JAPAN LIFELINE CO., LTD. (7575 JP)

REVISED MEDIUM-TERM MANAGEMENT PLAN AIMS TO REALISE GROWTH ON THE REFINED BUSINESS PORTFOLIO

FY22 RESULTS

Japan Lifeline [JLL] reported FY22 results with OP of ¥10,837mil (+8.7% YoY) on sales of ¥51,750mil (+0.5% YoY). Sales surpassed the firm's guidance ¥51,090mil (-0.7% YoY), which was revised on 1 February 2023. There was an impact from the April 22 revision to prices for insurance reimbursement – a process that takes place every two years for certain medical devices– which led to the price of many items being revised down, reducing FY22 sales and GP by -¥1,835mil and -¥837mil, respectively.

In addition, COVID caused delays in procedures which had a negative impact on sales during Q2~Q3. However, those negative factors were offset by +6% YoY increase in sales volumes for ablation treatments for atrial fibrillation [AF or A-Fib: a condition that causes an irregular and often excessively fast heartbeat].

FY22 OP overshot the company's guidance of $\pm 10,241$ mil (+2.7% YoY), rising by + ± 863 mil YoY / +8.7% YoY thanks to 1) an improved sales mix (+ ± 483 mil) from a +2.5ppt YoY increase in the in-house product sales ratio, and 2) a decline (- $\pm 1,413$ mil) in the level of inventory evaluation losses associated with an early termination of the distribution of Orsiro, a drugeluting coronary stent; which had been written off in FY21 so was little hangover in FY22. As a result, FY22 OPM improved by +1.5ppt to 20.9%.

FY22 Net profit [NP] fell -7.9% YoY to ¥6,891mil principally due to an impairment loss of investment securities.

<u> </u>	FY2	1	FY22			
(¥mil)	1H	FY	1H	FY	YoY (%)	
Sales	25,130	51,469	25,489	51,750	0.5	
GP	14,292	28,835	14,546	29,895	3.7	
GPM (%)	56.9	56.0	57.1	57.8	+1.8pp	
SG&A	9,610	18,861	9,426	19,057	1.0	
SG&A / Sales (%)	38.2	36.6	37.0	36.8	+0.2ppt	
OP	4,681	9,973	5,119	10,837	8.7	
OPM (%)	18.6	19.4	20.1	20.9	+1.5ppt	
NP*	3,591	7,484	3,702	6,891	-7.9	
NPM (%)	14.3	14.5	14.5	13.3	-1.2ppt	
Source: Nippon-IBR based on JLL's FY21, FY22 earnings results materials * Net profit attributed to the parent's shareholders						

EXECUTIVE SUMMARY

- Japan Lifeline [JLL] reported FY22 results with OP of ¥10,837mil (+8.7% YoY) on sales of ¥51,750mil (+0.5% YoY). Sales surpassed the firm's guidance ¥51,090mil (-0.7% YoY), which was revised on 1 February 2023. There was an impact of the April 22 revision to prices for insurance reimbursement – a process that takes place every two years for certain medical devices– which led to the price of many items being revised down.
- OP overshot the company's guidance of ¥10,241mil (+2.7% YoY), mainly due to
 1) an improved sales mix as the inhouse product sales ratio rose by
 2.5ppt YoY, 2) fewer inventory evaluation losses associated with an early termination of the distribution of
 Orsiro, a drug-eluting coronary stent which had been written off in FY21 and there was little left to do in FY22.
- JLL is guiding for FY23 1H OP of ¥4,488mil (-12.3% YoY) on sales of ¥23,880mil (-6.3% YoY), and FY23 OP of ¥9,763mil (-9.9% YoY) on sales of ¥48,807mil (-5.7% YoY). JLL assumes that the termination of distribution of Baylis Medical's products – to now receiving a sales support fee – will lead to a drop in sales, although this will be partially offset by recovery in number of procedures at hospitals.
- Management expect SG&A to rise +4.6% YoY in FY23 – IT- and personnelrelated expenses, which squeeze OP.
- JLL announced its revised medium-term plan that covers the next five years (FY23~27). It will be reviewed every year to reflect upside and downside risks, with KPIs focusing on 1) the sales performance, 2) earnings from new business fields, 3) OPM, 4) EPS, and 5) ROIC.

