



**FujiPharma**

**Fuji Pharma Co., Ltd.**

Financial Results Briefing for the Fiscal Year Ended September 2019

November 19, 2019

## Event Summary

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<b>[Company Name]</b>	Fuji Pharma Co., Ltd.	
<b>[Event Type]</b>	Earnings Announcement	
<b>[Event Name]</b>	Financial Results Briefing for the Fiscal Year Ended September 2019	
<b>[Fiscal Period]</b>	FY2019 Annual	
<b>[Date]</b>	November 19, 2019	
<b>[Number of Pages]</b>	25	
<b>[Time]</b>	11:00 – 11:52 (Total: 52 minutes, Presentation: 26 minutes, Q&A: 26 minutes)	
<b>[Venue]</b>	Kabutocho Heiwa Building 2F, 3-3 Kabutocho Nihonbashi, Chuo-ku, Tokyo 103-0026 (Hosted by The Securities Analysts Association of Japan)	
<b>[Venue Size]</b>	145 m <sup>2</sup>	
<b>[Participants]</b>	30	
<b>[Number of Speakers]</b>	2	
	Hirofumi Imai	Chairman and Representative Director
	Takayuki Iwai	President
	Toyoyuki Kamide	Director/Executive Corporate Officer/Senior Manager/ Corporate Business Management Department
	Takeshi Sato	Corporate Officer, General Manager Corporate Planning Department
	Hiroshi Uji	Manager of Business Administration Group & Corporate Business Manager
	Mamiko Tanji	Corporate Planning Department
<b>[Analyst Names]*</b>	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.

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## Presentation

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**Moderator:** Thank you for waiting. Now that it is time, we will hold Fuji Pharma Co., Ltd.'s Financial Results Briefing for the Fiscal Year Ended September 2019.

First, I would like to introduce the six participants from the Company. Mr. Hirofumi Imai, Chairman and Representative Director.

**Imai:** Nice to meet you.

**Moderator:** Mr. Takayuki Iwai, President, General Manager of Research & Development Department.

**Iwai:** Nice to meet you.

**Moderator:** Mr. Toyoyuki Kamide, Director, Executive Corporate Officer, Senior Manager of Corporate Business Management Department.

**Kamide:** Nice to meet you.

**Moderator:** Mr. Takeshi Sato, Corporate Officer, General Manager of Corporate Planning Department.

**Sato:** Nice to meet you.

**Moderator:** Mr. Hiroshi Uji, Manager of Business Administration Group & Corporate Business Management Department.

**Uji:** Nice to meet you.

**Moderator:** Ms. Mamiko Tanji, Corporate Planning Department.

**Tanji:** Nice to meet you.

**Moderator:** Today, Mr. Sato and Mr. Iwai will give presentations and afterwards we would like to have a question-and-answer session as usual.

So, Mr. Sato, please.

**Sato:** I am Sato, General Manager of the Corporate Planning Department. Thank you for gathering today. I have been assigned to this position since October, so from this time I will walk you through the outline of the financial results and the forecast of business performance. I would like to ask for your support.

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## 2019年9月期連結決算概要

- 売上高：ブランド造影剤移管、ルナベルAG発売の影響により-1,630百万円（前期比-4.3%）
- 営業利益：販売製品構成で粗利率改善するも、研究開発費増加等により-218百万円（前期比-5.0%）
- 当期純利益：OLICへの造影剤製造移管に伴う富山工場固定資産減損等により-410百万円（前期比-12.2%）

(百万円)	18/9月期	19/9月期	前期比		19/9月期	予想比
	通期	通期	増減額	増減率	予想	増減額
売上高	37,909	<b>36,279</b>	△ 1,630	-4.3%	36,815	△ 536
売上総利益	15,950	<b>15,796</b>	△ 154	-1.0%	-	-
粗利率	42.1%	43.5%			-	-
販売管理費	11,559	<b>11,622</b>	63	0.5%	-	-
販売管理費率	30.5%	32.0%			-	-
営業利益	4,391	<b>4,173</b>	△ 218	-5.0%	4,535	△ 362
営業利益率	11.6%	11.5%			12.3%	
経常利益	4,472	<b>4,169</b>	△ 303	-6.8%	4,506	△ 337
経常利益率	11.8%	11.5%			12.2%	
親会社株主に帰属する当期純利益	3,372	<b>2,962</b>	△ 410	-12.2%	3,396	△ 434
当期純利益率	8.9%	8.2%			9.2%	
ROE	9.9%	<b>7.9%</b>				
1株当たり当期純利益	112.68	<b>97.04</b>	△ 15.64	-13.9%		
設備投資額	1,109	<b>1,965</b>	856	77.2%		
減価償却費（設備リース費含む）	2,060	<b>1,934</b>	△ 126	-6.1%		
研究開発費	1,760	<b>2,052</b>	292	16.6%		
研究開発費率	4.6%	5.7%				



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Now, I will explain the consolidated financial results for the fiscal year ended September 30, 2019. Please refer to the information on hand, starting at page four on the bottom right.

