

a) Cardiac Rhythm Management

Cardiac Rhythm Management handles for treating cardiac arrhythmia. The main products are implantable devices that use electrical stimulation to ensure that the heart beats normally, including cardiac pacemakers, ICDs (implantable cardioverter defibrillators), and CRT-Ds (cardiac resynchronization therapy defibrillators). It also handles AEDs (automated external defibrillators). In the cardiac pacemaker market, MRI-compliant pacemakers have rapidly become the mainstream product in recent years, so the Company has also launched the KORA 250 and other MRI-compliant products. All of the items in this segment are purchased products.

The cardiac pacemaker (LivaNova) is an implantable medical device that is used when the pulse is less than normal. It constantly monitors the heart beat and when it senses that the pulse has been interrupted, it sends out an electrical stimulus and returns the heart beat to normal. The ICD (implantable cardioverter defibrillator, LivaNova) automatically senses high-risk arrhythmias, such as sudden ventricular fibrillation and ventricular tachycardia, and also returns the heart beat to normal by performing electrical therapy. In the event of severe heart failure, the CRT-D (cardiac resynchronization therapy defibrillator, LivaNova) prepares for ventricular dyssynchrony and improves the heart's pump function by electrically stimulating both the left and right ventricles of the heart, while it also has a defibrillation function, the same as the ICD. The pacemaker lead (LivaNova) is a conducting wire used to connect to the cardiac pacemaker in order to transmit an electrical stimulation to the myocardium. The ICD lead (LivaNova) for transmitting the electrical stimulation emitted by the ICD to the myocardium is equipped with a coil for treatment by electric shock. The event recorder (LivaNova) is an extracorporeal electrocardiograph that detects and records cardiac events. It can confirm changes in an electrocardiogram and its uses include the analysis of arrhythmia. The AED (automated external defibrillator, NANOOMTECH) automatically determines the state of the heart, and when it senses it is in a convulsive state, such as ventricular fibrillation, it gives it an electric shock and returns it to a normal state.

The Company is supplied with cardiac pacemakers and related products by LivaNova. The number of units sold had declined due to a delay in launching pacemakers compliant with MRI, but in FY3/18, its market share recovered to 15%. However, in FY3/19, as the number of insurance points for remote medical treatment has increased following the revisions to medical fees in April, the needs of medical facilities have shifted toward remote monitoring. But there is a problem with the supply capabilities of LivaNova PLC for remote monitoring devices, and it estimated that sales volume in FY3/19 would decline YoY.

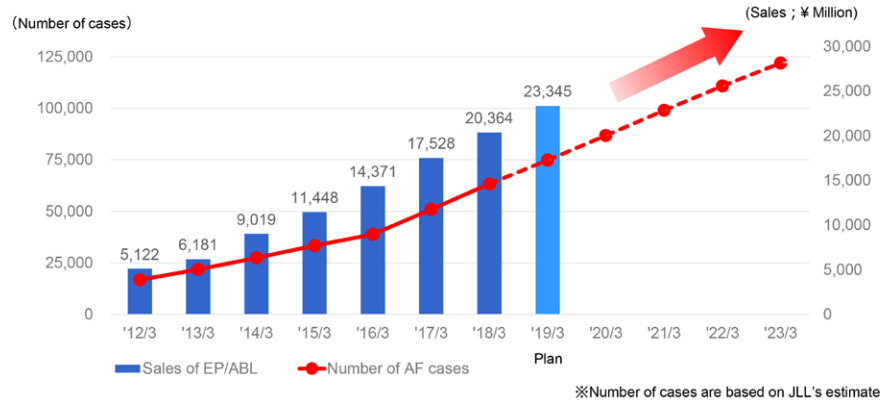
Cardiac Rhythm Management

Source: The Company's results briefing materials

b) EP/Ablation

In EP/Ablation, the Company handles disposable electrode-equipped catheter for the examination and treatment of arrhythmia. In FY3/18, the number of cases increased 22% YoY, and in recent years, the number of cases of atrial fibrillation treated with ablation has been rapidly increasing. A catheter broadly refers to a medical device that is a hollow, soft, and thin tube that is inserted into a blood vessel from the surface of the skin to provide treatment.