FY22 EARNINGS BY PRODUCTS

JLL operates four product groups:

- 1. Cardiac Rhythm Management,
- 2. EP / Ablation,
- 3. Cardiovascular Surgery, and
- 4. Gastrointestinal [GI]/ Percutaneous Intervention [PI].

	FY21		FY22		
(¥mil)	1H	FY	1H	FY	YoY (%)
Pacemaker	3,015	5,862	2,530	4,938	-15.8
ICD	3,393	6,785	3,595	7,090	4.5
Others	166	329	167	374	13.5
Cardiac Rhythm Management	6,577	12,977	6,293	12,403	-4.4
EP Catheter	8,973	18,412	9,780	19,654	6.8
ABL Catheter	556	1,232	496	1,011	-17.9
Others	2,801	5,455	2,735	5,626	3.1
EP / Ablation	12,331	25,099	13,012	26,292	4.8
Vascular Graft	4,222	9,370	4,837	10,353	10.5
Others	185	286	85	289	1.0
Cardiovascular Surgery	4,409	9,657	4,922	10,643	10.2
Gastrointestinal	186	448	285	645	44.2
PI	1,622	3,285	974	1,765	-46.3
Gastrointestinal / PI	1,810	3,733	1,260	2,411	-35.4
Consolidated Net Sales	25,130	51,469	25,489	51,750	0.5

1. Cardiac Rhythm Management (CRM)

There are two main product groups in CRM, (1) pacemakers and (2) implantable cardioverter-defibrillators [ICDs]. JLL sources the full line-up of products from Boston Scientific Japan, the Japan entity of Boston Scientific Corporation (BSX:US) with which JJL has a long-term exclusive distributor contract in Japan.

The CRM product group saw FY22 sales decline -4.4% YoY to ¥12,403mil due to the reimbursement price cuts. Products such as pacemakers faced intensified competition from new product launches and aggressive pricing. Pacemaker sales fell -15.8% YoY to ¥4,938mil (comprising 40% of FY22 CRM sales).

FY22 sales of ICD- related products – the dominant product group among JLL's CRM sales – rose +4.5% YoY to ¥7,090mil (56% of CRM sales). There are two types of ICD devices:

- 1. **Traditional-ICD [T-ICD]:** This battery-operated unit is implanted in the chest. The procedure requires the leads to be attached to the heart via invasive surgery. New T-ICD devices are put in when the battery is exchanged, usually in ten years. In FY22, JLL obtained replacement demand in the timing of battery exchange.
- Subcutaneous ICD [S-ICD]: This device is implanted under the skin at the side of the chest below the armpit. It is attached to an electrode that runs along the breastbone. Although the device is larger than a T-ICD, its lead is not implanted in the heart, hence least likely causes serious complications. JLL is the sole distributor of S-ICD in Japan. FY22 sales remained flat YoY.

Others products including AED: Both sales and rental of AED remained solid during FY22, earnings sales of ¥374mil (+13.5% YoY).

Electrophysiology [EP] / Ablation

JLL identifies one-of-a-kind products that do not have competitive products as "only-one" products. In the EP catheter product arena, BeeAT, a catheter with intracardiac cardioversion functions, is categorised as an "only-one" product.

Although the EP catheter market in Japan was dominated by overseas device makers, JLL holds top market share of 45% with its in-house EP catheter products used in heart check-ups.

The EP / Ablation product group consists of three product sub-categories: (1) EP Catheters, (2) Ablation Catheters and (3) Others which includes disposable products such as radiofrequency [RF] needles and steerable sheaths.

- Although the insurance reimbursement price revision affected all of the EP Catheter products, FY22 sales rose +4.8%
 YoY to ¥26,292mil thanks to solid sales volume increases in the EP Catheter products.
- Steady growth in AF cases, which saw an increase of +6% YoY, led to an increase in sales of in-house ablation products. In Q4 alone, AF cases improved approx. +10.0% YoY, on the back of supply issues of the rival products and the effects from COVID easing. However, Ablation Catheters continued to see components shortages specifically, due to a delay in shipments of an endoscope laser ablation catheter, the *HeartLight X3*, from the manufacturer throughout FY22. As a result, FY22 Ablation Catheter sales slumped -17.9% YoY to ¥1,011mil.
- The Others product group, which includes RF Needles and steerable sheaths, saw steady sales growth of +3.1% YoY to ¥5,626mil. In Q4 alone, the sub-segment earned sales of ¥1,532mil (+22.8% YoY).