As disclosed on November 8, the Company initially forecast lower sales but higher profits, but both sales and profits declined. Net sales decreased by 1.630 billion yen or 4.3% year-on-year, mainly due to the transfer of brand contrast media and the launch of LUNABELL®'s authorized generic product.

In terms of operating profit, while the gross margin improved due to factors such as a decrease in the ratio of contrast media from 38% in the previous fiscal year to 29%, operating profit decreased by 218 million yen or 5.0% from the previous fiscal year due to factors such as an increase in R&D expenses of 300 million yen.

Net income declined 410 million yen or 12.2% from the previous fiscal year, due to an impairment loss recorded at the Toyama Plant following the transfer of the manufacturing of contrast media to OLIC.

As a result, ROE declined 2 percentage points year-on-year to 7.9%, well below the medium-term target of 11%.

The increase in capital expenditures was due to the reinforcement of the Toyama Plant's facilities.

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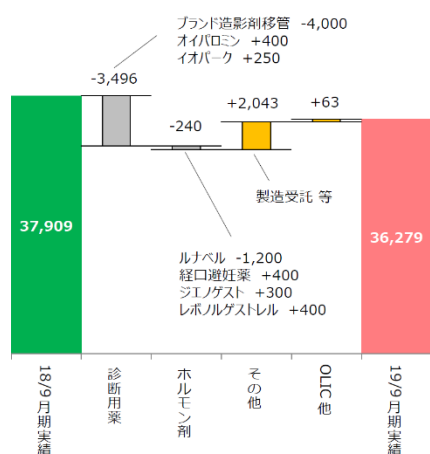
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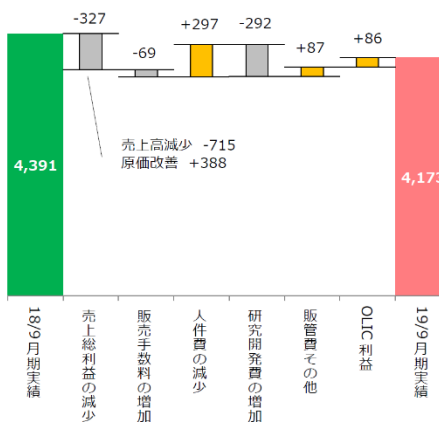


## 2019年9月期連結決算概要

売上高 (単位: 百万円)



営業利益 (単位: 百万円)



※OLIC: 当社子会社で、タイに本社・工場を所有するCMO企業

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I will move on to the next page to explain the major factors behind changes in net sales and operating profit. For sales, please see the chart on the left. As I mentioned, the impact of contrast media was approximately 4 billion yen and even though some of it was offset by our generics, the overall negative impact was 3.5 billion yen. Regarding hormone drugs, although LUNABELL® and authorized generics were supplemented with other drugs such as LEVONORGESTREL, they were not able to fully compensate for the impact and sales decreased slightly. These declines were not fully offset by increases in contract manufacturing and OLIC sales, resulting in a decline in overall sales.

The chart on the right shows operating profit. The decrease in sales and the increase in R&D expenses were not offset by the decrease in personnel expenses and SG&A expenses, as well as OLIC. As a result, operating profit declined.

The increase in R&D expenses was mainly due to the development of new drugs. Sales commissions increased slightly, but this was due to a combination of the partial termination of contrast media in December 2018 and the launch of LUNABELL®'s authorized generics.