Forecast number of cases of EP/ABL ablation



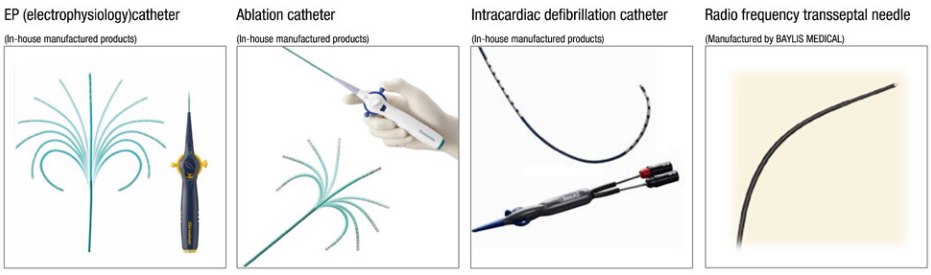
Source: The Company's medium-term management plan briefing materials

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

The ablation catheter (Japan Lifeline) is an electrode catheter that locally cauterizes and treats the stimulation conduction pathway causing local arrhythmia (tachycardia) with a high frequency current. The same as the EP catheter, it comes in an abundance of types so that various parts of the heart can be cauterized. In addition, the irrigation catheter is one type of ablation catheter, and at the tip of the catheter there is a hole that enables the injection of a physiological saline solution. It has a function to reduce the occurrence of thrombus in the body by performing cauterization, while cooling the tip electrode.

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

EP/Ablation catheter



Source: The Company's results briefing materials

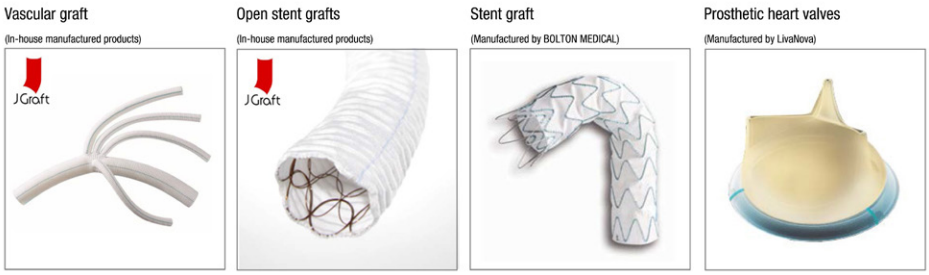
c) Cardiovascular & Vascular Surgery

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 15% market share in FY3/18. 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 from the blood vessel at the base of the foot until inserted at the treatment site, at which point the force of the springs press against the blood vessel to fix it in place.

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

The thoracic stent graft (Bolton Medical) is a medical device for treating thoracic aortic aneurysms. Unlike vascular grafts, open chest-surgery is not required, and they are a treatment in which a vascular graft, onto which is sewn metallic stents that are able to expand, is carried from the blood vessel at the base of the foot to the treatment site in the chest through the catheter, where it is deployed to block the blood flow to the aortic aneurysm. The abdominal stent graft (Endologix) is a medical device for treating abdominal aortic aneurysm, and similar to the thoracic stent, it is carried to the treatment site in the abdomen where it is deployed to block the blood flow to the aortic aneurysm. Other products include the prosthetic heart valve (LivaNova), which is a medical device used to replace a valve in the heart that has ceased its original function due to conditions such as stenosis and valve dysfunction.