Cardiovascular Surgery

JLL has a rich portfolio of in-house products among the Cardiovascular Surgery products. In this category, artificial blood vessels, which include open stent grafts, are also deemed as an "only-one" product. The firm holds top market share of 75% in the artificial blood vessels market.

The Cardiovascular Surgery products sales saw rise +10.2% YoY to FY22 sales of ¥10,643mil, thanks to continued growth in vascular grafts (FY22 sales ¥10,353mil +10.5% YoY). In-house products such as artificial blood vessels and open stent grafts contributed to the sales growth. Increases in the number of emergency treatments led to a rapid growth in sales of open stent grafts (+4.7% YoY). Sales of abdominal stent grafts that the firm distributes in Japan also grew 19.2% thanks to synergy effects with the new product, abdominal stent graft [Alto].

The development of the embolic coil, Avenir – currently sold for use in abdominal cases but as of Q1, it is also being sold for use in neurovascular cases – will likely become a new pillar of growth for JLL in the neurovascular area. Others product group, which includes the embolic coil, in the segment earned FY22 sales of ¥289mil (+1.0% YoY). In Q4 alone, the sales of the Others product group surged to ¥115mil (+443.5% YoY) on the back of steady expansion of depository facilities for embolic coils.

Gastrointestinal [GI] and Percutaneous Intervention [PI]

JLL reported FY22 GI / PI sales of ¥2,411mil (-35.4% YoY). Stable sales growth of (1) GI products, thanks to expanding depository facilities for large intestinal / stomach / duodenum stents and (2) Ablation needles for the treatment of liver cancer also performed well, were offset by severe business conditions in the PI business. PI sales have suffered due to:

- the early termination of the exclusive distribution contract of Orsiro's drug-eluting coronary stent in June 2022, FY22 PI sales, whose major contributor was Orsiro, significantly declined to ¥1,765mil versus FY21 sales of ¥3,285mil.
- 2. Other PI products (guidewire, balloon catheter) downsized as JLL withdrew from the coronary intervention business.

FY23 GUIDANCE

JLL is guiding for FY23 1H OP of ¥4,488mil (-12.3% YoY) on sales of ¥23,880mil (-6.3% YoY), and FY23 OP of ¥9,763mil (-9.9% YoY) on sales of ¥48,807mil (-5.7% YoY). The company assumes that the termination of distribution of Baylis Medical's products – to now receiving just a sales support fee – will lead to a decline in sales, although that is expected to be partially offset by a recovery in the number of procedures at hospitals.

The firm is also guiding for SG&A to rise +4.6% YoY – with increases in IT-related and personnel expenses – which will squeeze FY23 OP growth. Although positive factors such as 1) an increase in the (high-margin) in-house product ratio by +5.5ppt YoY to 60.4%, 2) the change to a sales support service for RF Needle, and 3) declines in inventory disposal and revaluation losses by -¥295mil will not offset the increase in SG&A, hence FY23 OPM is expected to worsen by 0.9ppt to 20.0%.

Cardiac Rhythm Management (CRM)

JLL guides for FY23 CRM product sales of ¥12,431mil (+0.2% YoY). Sales of pacemaker products are expected to be flat at ¥5,011mil (+0.6% YoY) as competitors' new products come to market. ICD-related products sales are also estimated to be flat at ¥7,057mil (+0.1% YoY) as T-ICD sales will likely peak out due as the demand for battery replacement will likely have run its course.

Electrophysiology [EP] / Ablation

FY23 EP / Ablation products sales are guided to decline -10.9% YoY to ¥23,414mil. On the positive side, the company expects EP catheter sales of ¥20,493mil (+4.3% YoY), with the assumption that the number of AF procedures will rise +6% YoY and greater sales of its one-off product, BeeAT. On the other hand, the ABL catheter product, HeartLight X3, will likely be hit by continued supply issues, leading to a -3.4% YoY to FY23 sales of ¥976mil.

