Fuji Pharma Co., Ltd.

Q2 Financial Results Briefing for the Fiscal Year Ending September 2019

May 17, 2019

Event Summary

[Company Name]	Fuji Pharma Co., Ltd.
[Event Type]	Earnings Announcement
[Event Name]	Q2 Financial Results Briefing for the Fiscal Year Ending September 2019
[Fiscal Period]	FY2019 Q2
[Date]	May 17, 2019
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[Time]	09:00 – 09:55 (Total: 55 minutes, Presentation: 27 minutes, Q&A: 28 minutes)
[Venue]	Nikkei Kayabacho Bekkan, B1 2-6-1 Kayabacho Nihonbashi, Chuo-ku, Tokyo, 103-0025 (Hosted by The Securities Analysts Association of Japan)
[Venue Size]	
[Participants]	
[Number of Speakers]	4

Eiji Takemasa	President and CEO
Toyoyuki Kamide	Director /Executive Corporate Officer / General Manager / Corporate Planning Department
Hiroshi Uji	Manager / Corporate Planning Office / Corporate Planning Department
Mamiko Tanji	Corporate Planning Office / Corporate Planning Department

[Analyst Names]*	Masao Yoshida	Ichiyoshi Research Institute
	Takashi Akahane	Tokai Tokyo Research Center

*Analysts that SCRIPTS Asia was able to identify from the audio who spoke during Q&A.

Presentation

Moderator: We will now start the financial results briefing for Fuji Pharma Co., Ltd. for the first half of the fiscal year ending September 30, 2019. First of all, I would like to introduce the four speakers.

Mr. Eiji Takemasa, President and CEO.

Toyoyuki Kamide, Director /Executive Corporate Officer / General Manager / Corporate Planning Department.

Hiroshi Uji, Manager / Corporate Planning Office / Corporate Planning Department.

Ms. Mamiko Tanji, Corporate Planning Office / Corporate Planning Department.

Today, Mr. Takemasa, President and CEO, will give a presentation. After the presentation, we will take time for the Q&A session. I would like to ask for your cooperation.

Takemasa: Good morning. Thank you very much for gathering today, so early in the morning. I am Takemasa of Fuji Pharma.

I would like to walk you through the financial results for the first half, based on the handouts, and then talk about the current status of new products and new drug development pipelines that have been announced, as well as our alliance with the Alvogen Group and the overseas sales business.

2019年9月期第2四半期連結決算概要

- 売上高：ジェネリック造影剤・新製品寄与により+521百万円（前年同期比+2.9%）
- 営業利益：研究開発費の効率的使用により+192百万円（前年同期比+8.4%）
- 経常利益：子会社との取引等での為替差損により+141百万円（前年同期比+6.0%）

（単位：百万円）	18/9月期 上半期	**19/9月期 上半期**	前年同期比 増減額	前年同期比 増減率	19/9月期上半期 予想	19/9月期上半期 予想比
売上高	17,961	**18,483**	521	2.9%	18,751	98.6%
売上総利益	7,919	**7,921**	2	0.0%		
粗利益率	44.1%	**42.9%**				
販売費及び一般管理費	5,644	**5,454**	△ 190	-3.4%		
販売管理費率	31.4%	**29.5%**				
営業利益	2,275	**2,467**	192	8.4%	2,574	95.8%
営業利益率	12.7%	**13.3%**				
経常利益	2,360	**2,501**	141	6.0%	2,611	95.8%
経常利益率	13.1%	**13.5%**				
親会社株主に帰属する四半期純利益	1,743	**1,695**	△ 48	-2.8%	1,886	89.9%
当期純利益率	9.7%	**9.2%**				
設備投資額	557	**326**	△ 231	-41.5%		
減価償却費（設備リース費含む）	1,003	**972**	△ 31	-3.1%		
研究開発費	913	**699**	△ 214	-23.4%		
研究開発費率	5.1%	**3.8%**				

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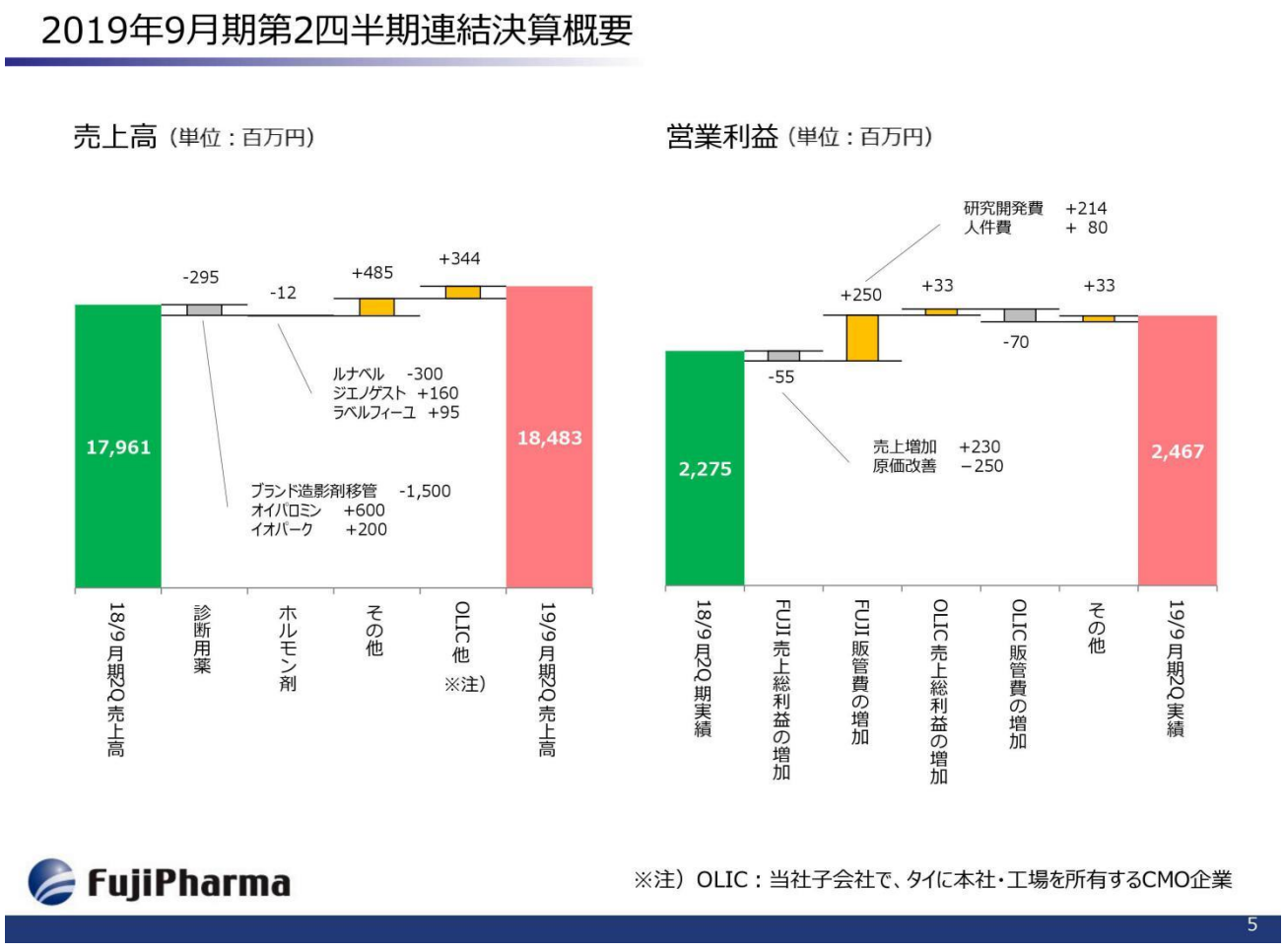
Please see page four. I will walk you through the overview of the consolidated financial results for the first half of the fiscal year ending September 30, 2019.

Net sales increased 2.9% year-on-year to 18.483 billion yen. The increase was mainly attributable to contributions from mainstay X-ray generic contrast media, the new product GABAPEN®(antiepileptic drug), and endometriosis DIENOGEST tablets, which contributed to a 521-million-yen increase in sales compared with the same period of the previous fiscal year.

Consolidated gross margin was 42.9%. It decreased by 1.2 percentage points from the same period of the previous fiscal year, due in part to the collection of products from the market.

Selling, general and administrative (SG&A) expenses were 5.454 billion yen, mainly due to the efficient use of R&D expenses and a decrease due to the delay in the accounting period for some projects. Operating profits increased 192 million yen to 2.467 billion yen. The operating margin increased by 0.6 percentage points to 13.3%.