Products for Cardiovascular & Vascular Surgery



Source: The Company's results briefing materials

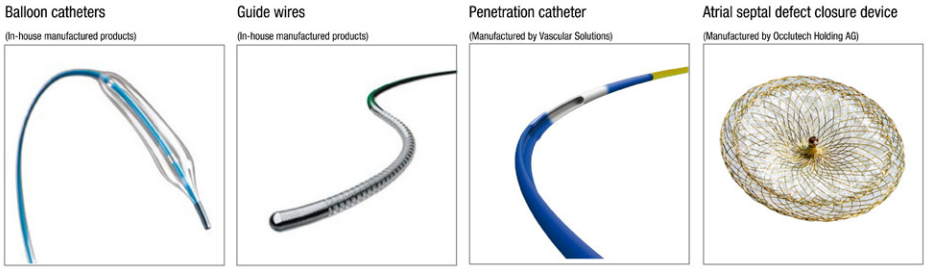
d) Transvascular Intervention

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, 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 device through the blood vessels to the treatment site. It is inserted into the blood vessel, such as via the thigh, and passed through the stenosis in the coronary arteries and peripheral arteries, and the 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 the blocking of the coronary arteries. They are treated by inflating the balloon on the catheter (thin tube) from inside the blood vessel and expanding the blood vessel. The penetration catheter (Vascular Solutions) is a medical device used to support the passage of guide wires through lesions in coronary arteries and peripheral arteries.

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

Transvascular Intervention



Source: The Company's results briefing materials

Performance trends

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

1. The turning point

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

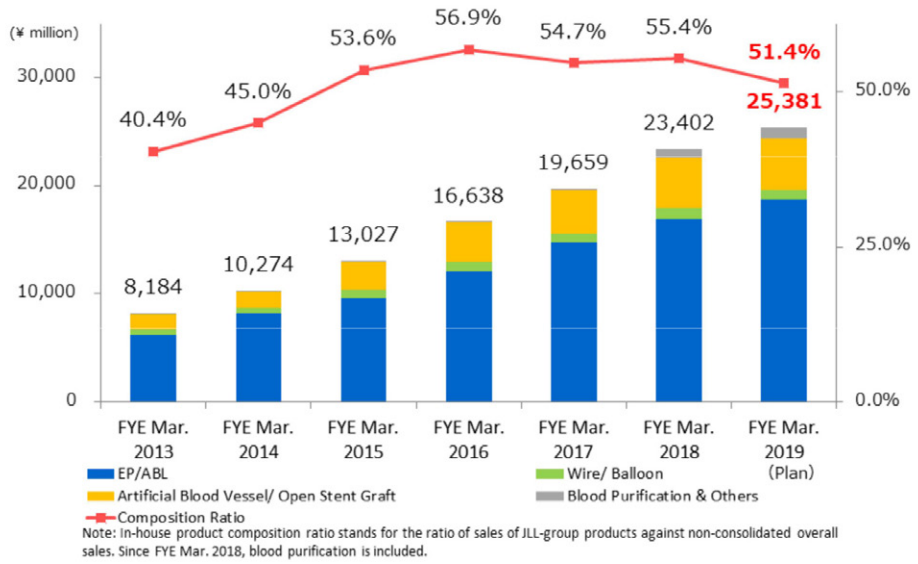
In 2001, it launched guide wires as its first in-house manufactured product, and subsequently expanded its lineup to include EP catheters and ablation catheters. In FY3/09, the Company acquired Ube Junken, which was a subsidiary of Ube Industries, Ltd. <4208> and the only manufacturer of vascular grafts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

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

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. However, for the time being from FY3/19, the ratio of in-house products is forecast to decrease slightly due to multiple sales of large purchased products.

Performance trends

Sales of in-house group products



Note: In-house product composition ratio stands for the ratio of sales of JLL-group products against non-consolidated overall sales. Since FYE Mar. 2018, blood purification is included.

Source: The Company's results briefing materials

Major increase in profits in FY3/18, even on an actual-capabilities basis excluding the unrealized gain

2. Trends in FY3/18

In the FY3/18 results, net sales were ¥42,298mn (up 13.8% YoY), operating income was ¥10,671mn (up 38.9%), ordinary income was ¥10,730mn (up 34.0%), and net income attributable to owners of the parent was ¥7,478mn (up 39.8%). The number of cases in the cardiovascular field, which is the Company's foundation, continued to grow significantly, and alongside this, results were strong for both in-house manufactured products and purchased products. In addition, gross profit grew from the adjustment of an unrealized gain, greatly raising the gross profit margin. Therefore, the Company was able to absorb the increases in travel costs, development costs, and SG&A expenses such as payment commissions, and also the costs of relocating a subsidiary's factory and a disposal loss, to achieve significantly higher profits.