Furthermore, EP / Ablation sales will be hit by the change in contract with Baylis Medical, which was acquired by Boston Scientific [BSC US]. As a result, the exclusive distribution contract with JLL changed to a sales support contract from FY23 will see sales decline by approx. ¥3.3bln / -85%. Also, sales support contract is almost 100% GPM business, which will likely improve the segment profitability.

Cardiovascular

JLL guides for steady expansion in FY23 Cardiovascular products sales, rising +6.5% YoY to ¥11,724mil, thanks to continued growth in vascular grafts (+3.2% YoY to ¥10,681mil). In-house products such as artificial blood vessels and open stent grafts are also expected to contribute to the sales growth as the product line-up expands to meet unmet needs by doctors. The firm expects solid sales of (1) abdominal stent grafts and (2) the embolic coil, Avenir, with demand for the latter rising on the back of an increase in the number of facilities that use the product. New products, such as aspiration catheter for treating acute ischemic stroke, will also be launched in Q1.

Gastrointestinal

FY23 Gastrointestinal sales are forecast to decline -39.6% YoY to ¥1,236mil, due to the termination of distribution contract of Orsiro in FY22.

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ímil)	FY22 (in old segment name)			FY22 (in new segment name)	FY23 CE	
,	FY	YoY (%)		FY	FY CE	YoY (%)
Old Sub Segment name			New Sub Segment name			
Pacemaker	4,938	-15.8	Pacemaker	4,979	5,011	0.6
ICD	7,090	4.5	ICD	7,049	7,057	0.1
Others	374	13.5	Others	374	361	-3.2
ardiac Rhythm Management	12,403	-4.4	Cardiac Rhythm Management	12,403	12,430	0.2
EP Catheter	19,654	6.8	EP Catheter	19,654	20,493	4.3
ABL Catheter	1,011	-17.9	ABL Catheter	1,011	976	-3.4
Others	5,626	3.1	Others	5,626	1,944	-65.4
P / Ablation	26,292	4.8	EP / Ablation	26,292	23,414	-10.9
Vascular Graft	10,353	10.5	Vascular Graft	10,353	10,681	3.2
Neurovascular	-	n/a	Neurovascular	230	622	170.6
Others	289	1.0	Others	423	421	-0.4
ardiovascular Surgery	10,643	10.2	Cardiovascular	11,006	11,724	6.5
Gastrointestinal	645	44.2	Gastrointestinal	654	1,125	72.1
PI	1,765	-46.3	Others	1,394	111	-92.0
astrointestinal/PI	2,411	-35.4	Gastrointestinal	2,048	1,236	-39.6
onsolidated Net Sales	51,750	0.5	Consolidated Net Sales	51,750	48,807	-5.7

MEDIUM-TERM MANAGEMENT PLAN (FY23~FY27)

JLL announced its revised medium-term plan that covers the next five years (FY23~27). The plan will be reviewed annually to reflect upside and downside risks, with KPIs focusing on 1) the sales performance, 2) earnings from new business fields, 3) OPM, 4) EPS, and 5) ROIC as below:

- FY27 sales of ¥63,000mil (CAGR of 4.0%)
- Sales from new business areas such as cerebrovascular and gastrointestinal products of ¥8,000mil
- OPM 20% every year throughout the five years
- EPS ¥120/share (CAGR +6.3%)
- ROIC 12% as of FY27 from current 11.9%

The firm aims to achieve the aforementioned KPIs by

- **Expanding new business / products:** focus will be given to cerebrovascular and gastrointestinal products.
- Continuous launch of competitive products: JLL plans to focus on (a) boosting sales of one-and-only products, (b) launching new products to maintain competitiveness and high GPM (approx. 55~58%), and (c) enhancing its R&D capabilities.
- Capital efficiency: Management will endeavour to (a) promote efficient capital management, (b) reinforce ICT investment, (c) improve operational efficiency such as efficient marketing and inventory management, and (d) reinforcing shareholder return.