Ordinary profit increased 6.0% to 2.501 billion yen. Net income declined 2.8% to 1.695 billion yen, due to the impact of foreign exchange fluctuations on loans to Thai subsidiary OLIC and imported contrast media.



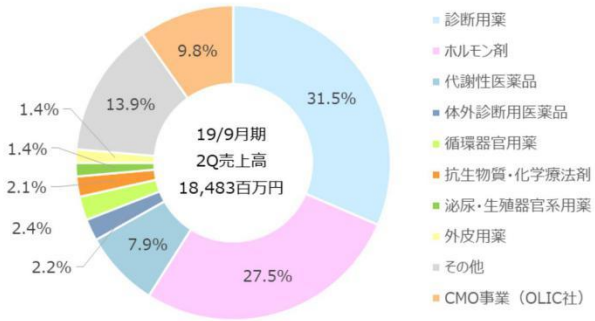
Please see page five, which shows a year-on-year comparison of consolidated net sales on the left and a comparison of consolidated operating profit on the right.

薬効別売上高

(単位：百万円)	18/9月期 上半期	**19/9月期 上半期**	前年同期比 増減額	増減率
診断用薬	6,323	**6,028**	△ 295	-4.7%
ホルモン剤	5,290	**5,278**	△ 12	-0.2%
代謝性医薬品	1,442	**1,505**	63	4.4%
体外診断用医薬品	581	**431**	△ 150	-25.8%
循環器官用薬	460	**466**	6	1.3%
抗生物質・化学療法剤	409	**397**	△ 12	-2.9%
泌尿・生殖器官系用薬	246	**266**	20	8.1%
外皮用薬	198	**265**	67	33.8%
その他	1,716	**2,656**	940	54.8%
CMO事業（OLIC社）	1,529	**1,873**	344	22.5%
合計	17,961	**18,483**	521	2.9%

※合計額は連結調整後の金額

薬効別売上高構成



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主要製品売上高

製品名（単位：百万円）	薬効分類	18/9月期 上半期	19/9月期 上半期	前年同期比 増減額	前年同期比 増減率	19/9月期 期初通期予想	19/9月期 進捗率
オイパロミン注	診断用薬	2,947	**3,580**	633	21.5%	7,763	46.1%
イオパーク注	診断用薬	910	**1,115**	205	22.5%	2,476	45.0%
ルナベル配合錠(LD/ULD)	ホルモン剤	1,289	**978**	△ 311	-24.1%	1,975	49.5%
フィルグラスチムBS注	代謝性医薬品	847	**945**	98	11.6%	1,752	53.9%
オプチレイ注	診断用薬	1,054	**731**	△ 323	-30.6%	629	116.2%
ジエノゲスト錠	ホルモン剤	373	**532**	159	42.6%	941	56.5%
デキサート注射液	ホルモン剤	431	**435**	4	0.9%	891	48.8%
HMG筋注用	ホルモン剤	447	**400**	△ 47	-10.5%	916	43.7%
ウトロゲスタン膣用カプセル	ホルモン剤	298	**332**	34	11.4%	869	38.2%
ファボワール錠	ホルモン剤	335	**328**	△ 7	-2.1%	600	54.7%
ラベルフィーユ錠	ホルモン剤	223	**316**	93	41.7%	649	48.7%
フォリルモンP注	ホルモン剤	304	**316**	12	3.9%	751	42.1%
リマプロストアルファデクス錠	代謝性医薬品	316	**300**	△ 16	-5.1%	650	46.2%
アルプロスタジル注	循環器官用薬	256	**276**	20	7.8%	526	52.5%
上位14品目合計		10,028	**10,585**	557	5.6%	21,395	49.5%
売上高に占める構成比		55.8%	57.3%				
新製品		2,477	**1,358**	△ 1,119	-45.2%		
その他の製品		4,162	**5,352**	1,190	28.6%		
OLIC社CMO事業（グループ間取引除く）		1,362	**1,358**	△ 4	-0.3%		
合計		17,961	**18,483**	521	2.9%	36,815	50.2%

急性期医療　女性医療

＊新製品：14/9月期以降発売品（上位15品目を除く）
＊下線の製品は、当社でのブランド薬（ブランド薬・ブランドジェネリック（承継品）・バイオシミラー）
＊合計額は連結調整後の金額

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See pages six and seven for a breakdown of net sales. Page six shows sales by medicinal effect.

First, diagnostic drugs. As shown in the table of main product sales on page seven, OYPALOMIN® injection, a contrast media, generated 3.58 billion yen, an increase of 633 million yen, or 21.5%, from the same period of the previous fiscal year. IOPAQUE® injection generated 1.115 billion yen, an increase of 205 million yen, or 22.5%, compared to the same period of the previous fiscal year.

Last year, we integrated sales of the products of Konica Minolta Japan. Since then, the customer succession has gone well and we have maintained sales. Total sales of diagnostic drugs decreased by 295 million yen, or 4.7%, from the same period of the previous fiscal year, to 6.028 billion yen, due in part to the impact of the transfer of brand contrast media in the previous fiscal year.

Regarding hormone drugs, sales of our mainstay LUNABELL® tablets, for dysmenorrhea, decreased 24.1%, or 310 million yen, compared with the same period of the previous fiscal year, due in part to the effects of ultra-low-dose, generic ULD tablets, and competitive products.

UTROGESTAN® vaginal capsules for assisted reproduction amounted to 332 million yen, an increase of 34 million yen from the same period of the previous fiscal year. DIENOGEST tablets for endometriosis recorded an increase of 159 million yen from the same period of the previous fiscal year, to 532 million yen.

Total net sales of hormone drugs were 5.278 billion yen. This was a decrease of 12 million yen, or 0.2%, compared to the same period of the previous fiscal year.

Regarding UTROGESTAN®, the overall market grew by 3.7% to 2.8 billion yen on a 2018 basis. There are now four companies, including our competitors, but the growth rate has slowed. In order to increase the value of our products, we will continue to make efforts to steadily increase sales, including inviting doctors who are key opinion leaders from overseas to carry out online lectures to promote the unique value of the prescription.

In metabolic drugs, the mainstay biosimilar Filgrastim BS injection generated 945 million yen, an increase of 98 million yen, or 11.6%, compared to the same period of the previous fiscal year. The total net sales of metabolism agents were 1.505 billion yen, an increase of 63 million yen, or 4.4%, compared to the same period of the previous fiscal year.

The CMO (contract manufacturing organization) business of the Thai subsidiary OLIC generated 1.873 billion yen, an increase of 344 million yen, or 22.5%, compared to the same period of the previous fiscal year.

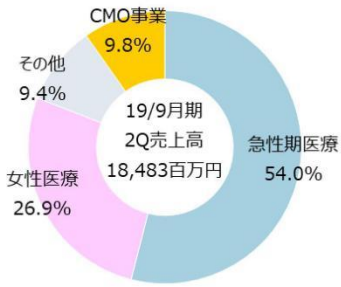
Please refer to page seven for sales of major products and full-year forecasts on the right.

医療領域・剤形別売上高

(単位：百万円)	18/9月期 上半期	**19/9月期 上半期**	前年同期比 増減額	増減率
急性期医療	9,980	**10,347**	367	3.7%
女性医療	5,222	**5,154**	△ 68	-1.3%
その他	1,464	**1,795**	331	22.6%
CMO事業（OLIC社）	1,529	**1,873**	344	22.5%
合計	17,961	**18,483**	521	2.9%

※合計額は連結調整後の金額

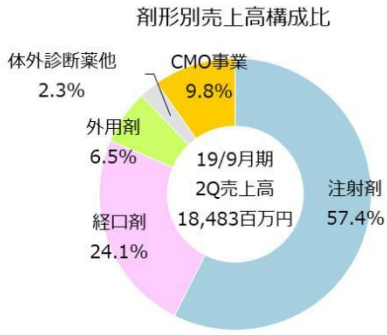
医療領域別売上高構成比



(単位：百万円)	18/9月期 上半期	**19/9月期 上半期**	前年同期比 増減額	増減率
注射剤	10,603	**10,998**	395	3.7%
経口剤	4,362	**4,614**	252	5.8%
外用剤	1,104	**1,238**	134	12.1%
体外診断薬他	583	**445**	△ 138	-23.7%
CMO事業（OLIC社）	1,529	**1,873**	344	22.5%
合計	17,961	**18,483**	521	2.9%

※合計額は連結調整後の金額

剤形別売上高構成比



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Page eight shows net sales and year-on-year changes by medical field and dosage form. Acute medical care is mainly the result of injectable products for DPC target hospitals and the biosimilar Filgrastim BS injection. As I mentioned earlier, sales of products for Konica Minolta Japan were steadily unified, and the government's policy of curbing growth in national medical expenditures led to the steady penetration of generic drugs among DPC target hospitals, and increased 3.7% year-on-year.