One of the reasons for the extremely high profit growth was the adjustment of an unrealized gain. This was following the absorption merger of the consolidated subsidiary JUNKEN MEDICAL on April 1, 2017, after which the Company adjusted the unrealized gain relating to inventory purchased before the merger and recorded negative costs of sales of ¥1,170mn. This overlapped with factors including the contribution to profits of products manufactured in-house, and so the gross profit margin rose by 3.6 percentage points. As this unrealized gain is not part of the Company's original, actual capabilities, when provisionally calculating the results excluding this unrealized gain, even then profits increased considerably by around 20%, for operating income of ¥9,201mn (up 19.7%), ordinary income of ¥9,560mn (up 19.4%), and net income attributable to owners of the parent of ¥6,423mn (up 20.0%). So even when based on its actual capabilities, the Company's results grew significantly.

Performance trends

FY3/18 results

(¥mn)

	FY3/17	% of sales	FY3/18	% of sales	Change rate
Net sales	37,181	100.0	42,298	100.0	13.8
Gross profit	21,998	59.2	26,576	62.8	20.8
SG&A expenses	14,313	38.5	15,904	37.6	11.1
Operating income	7,685	20.7	10,671	25.2	38.9
Ordinary income	8,010	21.5	10,730	25.4	34.0
Net income attributable to owners of the parent	5,350	14.4	7,478	17.7	39.8

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

The strong sales of existing products covered for the delays in the releases of large-scale products

3. Sales trends by product in FY3/18

In sales conditions by product, each product sold strongly and exceed the initial forecasts. In Cardiac Rhythm Management, as the Company was able to offer a full lineup of cardiac pacemakers compliant with MRI, including the leads, its share of the cardiac pacemaker market recovered greatly to 15%. In EP/Ablation, since the number of cases of ablation treatment for atrial fibrillation increased significantly, rising 22%, which was higher than the initial assumption of a rise of 17%, sales increased of BeeAT, an intracardiac defibrillation catheter and “only-one” product, and also of products related to atrial fibrillation treatment.

In Cardiovascular & Vascular Surgery, sales grew of the abdominal stent graft AFX2, and also of FROZENIX, an open stent graft that was highly evaluated for its contribution to realizing minimally invasive treatment. In Transvascular Intervention, sales increased of balloon catheters for peripheral blood vessels and of atrial septal defect closing devices. Also, following the launch in March 2018 of the drug-eluting coronary stent Orsiro, it had a sales period of 1 month and thereby contributed to the increase in sales. In addition, the Company is taking on the challenge of entering-into a new area, the gastrointestinal area, with JENTLLY, a colonic stent that it released in a limited way in June 2017, and then began its fully fledged sales in January 2018.

The launches of the endoscopic ablation system HeartLight and the sutureless bio-prosthetic valve PERCEVAL were later than initially forecast, but this was covered by the strong sales of existing products.

Performance trends

Net sales by product

(¥mn)

	FY3/17	% of sales	FY3/18	% of sales	Change rate
Pacemaker-related	5,674	15.3	6,463	15.3	13.9
ICD related	724	1.9	584	1.4	-19.4
Others	218	0.6	200	0.5	-8.4
Cardiac Rhythm Management	6,617	17.8	7,247	17.1	9.5
EP catheter	13,160	35.4	15,354	36.3	16.7
ABL catheter	1,258	3.4	1,161	2.7	-7.7
Others	3,109	8.4	3,848	9.1	23.8
EP/ABL total	17,528	47.1	20,364	48.1	16.2
Heart valve related	1,755	4.7	1,742	4.1	-0.7
Cardiopulmonary related	113	0.3	106	0.3	-6.2
Vascular graft related	7,229	19.4	8,469	20.0	17.2
Blood purification	1,152	3.1	1,131	2.7	-1.8
Other	-	-	12	0.0	-
Cardiovascular Surgery related	10,251	27.6	11,464	27.1	11.8
Balloon catheter	814	2.2	950	2.2	16.8
Guide wire	373	1.0	371	0.9	-0.4
Others	1,596	4.3	1,899	4.5	19.0
Transvascular Intervention	2,783	7.5	3,221	7.6	15.7
Others	1,152	3.1	-	-	-
Total	37,181	100.0	42,298	100.0	13.8

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

The outlook for the FY3/19 results is for profits to again increase by more than 20% on an actual-capabilities basis