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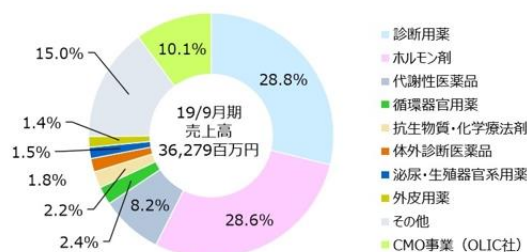


## 薬効別売上高

(百万円)	15/9月期	16/9月期	17/9月期	18/9月期	19/9月期	前期比	
						増減額	増減率
診断用薬	11,123	13,808	13,473	14,323	10,827	△ 3,496	-24.4%
ホルモン剤	10,071	9,709	10,275	10,981	10,741	△ 240	-2.2%
代謝性医薬品	2,893	2,706	2,828	2,882	3,074	192	6.7%
循環器官用薬	937	1,008	945	925	891	△ 34	-3.7%
抗生物質・化学療法剤	874	812	874	801	820	19	2.4%
体外診断用医薬品	742	695	805	784	667	△ 117	-14.9%
泌尿・生殖器官系用薬	464	486	492	533	556	23	4.3%
外皮用薬	327	352	384	505	537	32	6.3%
その他	2,055	2,414	2,907	3,695	5,623	1,928	52.2%
CMO事業 (OLIC社)	2,255	2,309	2,576	3,452	3,809	357	10.3%
合計	31,680	34,229	35,387	37,909	36,279	△ 1,630	-4.3%

※合計額は連結調整後の金額

薬効別売上構成比



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Please go to page six. Looking at net sales by efficacy, I have already explained the factors behind the decline in the first row, the diagnostic drugs and the second row, hormone drugs.

The others in the second row from the bottom line have grown greatly, but this is mainly due to inherited products or consigned products.

Looking at the pie chart, you can see that the share of diagnostic drugs and hormone drugs is roughly the same. Later, I will talk about our forecast for the current fiscal year, but in this share of sales, we expect the ranking to reverse this fiscal year.

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## 主要製品売上高

製品名 (百万円)	薬効分類	15/9月期	16/9月期	17/9月期	18/9月期	19/9月期	前期比	
							増減額	増減率
オイバロミン注	診断用薬	6,500	7,029	6,879	6,769	7,192	423	6.2%
イオバーク注	診断用薬	1,968	2,133	2,162	2,010	2,287	277	13.8%
フルグラスチムBS注シリンジ	代謝性医薬品	1,344	1,481	1,671	1,721	1,974	253	14.7%
ルナベル配合錠(LD/ULD)	ホルモン剤	3,756	3,017	2,845	2,769	1,583	△ 1,186	-42.8%
ジエノゲスト錠	ホルモン剤	-	-	307	828	1,136	308	37.2%
デキサート注射液	ホルモン剤	724	813	866	870	894	24	2.8%
HMG筋注用	ホルモン剤	939	917	891	880	811	△ 69	-7.8%
ウトロゲスタン錠用カプセル	ホルモン剤	-	254	578	649	788	139	21.4%
ファボワール錠	ホルモン剤	456	537	601	552	768	216	39.1%
オプトレイ注	診断用薬	1,972	1,927	1,923	2,193	741	△ 1,452	-66.2%
ラベルフィーユ錠	ホルモン剤	326	354	398	526	709	183	34.8%
フォルモンプ注	ホルモン剤	507	512	583	638	632	△ 6	-0.9%
リマプロストアルファデクス錠	代謝性医薬品	600	588	572	621	591	△ 30	-4.8%
アルプロスタシル注	循環器官用薬	550	593	536	534	532	△ 2	-0.4%
クロミッド錠	ホルモン剤	473	457	474	480	451	△ 29	-6.0%
上位15品目合計		20,120	20,620	21,294	22,047	21,097	△ 950	-4.3%
売上高に占める構成比		63.5%	60.2%	60.2%	58.2%	58.2%		
その他の製品		9,369	11,372	11,692	13,385	12,642	△ 743	-5.6%
OLIC社CMO事業 (グループ間取引除く)		2,231	2,281	2,464	2,636	2,870	234	8.9%
合計		31,680	34,229	35,387	37,909	36,279	△ 1,630	-4.3%

急性期医療 女性医療

\* 下線製品は、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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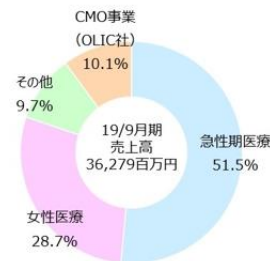
Moving on to page seven. The top 15 products in terms of net sales are listed here. As major factors, sorry to repeat but changes are mainly attributable to contrast media and LUNABELL®.