In the domestic X-ray contrast media market, sales of generic contrast media increased by 2.6% on a value basis and 8.0% on a volume basis. Sales of new drug contrast media were down 10% on a value basis and down 3% on a volume basis.

As the number of DPC hospitals increased by 62 in the past year and the government's measures to promote generic pharmaceuticals will continue, we believe that the growth of generic contrast media is still likely.

In the women's healthcare field, sales of UTROGESTAN® vaginal capsules and DIENOGEST tablets, a generic endometriosis drug, increased. However, due to the impact of generic competition for LUNABELL®, as I explained at the beginning, sales decreased 1.3% year-on-year.

In the CMO business, the Thai subsidiary OLIC began shipments of generic X-ray contrast media for the Japanese market in the previous fiscal year, starting to make a sales contribution. As a result, we saw a 22.5% year-on-year increase in sales.

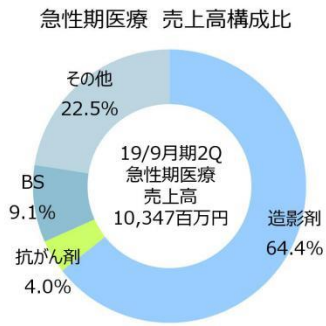
Sales of in vitro diagnostics significantly declined year-on-year due to the fact that the demand for influenza diagnostic kits was low and shipments did not occur at the expected level.

急性期医療・女性医療売上高

◆急性期医療

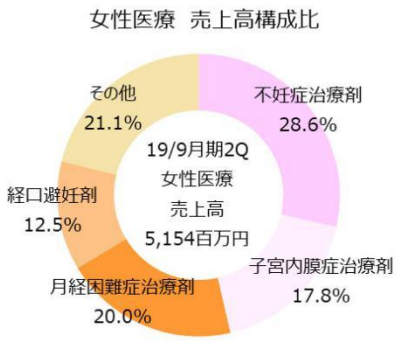
（単位：百万円）	18/9月期 上半期	**19/9月期 上半期**	前年同期比 増減額	増減率
造影剤	6,194	**6,661**	467	7.5%
抗がん剤	462	**410**	△ 52	-11.3%
BS ※注）	847	**945**	98	11.6%
その他	2,476	**2,329**	△ 147	-5.9%
合計	9,980	**10,347**	367	3.7%

※注）BS：バイオシミラー



◆女性医療

（単位：百万円）	18/9月期 上半期	**19/9月期 上半期**	前年同期比 増減額	増減率
不妊症治療剤	1,468	**1,475**	7	0.5%
子宮内膜症治療剤	741	**915**	174	23.5%
月経困難症治療剤	1,435	**1,030**	△ 405	-28.2%
経口避妊剤	557	**644**	87	15.6%
その他	1,019	**1,088**	69	6.8%
合計	5,222	**5,154**	△ 68	-1.3%



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Please refer to page nine for a breakdown of sales in the acute medical care and women's healthcare fields. The decline in sales of dysmenorrhea treatment in the women's healthcare field was due to the impact of generic competition for LUNABELL® tablets, as explained earlier.

2019年9月期第2四半期連結貸借対照表概要

(単位：百万円)	18/9月期 期末	**19/9月期 上半期**	前期末比 増減額	増減率
資産の部				
流動資産	34,927	**34,753**	△ 174	-0.5%
現金及び預金	6,251	**6,435**	184	2.9%
売上債権	16,903	**15,693**	△ 1,210	-7.2%
たな卸資産	11,285	**11,176**	△ 109	-1.0%
その他	486	**1,447**	961	197.7%
固定資産	18,189	**24,259**	6,070	33.4%
有形固定資産	11,700	**11,688**	△ 12	-0.1%
無形固定資産	2,220	**3,409**	1,189	53.6%
投資その他の資産	4,269	**9,162**	4,893	114.6%
資産合計	53,117	**59,013**	5,896	11.1%
負債の部				
流動負債	11,546	**12,383**	837	7.2%
仕入債務	6,746	**5,562**	△ 1,184	-17.6%
その他	4,800	**6,821**	2,021	42.1%
固定負債	6,220	**9,875**	3,655	58.8%
負債合計	17,767	**22,258**	4,491	25.3%
純資産の部				
株主資本	34,438	**35,747**	1,309	3.8%
資本金	3,799	**3,799**	0	0.0%
資本剰余金	5,023	**5,023**	0	0.0%
利益剰余金	27,119	**28,411**	1,292	4.8%
自己株式	△ 1,504	**△ 1,486**	18	-1.2%
その他の包括利益累計額	909	**1,004**	95	10.5%
純資産合計	35,350	**36,754**	1,404	4.0%
負債純資産合計	53,117	**59,013**	5,896	11.1%

ガバペン販売権取得

Alvotech HD株式取得

Alvotech HD出資等を目的とした銀行借入

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The consolidated balance sheet for the second quarter of the fiscal year is shown on page 10. In the Assets section, in current assets, trade receivables and inventories decreased, mainly due to the transfer of brand contrast media. In fixed assets, there was an increase in intangible assets, due to the acquisition of marketing rights for the antiepileptic drug GABAPEN® from Pfizer, and an increase in investments due to the acquisition of the Icelandic company Alvotech's shares, with the intention to enter the biosimilars business. Total assets amounted to 59.013 billion yen.

In liabilities, the Company took out a bank loan for the purpose of investing in Alvotech, resulting in an increase of the current portion of long-term debt and long-term debt as a non-current liability.

As a result, total assets at the end of the second quarter amounted to 59.013 billion yen, an increase of 5.896 billion yen from the end of the previous fiscal year. Net assets increased 1.404 billion yen to 36.754 billion yen. As a result, the equity ratio was 62.3%.

2019年9月期第2四半期連結キャッシュ・フロー計算書概要

(単位：百万円)	18/9月期 上半期	**19/9月期 上半期**	前年同期比 増減額	増減率
営業活動によるキャッシュ・フロー	1,702	**2,281**	579	34.0%
（主な内訳）				
税金等調整前四半期純利益	2,360	**2,499**	139	5.9%
減価償却費	961	**930**	△ 31	-3.2%
のれん償却額	138	**139**	1	0.7%
売上債権の増減額（△は増加）	601	**1,207**	606	100.8%
たな卸資産の増減額（△は増加）	△ 101	**105**	206	-204.0%
仕入債務の増減額（△は減少）	△ 450	△ **1,178**	△ 728	161.8%
法人税等の支払額	△ 911	△ **308**	603	-66.2%
投資活動によるキャッシュ・フロー	△ 233	△ **8,150**	△ 7,917	3397.9%
（主な内訳）				
投資有価証券の取得による支出	-	△ **5,548**	△ 5,548	-
有形固定資産の取得による支出	△ 662	△ **783**	△ 121	18.3%
有形固定資産の売却による収入	1,272	**1**	△ 1,271	-99.9%
無形固定資産の取得による支出	△ 120	△ **1,499**	△ 1,379	1149.2%
財務活動によるキャッシュ・フロー	△ 1,322	**6,068**	7,390	-559.0%
（主な内訳）				
長期借り入れによる支出	-	**7,000**	7,000	-
長期借入金の返済による支出	△ 653	△ **210**	443	-67.8%
配当金の支払額	△ 374	△ **419**	△ 45	12.0%
リース債務の返済による支出	△ 263	△ **302**	△ 39	14.8%
現金及び現金同等物の期首残高	5,503	**6,251**	748	13.6%
現金及び現金同等物の四半期末残高	5,624	**6,435**	811	14.4%
フリー・キャッシュ・フロー	1,469	△ **5,869**	△ 7,338	-499.5%

Alvotech HD株式取得

ガバペン販売権取得

Alvotech HD出資等を目的とした銀行借入

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Please see page 11. In the consolidated statement of cash flows at the end of the second quarter, free cash flows at the end of the second quarter amounted to negative 5.869 billion yen, a decrease of 7.338 billion yen from the same period of the previous fiscal year. As mentioned in the explanation on the balance sheet, this is the result of cash flows from investing in Alvotech and acquiring rights to sell GABAPEN® from Pfizer.