4. FY3/19 outlook

For the FY3/19 results, the Company is forecasting net sales of ¥49,411mn (up 16.8% YoY), operating income of ¥11,202mn (up 5.0%), ordinary income of ¥11,482mn (up 7.0%), and net income attributable to owners of the parent of ¥7,825mn (up 4.6%). Results in FY3/18 were strongly affected by the recording of an unrealized gain of ¥1,170mn, which meant each profit item was calculated lower in the range of 1 digit. But on conducting provisional calculations excluding this item (FISCO’s provisional calculations), we find that the increases in profits become 21.7% for operating income, 20.1% for ordinary income, and 21.8% for net income attributable to owners of the parent, and all profit items grew strongly by more than 20%. So an actual-capabilities basis, we can say that the Company is continuing to maintain high growth.

In sales, as the number of cases of ablation treatment for atrial fibrillation is expected to continue to increase significantly, sales of related products are forecast to grow. In addition, the full fiscal year contribution of Orsiro, which was launched in March 2018 as a product for which there are high expectations, is forecast to be net sales of ¥5bn. The April revisions to the insurance reimbursement prices had a negative effect on the Company’s net sales, but the extent of the decline will be small for the products that are driving sales, such as “only-one” products, and will be 5.8% for all the products it handles, so it seems their impact on results will be limited. On the other hand, in Cardiac Rhythm Management, demand for remote monitoring devices is increasing due to the receipt of medical fee incentives for remote treatment, but as the Company’s supplier manufacturers are experiencing supply-side problems, the outlook is for a decline in sales.

In profits, the gross profit margin is forecast to decline due to the end of the adjustment of the temporary unrealized gain that was recorded in FY3/18, the lowering of insurance reimbursement prices, and a change to the product mix through Orsiro, a large-scale purchased product with major sales. Conversely, SG&A expenses are expected to rise because of an increase in advertising expenses for the promotion of large-scale products and the establishment of a logistics base in Kansai, and also due to increases in other costs, including development-related costs to expand the lineup of in-house manufactured products, and clinical trial expenses and examination expenses toward obtain drug regulatory approval for new products. Therefore, the outlook is for profits to increase only by a single digit. But when excluding the effects of above-described unrealized gain, the forecast is actually for a major rise in profits, with each profit item to increase by more than 20%.

FY3/19 outlook

(¥mn)

	FY3/18	% of sales	FY3/19 E	% of sales	Change rate
Net sales	42,298	100.0	49,411	100.0	16.8
Gross profit	26,576	62.8	29,455	59.6	10.8
SG&A expenses	15,904	37.6	18,252	40.4	14.8
Operating income	10,671	25.2	11,202	22.7	5.0
Ordinary income	10,730	25.4	11,482	23.2	7.0
Net income attributable to owners of the parent	7,478	17.7	7,825	15.8	4.6

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

In FY3/19, will launch 3 large-scale products for which there are major expectations

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

By product, in Cardiac Rhythm Management, while demand for remote monitoring devices is increasing, there remain supply problems, so the forecast is that the sales volume of pacemakers will decline. In EP/Ablation, assuming that the number of cases of atrial fibrillation will increase by 18%, sales of BeeAT and other related products will continue to grow, while the endoscopic ablation system HeartLight is set to be added as a new product. The Company has already launched its in-house manufactured open stent graft in Taiwan in February 2018, and the first case occurred in April, while it plans to also develop it in Europe in the 2H. In Cardiovascular & Vascular Surgery, sales of the open stent graft FROZENIX and the abdominal stent graft AFX2 are expected to continue to increase. In Transvascular Intervention, the forecast is for sales to decrease due to the reduction in the insurance reimbursement prices of balloon catheters and guide wires. But overall, sales are expected to increase greatly because of the contribution of Orsiro.