## 医療領域・剤形別売上高

医療領域別 (百万円)	15/9月期	16/9月期	17/9月期	18/9月期	19/9月期	前期比	
						増減額	増減率
急性期医療	17,082	19,997	20,264	21,895	19,340	△ 2,555	-11.7%
女性医療	9,943	9,582	10,212	10,802	10,756	△ 46	-0.4%
その他	2,463	2,413	2,509	2,734	3,643	909	33.2%
CMO事業 (OLIC社)	2,255	2,309	2,576	3,452	3,809	357	10.3%
合計	31,680	34,229	35,387	37,909	36,279	△ 1,630	-4.3%

※合計額は連結調整後の金額

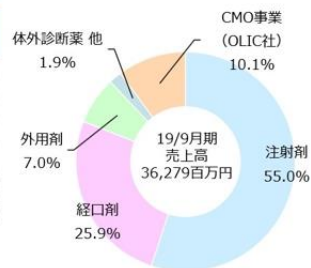
医療領域別売上高構成比



剤形別 (百万円)	15/9月期	16/9月期	17/9月期	18/9月期	19/9月期	前期比	
						増減額	増減率
注射剤	18,596	21,452	21,463	23,260	20,665	△ 2,595	-11.2%
経口剤	8,663	8,020	8,547	8,937	9,729	792	8.9%
外用剤	1,477	1,818	2,165	2,441	2,636	195	8.0%
体外診断薬 他	752	701	811	793	709	△ 84	-10.6%
CMO事業 (OLIC社)	2,255	2,309	2,576	3,452	3,809	357	10.3%
合計	31,680	34,229	35,387	37,909	36,279	△ 1,630	-4.3%

※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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Moving on to page eight. The status of sales by medical field and formulation are described here. By medical field on the upper half, nearly 60% of the total sales had come from the acute medical care field for three consecutive years from the fiscal years ended September 2016 to September 2018. But in the current fiscal

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year it has accounted for slightly more than 50%. The reason for this is the contrast media, which I have discussed already.

By formulation shown in the lower row, you can see similar changes for injectable drugs for the same reasons.

### 急性期医療・女性医療売上高

急性期医療 (百万円)	15/9月期	16/9月期	17/9月期	18/9月期	19/9月期	前期比	
						増減額	増減率
造影剤	10,788	13,491	13,193	14,062	11,852	△ 2,210	-15.7%
抗がん剤	448	508	862	1,166	988	△ 178	-15.3%
BS	1,344	1,481	1,671	1,721	1,974	253	14.7%
その他	4,500	4,516	4,537	4,945	4,524	△ 421	-8.5%
合計	17,082	19,997	20,264	21,895	19,340	△ 2,555	-11.7%

※BS：バイオシマラー



女性医療 (百万円)	15/9月期	16/9月期	17/9月期	18/9月期	19/9月期	前期比	
						増減額	増減率
不妊症治療剤	2,202	2,467	2,865	3,021	3,100	79	2.6%
子宮内腺症治療剤	687	725	1,111	1,554	1,940	386	24.8%
月経困難症治療剤	3,756	3,354	3,139	3,043	1,694	△ 1,349	-44.3%
経口避妊剤	782	892	1,000	1,079	1,909	830	76.9%
その他	2,515	2,142	2,095	2,103	2,110	7	0.3%
合計	9,943	9,582	10,212	10,802	10,756	△ 46	-0.4%



Go to page nine. The breakdown of net sales for acute medical care and women's healthcare is shown here. I have already explained the reasons behind the decline in sales related to contrast media and dysmenorrhea treatment in women's healthcare in the lower table.

The figure for oral contraceptives in the second from bottom row has increased by about 800 million yen. The breakdown of the figure is as described elsewhere in this document, but Favoir® 120 million yen, Labellefile® 180 million yen, and LEVONORGESTREL 430 million yen adds up to an increase of about 800 million yen.