For these investments, 7 billion yen was borrowed from banks, and the balance of cash and cash equivalents at the end of the second quarter was 6.435 billion yen, an increase of 811 million yen from the end of the same period of the previous fiscal year.

2019年9月期連結業績予想

- 売上高：既存ホルモン剤及び新製品寄与するもブランド造影剤移管により前期比-2.9%は変わらず
- 営業利益：研究開発費は増加を見込むも原価低減及び販管費の効率的使用により増益を見込む

(百万円)	18/9月期	19/9月期 (予想)	前期比 増減額	前期比 増減率
売上高	37,909	36,815	△ 1,094	-2.9%
営業利益	4,391	4,535	144	3.3%
営業利益率	11.6%	12.3%	-	-
経常利益	4,472	4,506	34	0.8%
経常利益率	11.8%	12.2%	-	-
親会社株主に帰属する当期純利益	3,372	3,396	24	0.7%
当期純利益率	8.9%	9.2%	-	-
設備投資額	1,109	2,130	1,021	92.1%
減価償却費（設備リース費含む）	2,060	1,718	△ 342	-16.6%
研究開発費	1,760	2,439	679	38.6%
研究開発費率	4.6%	6.6%	-	-

FujiPharma

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Page 12 shows the full-year earnings forecast for the fiscal year ending September 30, 2019. We expect sales contribution of DIENOGEST tablets for the treatment of endometriosis in women's healthcare, hormone drugs including LEVONORGESTREL tablets for emergency contraceptives, which we will explain later, and generic contrast media, which are the mainstay of acute medical care. However, in view of the decrease in sales due to the transfer of brand contrast media in the previous fiscal year, the withdrawal of multiple products, and the restraint on sales of SOL-MELCORT in the acute medical care field, we are forecasting a 2.9% decrease in sales from the previous fiscal year. Increased profits are expected due to cost reductions and efficient use of selling, general and administrative expenses, including R&D.

After page 13, I will explain the current status of new products and the pipeline for new drug development that can be announced at the present time.

2019年新製品

レボノルゲストレル錠1.5㎎「F」

✓2019年3月19日発売

✓ジェネリック医薬品としては、国内初の緊急避妊薬
➢**患者様の経済的な負担を軽減**

✓避妊の失敗などによる性交後の予期せぬ妊娠を回避する方法として、緊急的に使用
➢**妊娠による女性の身体への負担を軽減**

ガバペン錠200㎎、同錠300㎎、同錠400㎎、同シロップ5%

✓2018年12月、ファイザー株式会社から日本国内の製造販売承認の承継に合意
（実際の製造販売承認の承継及び販売移管は2019年度中を予定）

✓抗てんかん剤として、日本では2006年9月に発売
2011年7月には、既存の適応に対する3歳以上の小児の用法・容量が承認、
その後、小児が服用しやすく用量調節に適した剤形として、同年10月にシロップ剤発売
➢**小児を中心とした希少疾患領域における事業展開の足掛かり**

FujiPharma

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For details, please refer to page 14. LEVONORGESTREL, an emergency contraceptive, was launched in March. This is Japan's first generic emergency contraceptive. Sales have been growing steadily since the product's launch due to the reduced financial burden on patients and other factors, and we forecast 546 million yen for the current fiscal year.

The awareness of an emergency contraceptive in Japan is approximately 45.5%, and we are committed to stimulating and expanding demand by raising awareness of the importance of improving the quality of life for women. We are confident that the usage of this product will increase further by explaining price differences to medical institutions that use original drugs, the rate of pregnancy discontinuation, adverse drug reactions, and differences in the number of doses to users of other contraceptives and drugs, and the quality difference to users of imported products.

In December 2018, Pfizer agreed to transfer manufacturing and marketing approval for GABAPEN®, an antiepileptic drug. The dosage regimen for children three years of age and older has been approved, and there are also standards for syrup preparations that are easy for children to take. Therefore, we believe that we made a step forward in expanding our business in the field of rare diseases, particularly in children.

主な新薬開発パイプライン

適応	地域	準備中	Ph Ⅰ	Ph Ⅱ	Ph Ⅲ	申請
更年期障害	日本	FSN-014 エステトロール			FSN-011-01 プロゲステロン	
	ASEAN*			FSN-014 エステトロール		
月経困難症	日本			FSN-013 エステトロール		
避妊	ASEAN*				FSN-013 エステトロール	

※2019年3月末時点の開発パイプライン

導入元 プロゲステロン Besins Healthcare社（当社は、「ウトロゲスタン®膣用カプセル200mg」を導入済み）
エステトロール Mithra Pharmaceuticals社

*ASEAN市場は、導入元による欧米での進捗状況

◆エステトロールの欧米での開発進捗状況（2019年3月末時点）
更年期障害 ： 欧州でのPh Ⅱ終了→Ph Ⅲ（国際共同治験）準備中
避妊 ： 欧州・米国ではPh Ⅲ終了→治験総括報告書作成中

FujiPharma

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Next, regarding the development of new drugs in the field of women's healthcare, the main pipelines that can be announced are summarized on page 15. The reason why we put Estetrol in the Japan and ASEAN boxes is that we have obtained exclusive development and marketing rights from Mithra Pharmaceuticals in Belgium in both areas.

The biggest benefit of Estetrol is that it has a mechanism of action that greatly reduces the risk of venous thromboembolism and breast cancer, which were issues associated with estrogen, a traditional follicular hormone. The indications are contraception, dysmenorrhea, and menopausal disorders. In your handouts, FSN-013 is for dysmenorrhea and contraception. FSN-014 is a medicine for menopausal disorders.

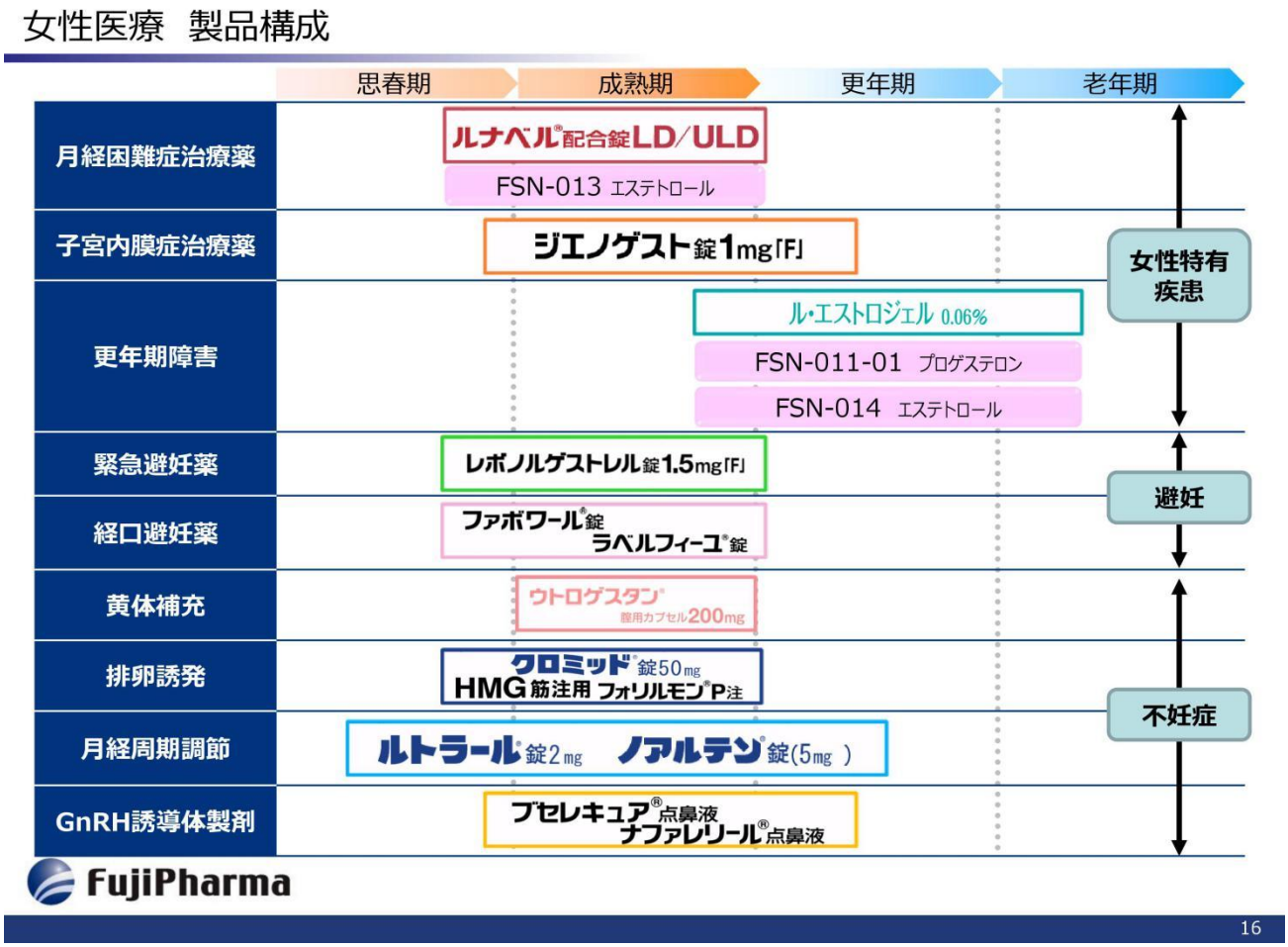
It is understood that this medicine contributes to the improvement of women's quality of life and labor productivity. In Japan, however, due to the excessive negative image of the side effects among doctors and patients, the spread of this medicine has been slower than in Europe and the U.S., and there was demand for an even safer product. In this sense, we believe that market demand for Estetrol is high.