Outlook of net sales by product in FY3/19

(¥mn)

	FY3/18	% of sales	FY3/19 E	% of sales	Change rate
Pacemaker-related	6,463	15.3	5,739	11.6	-11.2
ICD related	584	1.4	680	1.4	16.5
Others	200	0.5	305	0.6	52.7
Cardiac Rhythm Management	7,247	17.1	6,725	13.6	-7.2
EP catheter	15,354	36.3	17,225	34.9	12.2
ABL catheter	1,161	2.7	1,611	3.3	38.7
Others	3,848	9.1	4,509	9.1	17.2
EP/ABL total	20,364	48.1	23,345	47.2	14.6
Heart valve related	1,742	4.1	1,806	3.7	3.7
Cardiopulmonary related	106	0.3	58	0.1	-44.9
Vascular graft related	8,469	20.0	8,553	17.3	1.0
Blood purification	1,131	2.7	1,176	2.4	3.9
Other	12	0.0	10	0.0	-15.0
Cardiovascular Surgery related	11,464	27.1	11,606	23.5	1.2
Balloon catheter	950	2.2	781	1.6	-17.9
Guide wire	371	0.9	399	0.8	7.3
Others	1,899	4.5	6,553	13.3	245.1
Transvascular Intervention	3,221	7.6	7,734	15.7	140.0
Total	42,298	100.0	49,411	100.0	16.8

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

The three large-scale products, for which there are great expectations, are set to be rolled-out during this fiscal year. Needs for each at medical sites are thought to be high, and they are considered to be a product Group that will drive the Company's medium-term growth. First is the drug-eluting coronary stent Orsiro, which has already been launched in March and which will be a major device for coronary artery 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, that it uses nano-coating to prevent elution of metallic ions, and that it is extremely durable. Therefore, it was highly evaluated in the clinical trials and was forecast to obtain a 10% share of the drug-eluting coronary stent market in its first fiscal year (FY3/19), but this has been upwardly revised to 15%.

Second is the endoscopic ablation system HeartLight, which is scheduled to be released in July. It is a new product that incorporates the technology of laser cauterization into balloon technology, to make possible accurate cauterization with a laser while observing the endoscopic images. After its launch, the Company plans to progress the launch of a next-generation model with even more advanced functions. Third is the sutureless bio-prosthetic valve PERCEVAL, which is scheduled to be released in the 2H. Its features include that it can be expected to reduce the surgery time and the burden on the patient because sutures are not required and that is has excellent hemodynamics as it has a structure without a valve ring, so it is optimal for complex surgeries and keyhole surgeries. It is considered to be product that can be expected to create a new market for surgeons.

Large-scale products for which there are high expectations

Source: The Company's results briefing materials

The medium-term management plan

Even if the product mix is changed, strong growth is expected in the medium term

1. The medium-term management plan

The heart disease medical devices market continues to expand against the backdrop of the aging of the Japanese population and the advancement of medical devices. In this sort of environment, there is no other company in Japan that can provide sales and regulatory structures at the same levels as 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. In its medium-term management plan, the Company is aiming for net sales of ¥77.7bn and an operating income margin of 25% in FY3/23, and these targets can be said to be fully within range.

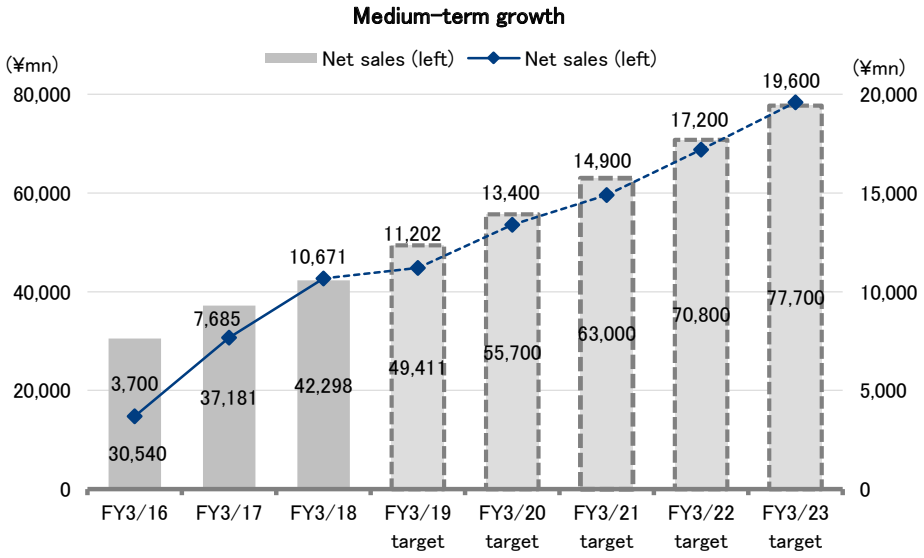
On the other hand, through the successive market launches of large-scale products, the ratio of in-house manufactured products, which was 55.4% in FY3/18, is expected to decline slightly to a level of around 50% in the medium term. In this way, it is inevitable that the Company's product mix will change and the gross profit margin will rise or fall depending on the timing of the product launches 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