Sales Growth by Product Group

During the new medium-term plan, the largest contributor to sales growth will likely be seen in EP/Ablation products. JLL expects sales CAGR of +5% over the four years (FY24~FY27, a period after the termination of RF needle in FY23) vs. +4~5% growth in the EP/Ablation market. In particular, the firm assumes that number of AF treatments will expand at a CAGR of +6% over the 5 years, therefore, aims to launch more in-house products to meet the demand.

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CAGR of Cardiac Rhythm Management sales, which earns approx. 25% of JLL's consolidated sales, will be flat over the five years. However, while the number of implants for both Brady (pacemakers) and Tachy (ICDs) markets are expected to grow, sales value will likely be flattish due greater competition.

Cardiovascular products can be largely divided in two: 1) Aorta and 2) Neurovascular:

- In the Aorta market, JLL has the top market share of 75%. The firm aims to outperform the market growth of +0~1%/annum and achieve CAGR of +3~4% by introducing more new and one-and-only products.
- In the neurovascular products market, JLL is a late comer. The firm assumes market CAGR of +8% in acute ischemic stroke, and +6% in Brain Aneurysm. The company has made an exclusive distribution contract with Wallaby Medical over 11 products, which will help improve its presence in the market. JLL aims to achieve FY27 sales of ¥4,500mil by increasing number of items to approx. 10 compared to FY22 sales of ¥230mil earned from only one item, embolic coil, the neurovascular products.

For gastrointestinal products, JLL plans to launch a series of differentiated in-house products in biliary-pancreatic area. FY27 sales target is ¥3,500mil vs. ¥650mil in FY22, CAGR of approx. 40.0% over five years vs. the market CAGR of 3~4%. Over the next two to three years, JLL plans to launch 3~4 products such as guide wire and dilator. JLL also made a model change of the existing gastrointestinal stent to meet the demand from the market.

Risks	Explanation	Assumptions factored in the plan	
Unexpected loss of market share for one-of-a-kind products	 Sales of BeeAT and Frozenix (one-of-a-kind products) accounted for more than 30% of total sales in FYE Mar. 2023 and contribution to profits is extremely high Assume competition from these products to emerge from FYE Mar. 2024 onwards. 	Expect certain market share loss, but maintain dominant market share after 5 years	
Slower-than-expected growth in both case numbers and market size	 Incorporate market growth data by product category into sales plans, using reports from research firms and other sources. Specifically, sales of the company's core product, EP catheters, are highly dependent on the growth rate of atrial fibrillation (AF) cases. 	Growth rate of AF case numbers: CAGR 6% (FYE Mar 2024-2028)	
Greater-than-expected decline n insurance reimbursement prices	 Reimbursement prices for specific insured medical materials are determined based on their functional category and are revised once every two years, which may result in a decline in prices. The year of revision can have a significant impact on net sales and gross profit. 	Assume reasonable decline in FYE Mar. 2025 and 2027 based on past declines and the current competitive status	
Launch delays or cancellations due to failure to meet product introduction milestones	 There are various milestones before the product is launched, including development, clinical trials, and obtaining regulatory approval. Failure to meet milestones or delays in schedule can cause actual results to deviate from plans. 	Product milestones for each product including a new product of open stent graft	
Soaring costs/expenses due to high inflation and weak yen	 Increasing costs of raw materials procurement, product purchases, and SG&A expenses due to inflation and yen depreciation => putting pressure on gross and operating profits. 	Expect an annual inflation rate of 2-3% and an FX rate of 1USE to 130JPY	

Source: JLL FY23~Fy27 Mid-Term Plan presentation material

CAPITAL ALLOCATION POLICY

During the 5-year medium-term plan, JLL aims to generate stable operating cash flow. Excess cash will be allocated to:

- 1. Acquiring business assets
- 2. Growth investment: plans to spend ¥4,000mil~¥5,000mil p.a.
- 3. CAPEX
- 4. Base dividend: 40% of net income or DOE 5%
- 5. M&A

- 6. Extra dividend / share buyback: additional return to shareholders will be considered by referring to earnings results, stock price, and EPS but also referring to ROIC compared to that of other investment. Treasury shares over 1% of shares outstanding will be cancelled.
- 7. Cash and deposit.

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