For FSN-013, Fuji Pharma is conducting the Phase 2 trial for dysmenorrhea in Japan. The licensor Mithra announced that Phase 3 had been completed in Europe and the United States for contraceptive use and that the application will be made in Europe and the United States in the second quarter of 2019. Data for a total of 3,725 people from the U.S. and Europe have been obtained at 146 facilities. Similar to LUNABELL® tablets, this is a drug that not only sells in the existing market but also develop new markets through raising awareness among women.

For FSN-014, Mithra has completed Phase 2 for menopausal disorders in Europe and the United States and is preparing Phase 3. Fuji Pharma intends to participate in an international clinical trial including Japanese patients.

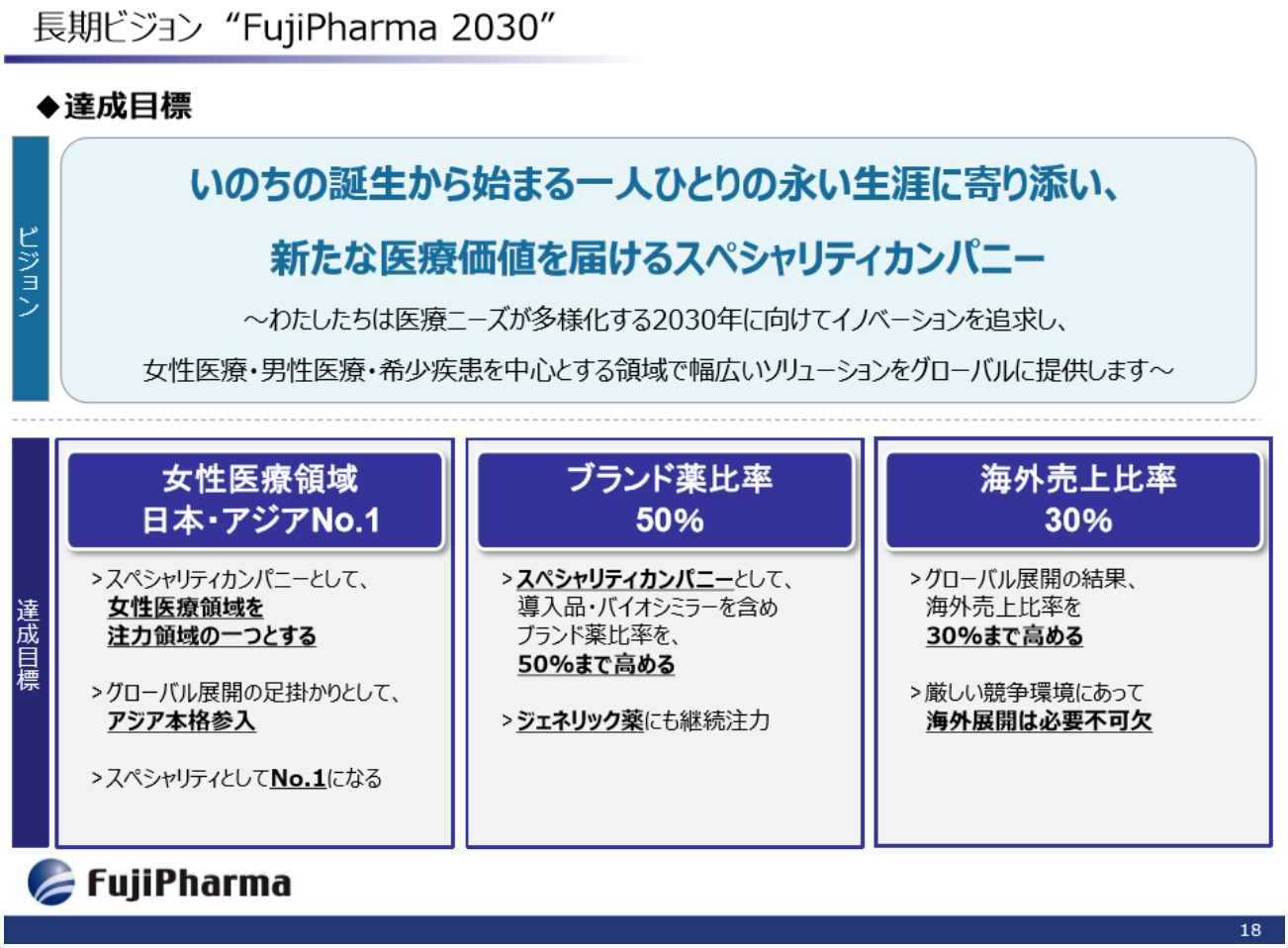
Another product is progesterone FSN-011-01. This is an unapproved drug that the Ministry of Health, Labour and Welfare has designated as a drug of high medical necessity. The product was provided in response to the request for development. It is a drug already sold overseas in more than 80 countries, as an adjunct to hormone replacement therapy in non-hysterectomized postmenopausal women. It also contributes to the elimination of drug lag.

Using the same substance, we sell UTROGESTAN® Vaginal Capsules 200mg, a natural luteinizing hormone drug that is indicated for luteinizing in assisted reproductive medicine. As the second step, we are currently conducting Phase 3 for oral UTROGESTAN® tablet 100mg for hormone replacement therapy targeting menopausal disorders.



Page 16 shows the positioning of these new drugs under development in women's healthcare.

Page 17 describes the progress of some projects related to the long-term vision "FujiPharma 2030" announced last year.



The vision is summarized in page 18. We focus on women's medicine, attaining top positions in Japan and Asia, as well as achieving a 50% ratio of branded drugs and 30% ratio of overseas sales.

Page 19 and beyond explain some of the current initiatives related to this vision.

（1）タイ国内での富士製薬ブランド医薬品販売開始　～①海外拠点OLIC社

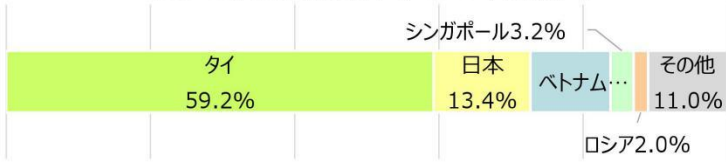
【海外拠点】 OLIC（Thailand）Limited

設　　立	1984年（1997年に現工場へ移転）
従業員数	771名（2018年9月30日時点）
所 在 地	タイ王国アユタヤ県
主要株主	富士製薬工業株式会社：99.93%

- ➢タイ最大の製造受託企業
- ➢錠剤、注射剤に加え、液剤、スプレー製剤など幅広い剤形の製造が可能
- ➢大手多国籍企業を中心に35社以上に供給（主に東南アジア向け）
- ➢タイ規制当局、PMDA、米国FDAなどからの厳格な製造管理・品質管理の要求や査察に対応できる生産能力を所有