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## 2019年9月期連結貸借対照表概要

(百万円)	18/9月期	19/9月期	前期比		
	期末	期末	増減額	増減率	
<b>資産の部</b>					
流動資産	34,927	<b>33,919</b>	△ 1,008	-2.9%	
現金及び預金	6,251	<b>8,494</b>	2,243	35.9%	
売上債権	16,903	<b>12,944</b>	△ 3,959	-23.4%	
たな卸資産	11,285	<b>10,712</b>	△ 573	-5.1%	
その他	486	<b>1,767</b>	1,281	263.6%	
固定資産	18,189	<b>26,817</b>	8,628	47.4%	製品販売権等取得
有形固定資産	11,700	<b>11,718</b>	18	0.2%	
無形固定資産	2,220	<b>3,300</b>	1,080	48.6%	
投資その他の資産	4,269	<b>11,798</b>	7,529	176.4%	Alvotech HD社及び Lotus社株式取得
<b>資産合計</b>	<b>53,117</b>	<b>60,737</b>	<b>7,620</b>	<b>14.3%</b>	
<b>負債の部</b>					
流動負債	11,546	<b>12,012</b>	466	4.0%	
仕入債務	6,746	<b>4,813</b>	△ 1,933	-28.7%	
その他	4,799	<b>7,198</b>	2,399	50.0%	Alvotech HD社出資等を目的とした銀行借入
固定負債	6,220	<b>9,360</b>	3,140	50.5%	
<b>負債合計</b>	<b>17,767</b>	<b>21,373</b>	<b>3,606</b>	<b>20.3%</b>	
<b>純資産の部</b>					
株主資本	34,438	<b>38,804</b>	4,366	12.7%	
資本金	3,799	<b>3,799</b>	0	0.0%	
資本剰余金	5,023	<b>5,841</b>	818	16.3%	
利益剰余金	27,119	<b>29,243</b>	2,124	7.8%	
自己株式	△ 1,504	<b>△ 78</b>	1,426	-94.8%	Lotus社宛割当
その他の包括利益累計額	909	<b>556</b>	△ 353	-38.8%	
<b>純資産合計</b>	<b>35,350</b>	<b>39,363</b>	<b>4,013</b>	<b>11.4%</b>	
<b>負債純資産合計</b>	<b>53,117</b>	<b>60,737</b>	<b>7,620</b>	<b>14.3%</b>	



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The status of the balance sheet is described on page 10. In "Property, plant and equipment" under "Assets," total assets increased by 7.620 billion yen or 14.3%, due to an increase in intangible assets resulting from the acquisition of sales rights to products and an increase in investment associated with capital and business alliances.

For liabilities, although borrowings have increased due to the acquisition of shares in connection with M&A, we do not think this is a concerning level in terms of the weight against of our total assets and net assets.

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## 2019年9月期連結キャッシュ・フロー計算書概要

(百万円)	18/9月期	19/9月期	前期比	
			増減額	増減率
営業活動によるキャッシュ・フロー	3,773	<b>7,035</b>	3,262	86.5%
(主な内訳)				
税金等調整前当期純利益	4,472	<b>3,961</b>	△ 511	-11.4%
減価償却費	1,976	<b>1,850</b>	△ 126	-6.4%
のれん償却額	275	<b>279</b>	4	1.5%
売上債権の増減額 (△は増加)	△ 1,731	<b>3,965</b>	5,696	-
たな卸資産の増減額 (△は増加)	235	<b>581</b>	346	147.2%
仕入債務の増減額 (△は減少)	994	<b>△ 1,937</b>	△ 2,931	-294.9%
法人税等の支払額	△ 1,797	<b>△ 957</b>	840	-46.7%
投資活動によるキャッシュ・フロー	△ 1,073	<b>△ 12,024</b>	△ 10,951	1020.6%
(主な内訳)				
投資有価証券の取得による支出	-	<b>△ 7,786</b>	△ 7,786	-
有形固定資産の取得による支出	△ 1,446	<b>△ 1,701</b>	△ 255	17.6%
有形固定資産の売却による収入	1,283	<b>4</b>	△ 1,279	-99.7%
無形固定資産の取得による支出	△ 184	<b>△ 1,583</b>	△ 1,399	760.3%
財務活動によるキャッシュ・フロー	△ 2,001	<b>7,265</b>	9,266	-
(主な内訳)				
自己株式の売却による収入	-	<b>2,225</b>	2,225	-
自己株式の取得による支出	△ 40	<b>0</b>	40	-
長期借入れによる収入	-	<b>7,000</b>	7,000	-
長期借入金の返済による支出	△ 653	<b>△ 630</b>	23	-3.5%
配当金の支払額	△ 794	<b>△ 839</b>	△ 45	5.7%
リース債務の返済による支出	△ 513	<b>△ 490</b>	23	-4.5%
現金及び現金同等物の期首残高	5,503	<b>6,251</b>	748	13.6%
現金及び現金同等物の期末残高	6,251	<b>8,494</b>	2,243	35.9%
フリー・キャッシュ・フロー	2,699	<b>△ 4,989</b>	△ 7,688	-284.8%

Alvotech HD社及び  
Lotus社株式取得

製品販売権等取得

Lotus社宛割当

Alvotech HD社出資等を  
目的とした銀行借入



11

The cash flows are described on page 11. The main reasons for the change are the same as what I mentioned about the balance sheet.