Steadily strengthening medium-term growth through equity finance

2. Developments for medium-term growth

From the viewpoint of medium- to long-term growth, an issue for the Company is expanding its business areas. At the present time, its growth potential for the cardiovascular field in Japan is forecast to be strong for the foreseeable future, while it also plans to expand its business areas, including by entering-into new areas. 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 sales and to accumulate expertise in this field. 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 and Europe. Most of the contribution to profits of this expansion of business areas has not been incorporated into the targets in the medium-term management plan.

On November 30, 2017, the Company issued share acquisition rights through a third-party allocation in order to strengthen medium-term growth and its management base. The issue is expected to raise funds of approximately ¥17,484mn, while the exercise period for the share acquisition rights is January 2018 to December 2020. In terms of the specific uses of the funds, ¥5,900mn will to be to secure the pipeline for new products, ¥5,300mn to strengthen the development and production structure, ¥4,200mn as working funds for the sales of large-scale new products, and ¥2,084mn as standby funds assuming, for example, M&A and other usages, and to repay borrowings. The expenditure periods for all of these items are scheduled to be from January 2018 to December 2020. The Company continues to conduct active management in the growth market of cardiovascular-related medical devices, while also entering-into new business areas, such as the gastrointestinal field and overseas. For a strongly growth-oriented enterprise such as the Company, we welcome the use of equity finance as it increases the likelihood of stronger growth in the medium term.



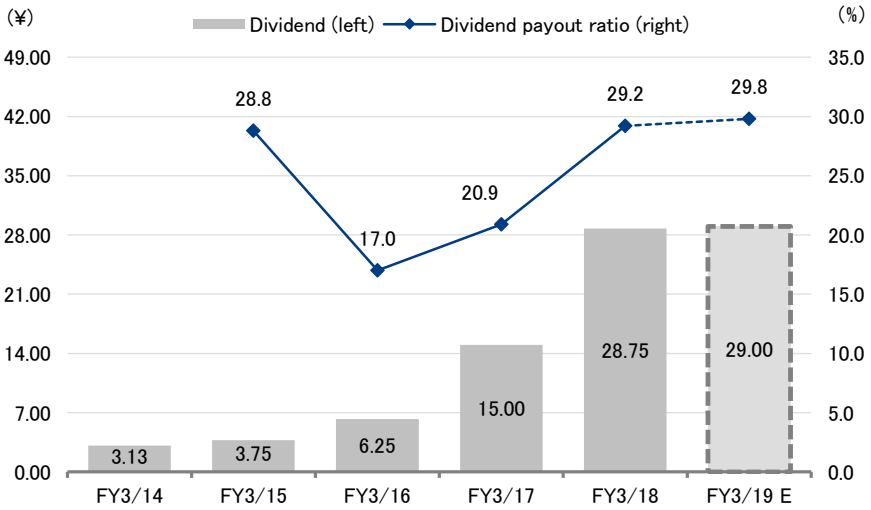
Source: Prepared by FISCO from the Company's results briefing materials

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 enterprise value by aiming to raise results and invest in developing and manufacturing products in-house that utilize our strengths," and going forward, it will raise the dividend in line with profit growth. It has carried out equity finance, but on considering the Company's medium-term management targets up to the present time, we estimate 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 have been improving, and it can be said to have reached a growth stage where it can return profit growth to shareholders.

Trends in the dividend and the dividend payout ratio



Notes; the amounts have been retroactively adjusted in relation to the 2-for-1 share splits in 2015, 2016, and 2018
Source: Prepared by FISCO from the Company's results briefing materials

Information security

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

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