『OLICを通じて、日本品質の医薬品を新興国へ』

［OLIC国別出荷割合（2017年実績）］



FujiPharma

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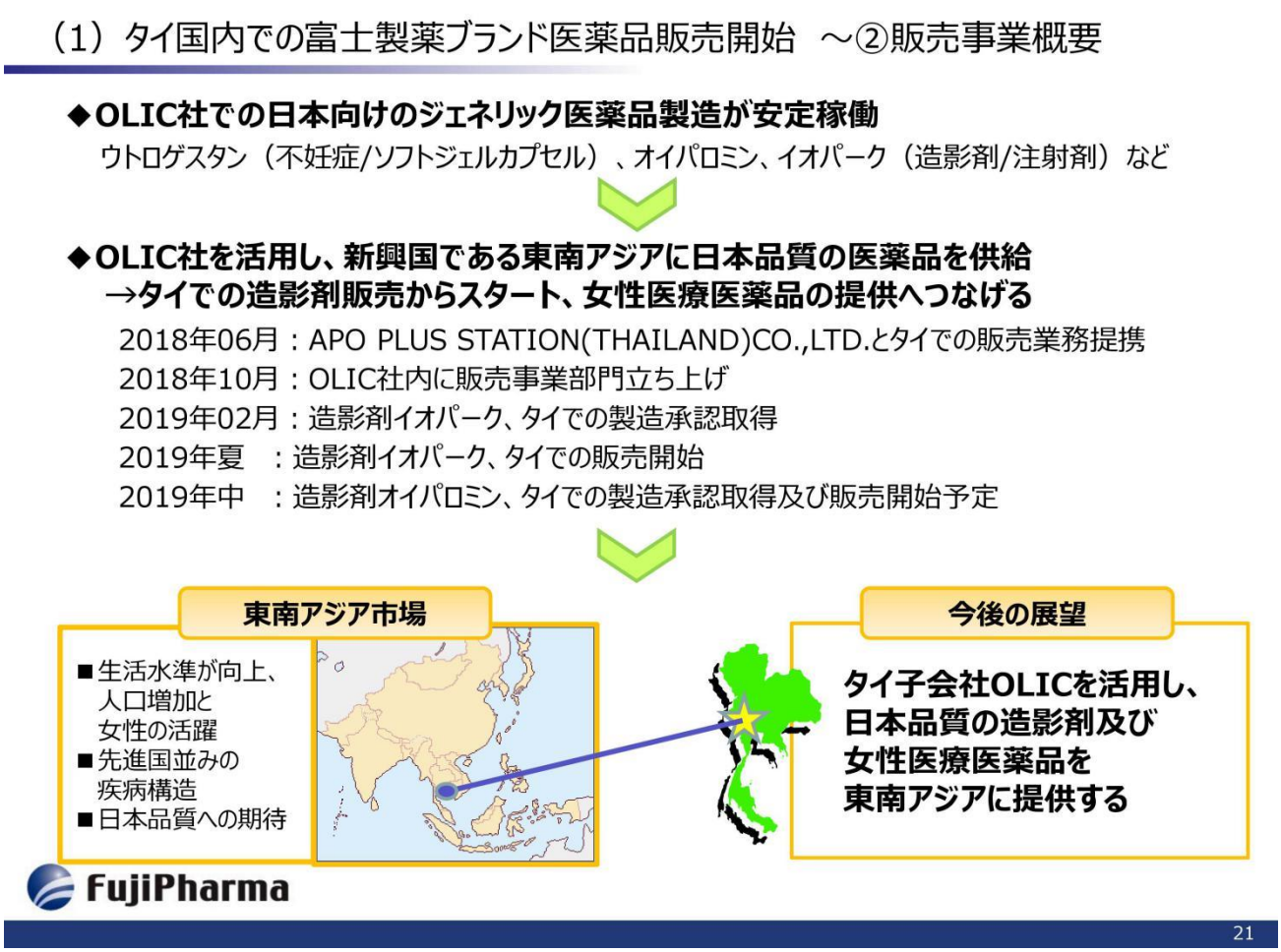
Page 20 describes the launch of branded drugs in Thailand. Our Thai subsidiary OLIC is the largest contract manufacturer and CMO company in Thailand, with more than 35 customers, mainly large multinational corporations.



As described on page 21, we are already exporting prescription pharmaceuticals manufactured by OLIC to Japan. As the first step in our overseas sales business, we will begin sales of generic contrast media, our mainstay products in Japan, in the Thai market. In addition, we have obtained exclusive development and marketing rights from Mithra, and we have begun discussions with potential marketing partners in ASEAN for Estetrol, a drug in the field of women's healthcare. I would like to explain to you in more detail once we become able to disclose the content.

（2）Alvogenグループとの提携

＜Alvogenグループとの取り組み＞

①Alvotech hf社との資本業務提携

②Lotus Pharmaceutical社（Lotus社）との資本業務提携

Alvogenグループ概要

➢2009年設立
➢グローバルにジェネリック、ブランド薬、バイオシミラーの開発、製造、販売に注力している製薬グループ
➢35カ国で事業を展開、従業員は約2,800名
➢米国、ルーマニア、韓国、台湾に製造及び開発拠点を所有

FujiPharma

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Please see page 23. As announced at the end of last year and in March of this year, we entered into capital and business alliances with the Icelandic company Alvotech and Taiwanese company Lotus.

The details of the Alvotech alliance is described on page 24. We have formed an alliance to obtain approval and sell several biosimilars(antibody drugs), developed and manufactured by Alvotech, in Japan.

Alvotech's strength lies in its integrated system that covers the entire process from API to final production. We have appointed a director to ensure our commitment to this business and the direction of the biosimilar(antibody drugs) businesses from a global perspective.

（2）Alvogenグループとの提携　～①Alvotech hf社との資本業務提携

バイオシミラーの開発と製造に特化した海外メーカーと業務提携

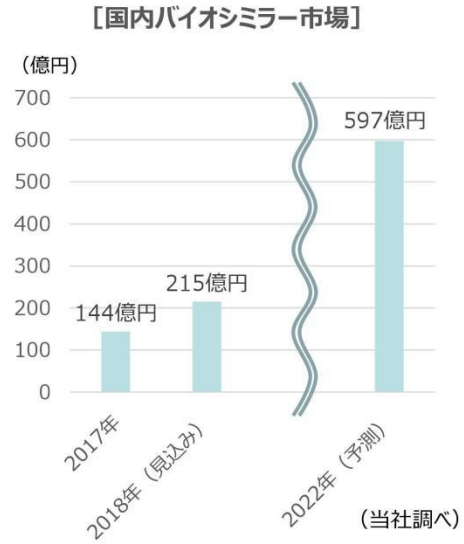
バイオシミラー事業を、女性医療・急性期医療に続く、**新たなコア事業へ**

欧州ではバイオシミラーの普及が進行。

日本国内バイオシミラー市場も成長を続けており、
2017年には144億円まで拡大。
2018年は215億円に到達する見込み。

バイオ医薬品の医薬品市場に占める割合は年々増加。薬価が高く、国民医療費における重荷に。

今後、国内医療費の増加を抑制するため、
バイオシミラーは日本でも急速に普及すると想定。



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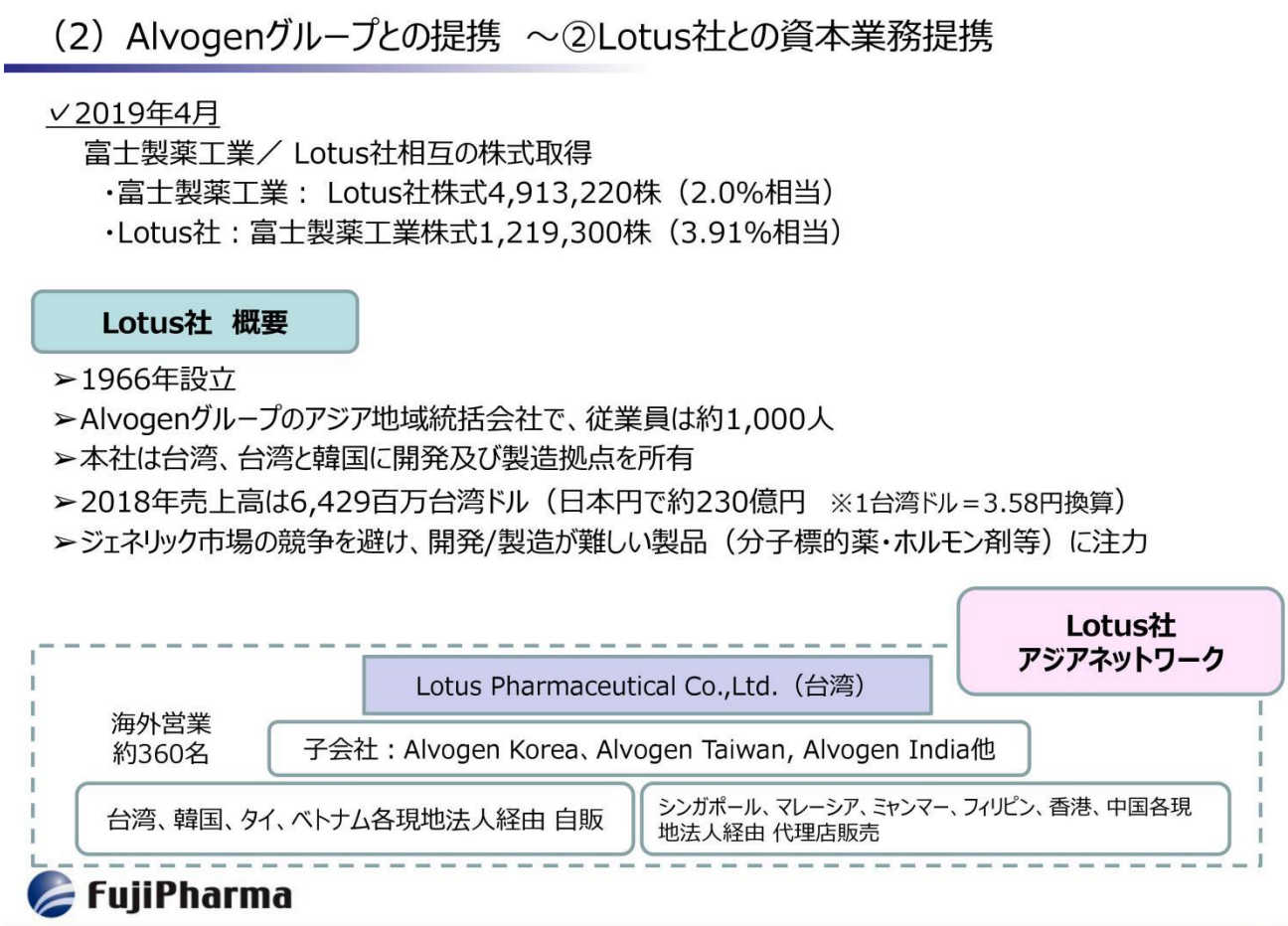
As described on page 25, in addition to providing high-quality healthcare for patients, as expensive biopharmaceuticals and healthcare expenses continue to increase, we aim to curb growth in healthcare expenses by cultivating our biosimilars business into a new core business after women's healthcare and acute medical care, centered on our alliance with Alvotech.