## 2020年9月期連結業績予想

- 売上高：年2回の薬価改定及びブランド造影剤移管の影響により-2,449百万円（前期比-6.8%）
- 営業利益：上記影響及び研究開発費の増加により-1,602百万円（前期比-38.4%）

(百万円)	19/9月期 実績	20/9月期 予想	前期比	
			増減額	増減率
売上高	36,279	33,830	△ 2,449	-6.8%
営業利益	4,173	2,571	△ 1,602	-38.4%
営業利益率	11.5%	7.6%	-	-
経常利益	4,169	2,501	△ 1,668	-40.0%
経常利益率	11.5%	7.4%	-	-
親会社株主に帰属する当期純利益	2,962	1,664	△ 1,298	-43.8%
当期純利益率	8.2%	4.9%	-	-
設備投資額	1,965	1,907	△ 58	-3.0%
減価償却費（設備リース費含む）	1,934	1,891	△ 43	-2.2%
研究開発費	2,052	2,879	827	40.3%
研究開発費率	5.7%	8.5%	-	-



13

I'd like to end the presentation on the consolidated financial results for the fiscal year ended September 30, 2019 and will now discuss the forecasts for the fiscal year ending September 30, 2020 from page 13.

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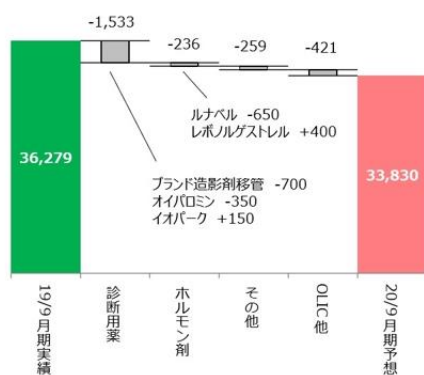
As described in the financial results summary submitted on November 8, we expect sales and profits to decline this fiscal year and the level of operating profit will be the lowest level in 10 years. We are very sorry to announce this forecast which fails to meet your expectations.

Net sales are expected to decrease by 2.449 billion yen or 6.8%, year-on-year due to the impact of the NHI drug price revisions in October and April and the transfer of contrast media. Operating income for the current fiscal year is forecast to decrease by 1.602 billion yen or 38.4%, from the previous fiscal year, due to an increase in R&D expenses in addition to the factors mentioned above.

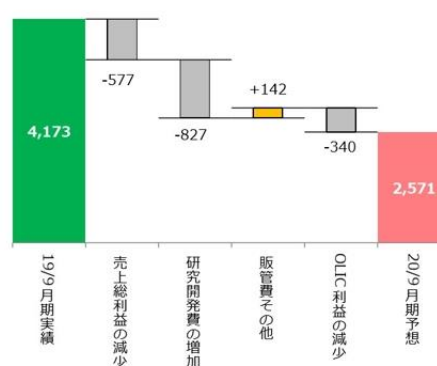
Although this year's forecast is a historically low level, it assumes of recovering business performance from the fiscal year ending September 30, 2021 onward. As President Iwai will explain later, we will strive to recover our business performance based on our basic management policy.

### 2020年9月期連結業績予想

売上高 (単位: 百万円)



営業利益 (単位: 百万円)



Page 14 shows the main factors behind changes in net sales and operating profit. Net sales are shown on the left-hand chart and operating profit is shown on the right-hand chart. Basically, as I have explained so far, the main factors behind this change are a decrease in sales of contrast media and hormone drugs and an increase in R&D expenses.

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## 薬効別・医療領域別売上高予想

(百万円)	19/9月期 実績	20/9月期 予想	前年同期比	
			増減額	増減率
診断用薬	10,827	9,294	△ 1,533	-14.2%
ホルモン剤	10,741	10,505	△ 236	-2.2%
代謝性医薬品	3,074	2,804	△ 270	-8.8%
循環器官用薬	891	807	△ 84	-9.4%
抗生物質・化学療法剤	820	866	46	5.6%
体外診断用医薬品	667	700	33	4.9%
泌尿・生殖器官系用薬	556	524	△ 32	-5.8%
外用薬	537	489	△ 48	-8.9%
その他	5,623	5,719	96	1.7%
CMO事業 (OLIC社)	3,809	3,219	△ 590	-15.5%
合計	36,279	33,830	△ 2,449	-6.8%

※合計額は連結調整後の金額

(百万円)	19/9月期 実績	20/9月期 予想	前年同期比	
			増減額	増減率
急性期医療	19,340	17,166	△ 2,174	-11.2%
女性医療	10,756	10,680	△ 76	-0.7%
その他	3,643	3,864	221	6.1%
CMO事業 (OLIC社)	3,809	3,219	△ 590	-15.5%
合計	36,279	33,830	△ 2,449	-6.8%

※合計額は連結調整後の金額



15

On page 15, sales forecasts by efficacy and medical field are shown. The decline in sales of diagnostic drugs in the top row of the upper table and acute medical care in the first row of the lower table, also affect sales forecasts.