Please see page 26, which describes the business of Lotus. It has manufacturing bases in Taiwan and South Korea, and has been avoiding competition in the generics market by developing unique generics that are difficult to develop and manufacture, and have recently taken over branded drugs from major global pharmaceutical companies. In addition to Taiwan and South Korea, it also has local subsidiaries in Thailand and Vietnam that conduct independent sales activities.

（2）Alvogenグループとの提携　～②Lotus社との資本業務提携

アジアに販路を持つ抗がん剤等のジェネリック開発に特化した海外メーカーと業務提携

◆4つの業務提携

1. 抗がん剤ジェネリックなどのLotus社パイプラインを日本に導入
2. Lotus社のASEAN市場販路を通じ、当社の女性医療医薬品などを販売
3. 当社とLotus社間における、製造機能相互活用による生産性の向上
4. 日本及びASEANの各市場にあった付加価値製品の共同開発

グローバル展開の追い風とする

FujiPharma

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Page 27 describes our alliance with Lotus. Specifically, we will introduce the generic anti-cancer drugs and molecular targeted drugs that Lotus is developing into Japan. We also plan to sell our women's healthcare medicines through Asian sales channels of Lotus. In addition, we will utilize each other's factories to improve overall productivity. We have plants in Toyama and Ayutthaya in Thailand, while Lotus has plants in Taiwan and South Korea. Finally, we will engage in joint development and introduction of value-added products suited to the Japanese and Asian markets. Those are the four points regarding business alliance. We are communicating with each other on a daily basis in order to deliver on these four objectives.

On page 28, please refer to the conceptual diagram that briefly summarizes our tie-up with the Alvogen Group.

Now I'll finish my explanation. Thank you very much for your attention.

Question & Answer

Moderator: Thank you very much. We will now start the question and answer session. This IR meeting, including the question-and-answer section, will be transcribed in full. When asking questions, your name and company will be disclosed as you mention them. If you wish to be anonymous, please omit your name.

Yoshida: I'm Yoshida from Ichiyoshi Research Institute. Thank you for your explanation. I have several questions. First, I would like to ask you to summarize the positive and negative aspects when looking at the forecast for the current fiscal year. Products like LUNABELL® seem to be a bit weak against the plan, but there might be some upside that was not included in the plan. It might overlap with your explanation, but this is the first point.

Takemasa: Thank you for your question. I understood that your question is about positive and negative factors in this fiscal year's outlook.

With regard to the positive factors, the emergency contraceptive LEVONORGESTREL tablets is due to contribute to sales. I explained about it as a new product, and it is having a greater impact on the market than initially expected. Another upside is the antiepileptic drug GABAPEN®, which we succeeded with at the end of last year, and which will generate larger sales than originally anticipated.

There is also contrast media and generic contrast media. As I repeatedly mentioned in the explanation, the succession from Konica Minolta Japan has gone well, and the government's generic incentive measures and the market for DPC hospitals have been firm. As a result, sales are expected to increase more than anticipated.

Looking at the negative factors, in addition to LUNABELL® LD tablets, the generic ULD tablets are eroding our new drug market, as its market penetration was high.

Those are the main points.

Yoshida: Understood. Do you think that the cost of recalling OPTIRAY® is not such a big one?

Takemasa: Right. It's already included.

Yoshida: I understand. If possible, can you give us your view on the sales forecast of LEVONORGESTREL? Revenue may be small just as it has just been launched, but what do you feel about this figure? I hope you will also tell us about the sales scale of GABAPEN®. I don't think this was a part of the list of sales by major product.

Takemasa: It was launched on March 19, 2019. First-half results were 47 million yen. For the full fiscal year, we expect 546 million yen.

Regarding GABAPEN®, we have promised a partner not to disclose yet, and I appreciate your understanding. For your information, the Japanese market for oral contraceptives, including emergency contraceptives, is approximately 8.6 billion yen. The pill market, which does not include this, is 6 billion yen.

Unfortunately, Japan's usage rate in this field is 3% to 4%, due to the slow adoption. In France and Spain, the percentage is more than 40%, so I've been using the term education several times in the explanation. We have been trying to promote this product, including with an app targeting women and explaining at several financial results briefings. We are using such media to expand demand by promoting awareness in this field,

including for appropriate usage and safety aspects, so this field will be an area of expectations for us in the future.

Yoshida: Thank you very much. The rest of my questions are about the contrast media in Thailand. After obtaining marketing approval, the product may be launched in the summer. Could you tell us about the size of the market, what is the current share between the original and generic brands, and what is your quantitative expectation?

Takemasa: Regarding your question concerning the contrast media sales business in Thailand, the size of the market for contrast media in Japan is now 56.4 billion yen. The Thai market is less than a 10th of that. However, our sales have not yet been disclosed, and I would like to explain more concretely, once it becomes possible.

From the perspective of original and generic, most of the current market is for original. We are attempting to capture the market with our second radiographic contrast media.

Yoshida: Understood. Lastly, with regard to the biosimilars, with the Alvotech alliance, how will we be able to see the pipelines in concrete terms? Or how should I say? Biosimilars tend not to release their pipelines, possibly because it links to their strategies, but around when should we expect the outcome shown in the materials to materialize? As we move on to next year and beyond, I hope you will tell me a little about the time horizon.

Takemasa: One thing I can surely say is that the items we work on will be announced, or clarified, around the year after next. As you mentioned, biosimilars have to consider the first patents. And there is competition with other companies, so the players, including ourselves, have thorough control of information. I hope you understand that this is inevitable if we consider the future of our business.

Yoshida: Then, if the specific products are revealed around the year after next, which stage will they be in? Are you going to announce it as soon as you have submitted an application for approval? Excuse me. I'd like to have a clearer idea.

Takemasa: Since this is development, there may be a delay, but it's right to say that information will start becoming open around the time of application for approval.

Yoshida: Thank you very much.

Moderator: Thank you very much. Next question, please.

Onishi: I'm Onishi from Toyo Keizai. I have two questions.

First, in October this year, there will be a revision related to the consumption tax hike, and in April next year there will be a revision that's done once every two years, and starting in 2021 there will be annual revisions. How do you think this will affect the Japanese generic market, which is the main market for your business?

I believe that the quantitative target will almost level off. Do you have a view within this medium-term management plan on the assumption that the Japanese market will shrink? I'd like to know about the President's view on the market environment for generic drugs in Japan.

Takemasa: Thank you for your question. From the viewpoint of national government guidance, the target of 80% is now becoming visible. However, some have said that the Ministry of Health, Labour and Welfare has presented its view that it will stabilize around there rather than going further beyond that. We share this view.