## 主要製品売上高予想

製品名 (百万円)	薬効分類	19/9月期 実績	20/9月期 予想	前期比	
				増減額	増減率
オイパロミン注	診断用薬	7,192	6,849	△ 343	-4.8%
イオパーク注	診断用薬	2,287	2,444	157	6.9%
フィルグラスチムB5注	代謝性医薬品	1,974	1,805	△ 169	-8.6%
ジェノグスト錠	ホルモン剤	1,136	1,121	△ 15	-1.3%
ルナル配合錠 (LD/LILD)	ホルモン剤	1,583	933	△ 650	-41.1%
デキサート注射液	ホルモン剤	894	875	△ 19	-2.1%
レボルグストレル錠	ホルモン剤	431	834	403	93.5%
ウトロゲスタン錠用カプセル	ホルモン剤	788	803	15	1.9%
ラベルフィーコ錠	ホルモン剤	709	769	60	8.5%
ファボール錠	ホルモン剤	768	766	△ 2	-0.3%
HMG筋注用	ホルモン剤	811	703	△ 108	-13.3%
フォルモン注	ホルモン剤	632	607	△ 25	-4.0%
リマプロストアルファデクス錠	代謝性医薬品	591	559	△ 32	-5.4%
クロミッド錠	ホルモン剤	451	456	5	1.1%
アルプロスタリル注	循環器官用薬	532	446	△ 86	-16.2%
上位15品目合計		20,787	19,975	△ 812	-3.9%
売上高に占める構成比		57.3%	59.0%		
その他の製品		12,952	11,736	△ 1,216	-9.4%
OLIC社CMO事業 (グループ間取引除く)		2,870	2,627	△ 243	-8.5%
合計		36,279	33,830	△ 2,449	-6.8%

急性期医療 女性医療

\* 下線製品は、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



16

The sales forecasts for major products are as shown on page 16. Regarding the contrast media group in the first and second rows, sales trends are reversed. This is because, while sales of OYPALOMIN®, which is

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undergoing a generic shift, continue to trend downward, there is still room to expand our share of the IOPAQUE® market and we anticipate an increase in sales.

In the hormone drugs business, LEVONORGESTREL, Labellefil® , and other products compensate for the decline in LUNABELL® sales.

That's all from myself, President Iwai will talk about the Company's basic management policy and major strategies. We would like to take your questions after the presentations are completed.

Finally, I would like to mention just one point before the next presentation. We hope that you will hear as much information as possible about our situation and understand it, but at the same time there are many products that we are developing with partners or licensors, and there are some points that we cannot discuss in detail due to contract obligations. Accordingly, there may be some explanations or answers to the questions you ask later that may not seem clear enough, but we appreciate your understanding based on these circumstances.

Now, I will hand it over to President Iwai.

## 本日のテーマ

新たな経営基本方針

女性医療領域の主な新製品の状況

女性医療領域の主な新薬開発パイプライン

抗体薬バイオシミラー取組状況

成長戦略実行に向けた取組



18

**Iwai:** Good morning. Thank you very much for coming to our briefing. I would like to walk you through the Company's basic policies and major strategies for future management policies.

I would like to start from page 18 of the materials on hand. As explained by Sato, General Manager of the Corporate Planning Department, the current situation is that the timing of the decline in sales associated with the launch of AG and generics of LUNABELL® and transfer of OPTIRAY® and other brand contrast media, did not correspond favorably with the timing of the launch of new products. As a result, the Company's business performance is expected to decline for two years in a row, i.e., the fiscal year ended September 30, 2019 and the fiscal year ending September 30, 2020.

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On the other hand, I would like to emphasize that sales of strategic products for the Company, centered on products launched over the five years of the previous medium-term management plan, in the field of women's healthcare and related fields are performing steadily.

Then another point, the pipeline. The development is also proceeding smoothly, so I would like to explain today about three points, namely the current strategic products, products in development, and biosimilars.