When considering the Japanese market, which is characterized by a declining birthrate and shrinking population, we do not believe that the market for pharmaceuticals and the generics market will expand further. However, since it is a very large market in terms of a single country after the United States and China, I believe that we should actively allocate management resources to the Japanese market once again.

With respect to generics, of course, we are actively introducing them or forming alliances with other companies. However, we believe that the most beneficial and profitable way is to develop formulations and manufacture them at our own factories and sell them through our own MRs. Therefore, from the perspective of our long-term vision, we explained that the ratio of branded drugs is targeted at 50%. Conversely, we have a policy of proactively allocating management resources to high-value-added generics for the remaining 50%.

Onishi: The reason I'm asking is that the President of [Nichiiko] holds the view that the generics market will still keep growing in value terms. Personally, I was a bit doubtful, and my view is that the market as a whole will either shrink or stagnate. So, I wanted to confirm whether such an opinion exists or not in the generics industry.

Takemasa: Maybe. We are not a company that necessarily pursues scale, and our strong focus is to pursue added value, so while we do not believe that the overall market will increase further, we recognize that the absolute value of the Japanese market is large. In this context, we will continue to develop high-value-added generics that generate earnings.

Onishi: My second point was about collaboration with the Alvogen Group.

I understand that you will partner with the Alvogen Group, to foster the biosimilars business, to make it the third pillar. You also mentioned the alliance with your Asian headquarters and Lotus. Is it right to understand that, apart from biosimilars, there will be other genres or generics businesses to be developed in Asia?

Takeshita: There are several objectives of the alliance. Of course, Lotus is an Asian member of the Alvogen Group, so it has a sales network in Asia. One purpose of the alliance is to leverage this strength to sell our women's healthcare products in the future.

Our greatest expectation is that the generic drugs that Lotus is developing include anticancer drugs, particularly molecular targeting drugs, for which there are also high expectations in the Japanese market. Rather than being independently developed by us, we decided that if they had already been formulated, introducing them into Japan would be better in terms of speed and efficiency.

Some of the drugs have already been cleared through audits by the PMDA or FDA, so we can import the drug product from such factories to Japan. We also think it is also possible to introduce technical information into Japan, so we are regularly discussing which developed products to introduce.

As you understood at the beginning, Alvotech focuses on biosimilars, while Lotus of the Alvogen Group has more intention to work on high-value-added generics in collaboration with Fuji Pharma, targeting both the Asian and Japanese markets.

Onishi: Combined, will your company's exposure to the group, or capital injection, amount to about 7 billion yen? Or is it more than 7 billion yen?

Takemasa: Yes, Alvotech is 50 million dollars, so it's 6 billion yen. We purchased Lotus in treasury stock, but it's equivalent, so it's 20 million dollars.

Onishi: Does that mean about 8 billion yen?

Takemasa: Yes, slightly more than 8 billion yen.

Onishi: Is this your greatest exposure to any one group, in terms of capital?

Takemasa: Yes, it's the biggest.

Moderator: Thank you very much. Next, to the attendee in the back row.

Akahane: I'm Akahane from Tokai Tokyo Research Center. First of all, let me confirm: are LEVONORGESTREL and GABAPEN® included in the new products on page seven?

Takemasa: Yes. As you mentioned, it is included in the new products.

Akahane: For LEVONORGESTREL, is 47 million yen in the first half included here?

Takemasa: Yes.

Akahane: And I'm not a professional so I don't understand well, but when I heard the discussion about LEVONORGESTREL, I thought the initial shipment might be very large, but while the recent results don't seem to be very strong, the mid-term forecast seems quite bullish. I assume this is based on very good response, but how should I think about this?

Takemasa: Since the product was launched in March, it was just before the closing of the first half of the fiscal year. Therefore, we think we can do well in the next six months, including pricing measures and market response, to grow sales strongly, or even more strongly than planned.

Akahane: I see. It was launched in March, so it hasn't made a big contribution in the last quarter. So, the initial shipment is being conducted right now, and it's going to be a lot more. This is essentially stocked at hospitals, for emergency situations, right?

Takemasa: Yes.

Akahane: Prescribed rather than used immediately.

Takemasa: Yes.

Akahane: Oh, I see. At the moment, since it's selling very well in April and May, your plan assumes sales will reach around 500 million yen.

Takemasa: Yes, that's right.

Akahane: Understood. The person before me also asked a related question, but a revision is likely to take place in October, although we don't know yet. The impact is not in September, of course, but since your fiscal year closes in September, there's likely to be a pullback in buying which hadn't happened in the past. I think it's different from other companies because you have many injection products, but do you think such a pullback will happen at the end of the fiscal year because of the NHI drug price revision following the consumption tax hike in October? Some people say the size of price reduction is not that large, so there wouldn't be a significant impact. Is this kind of impact included in your company's figures?

Takeshi: Rather than a pullback, we also assume an opposite response. Depending on the product, there may be a pullback from buying, or there might be a last-minute surge before the consumption tax hike. We assume that there will be these two aspects, and those are incorporated into our figures.

Akahane: Do you mean that the rate of the tax hike may be larger than the rate of price reduction, so there might be temporary demand?

Takemasa: Yes. In that sense, we also assume there will be a reverse effect from October.

Akahane: I understand well. And I've been hearing the financial results of many generics companies, so I'd like to ask your view on the current penetration of generics. I don't think you are the same as other companies, as you have focus on injection and gynecologic products, but what do you feel about the stance of hospitals on generics? Has it been almost the same?

Takemasa: We have many X-ray contrast media in generics. As I explained, we believe that there are increasing numbers of hospitals which are actively adopting generics from the standpoint of hospital business management.

The scale of DPC hospitals is becoming increasingly smaller in terms of the number of hospital beds. But the number of DPC hospitals increased by 60 since the last fiscal year, and centering on such hospitals, we believe that our injectable drugs that can be used in the acute phase will continue to grow steadily.

Akahane: Understood well. My last question is about biosimilars. Sorry to insist. Some people, including the company of the former chairman of the Japan Generics Association, say that this field is difficult for generics. Other people have a more optimistic approach. It seems that manufacturers of new drugs tend to be more positive about biosimilars, and there are cases in which all biosimilars are treated the same, but there are many different opinions, such as hormones are okay, but antibodies are difficult, or rheumatoid and EPO are okay but cancer is difficult.

There are actually a lot of conflicting views within the generics industry. But of course, you are saying you will do it because it has the effect of reducing medical costs. What do you think about areas like antibodies or cancer, rather than biosimilars in general?

Takemasa: As the proportion of antibody drugs in biopharmaceuticals is increasing, we have decided to work on antibody drugs with Alvotech, first from the market perspective.

We think that the penetration differs depending on the items. So, for example, the comprehensive payment in DPC is applied to Filgrastim, one of our products.

In addition, we expect that replacements will proceed in items that allow for a substantial reduction in patients' co-payments. Therefore, we will consider and decide whether to introduce which products in collaboration with Alvotech. We will make decisions based on business feasibility. From the perspective of social significance, we also believe that this is needed not only for patients, but also for the purpose of curbing the growth of national medical expenditures. So, we intend to stay actively involved in this field.

Akahane: Understood. In other words, rather than based on indications like cancer and rheumatoid arthritis, you will be focusing on areas with growth prospects in light of DPC application, such as with dialysis. Thank you very much.

Moderator: Thank you very much. We are nearing the end, but please tell us if anyone has a pressing question. I would also like to ask if the Company has any additional matters.

Takemasa: There was a question about emergency contraceptives. I think some of you are aware about topics of the possibility of online medical treatment or making it an OTC product being discussed in the media. The MHLW is leading discussions on lifting the ban on online medical treatment from the time of the first visit, as

well as improving access to emergency contraceptive methods that have not been available to date. And some individuals are privately importing goods from overseas, some without permission.

In addition, there have been cases of different methods of emergency contraception resulting in side effects. Therefore, we emphasized the good quality of our generic product and its affordability, and we believe this is why we were accepted by the market. Going forward, we will continue to actively convey this information, including how to use it, through education and awareness-raising.

Furthermore, there are opinions that it is still difficult for pharmacists to deal with the switch to OTC at pharmacies, and the discussion has been postponed a little. However, I would like to mention that the Ministry of Health, Labour and Welfare's opinion is that another discussion will not be hindered.

Moderator: Thank you very much. We would now like to close the briefing.

[END]

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2. *This document has been translated by SCRIPTS Asia.*

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