## 新たな経営基本方針

2030年に向けた成長戦略		
カテゴリー × モダリティ	富山からGlobal Marketへ	
女性医療	女性医療プラットフォームの構築 新薬・周辺領域強化、e-Promotion/Digitalへ	APACのCDMO + 製販事業の展開
注射剤	画像診断薬の新事業モデルの構築 Complex Generics、新モダリティの供給	次世代製剤技術・投与デバイス事業のGlobalな展開
ホルモン剤	多品種・大量供給体制の構築 男性ホルモン、オンコロジー、ペプチドの強化	<b>人財戦略</b> 次世代経営幹部・グローバルリーダー育成プログラムの充実
次世代技術	次世代製剤技術・投与デバイス事業の立上 Complex Generics・505(b)(2)へ参入	<b>戦略投資 400億円</b>
抗体薬 バイオシミラー	抗体薬バイオシミラー国内トップシェアを獲得 Alvotechとのアライアンスを推進	

2030年 ビジョン	
<input checked="" type="checkbox"/>	世界中の女性のwell-beingの向上に貢献している
<input checked="" type="checkbox"/>	薬の富山からGlobal Marketに進出している
<input checked="" type="checkbox"/>	世界一幸せな会社と社会貢献が一体化している

 **FujiPharma** 19

Looking at page 19, I would like to start with the new basic management policy. There is a lot of information here, but my message is that we are going to become a more development-oriented pharmaceutical company towards 2030.

There are three main points that summarize and convey the contents described here. The first point is where we have traditionally been strong. In this area, we will further strengthen both quality and quantity. In the field of women's healthcare, the Company will further strengthen its product portfolio, centered on new drugs, and it will expand its business by further creating markets. This is the first point.

Second, we have a plant and an R&D center in Toyama. We are currently considering strengthening our formulation technology centered on the Toyama Research & Development Center. Based on our proprietary formulation technology, we will work on the development of more technologically challenging generics and the development of new and improved versions of existing drugs that classify as 505(b)(2) in the United States.

Finally, the third point is obtaining approvals for biosimilars of antibodies based on alliances with Alvotech. We would like to advance this initiative.

In addition, we currently have OLIC in Asia and in Thailand, but in addition to this, in the process of applying for 505(b)(2) which I mentioned, we intend to establish a foothold for expansion into North America going forward.

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To achieve these goals, we will make strategic investments of approximately 40 billion yen over the next five years. At the same time, we will strengthen the Toyama R&D center, which I have just mentioned and hire and train global human resources more aggressively than before.

As an outcome, we will achieve our 2030 visions to contribute to improving women's well-being worldwide, as well as to expand from Toyama into the global pharmaceutical market. We want to be a company that is both the world's happiest and an active contributor to society.

### 女性医療領域の主な新製品の状況

- ✓ 女性医療領域の主な新製品は順調に推移
- ✓ 2019/9期売上合計50億円 → 2024/9期合計100億円を見込む

	製品名（一般名）	適応症	剤形／特許	状況
主要製品	レボノルゲストレル（同）*	緊急避妊	経口剤 製剤特許出願中	数量シェア80%超 ** 市場規模約2倍に成長
	ファボワール （エチニルエストラジオール/ デソゲストレル）*	避妊	経口剤	国内経口避妊薬市場 メーカー別数量シェア1位 **
	ラベルフィーユ （エチニルエストラジオール/ レボノルゲストレル）*			
	ウトロゲスタン （プロゲステロン）*	生殖補助医療に おける黄体補充	腔用カプセル	9月単月GP市場シェア1位 **
	ジエノゲスト（同）	子宮内膜症	経口剤	市場規模約2倍に成長
	ル・エストロジェル （エストラジオール）	更年期障害	ゲル剤	年間成長率20% （株資生堂より承継予定）
ほか	ガバペン（ガバペンチン）	てんかん患者の 部分発作	経口剤	ファイザー（株）より承継

下線：2019/9期上市／\* 薬価未収載品／\*\* 自社調査



20

I would like to move on to page 20 and explain our new strategic products for women's healthcare.

We have listed seven products, including two products that were launched in the fiscal year ended March 31, 2019. We have positioned these seven products as strategic products for women's healthcare and related areas, which will continue to grow in the future.

I would like to stress here that new products are steadily growing. First, sales of LEVONORGESTREL have been growing steadily since its launch and we have already captured 80% of the market in terms of volume.

Specifically, the total volume in July, including the original drug and our company, has doubled from the previous year. The overall market has expanded and our market share has grown significantly as well.

In addition, the oral contraceptive Favor® and Labellefil® have been on the market for five years, but they are still growing steadily. In the fiscal year ending September 30, 2024, we are forecasting a doubling over the fiscal year ended September 30, 2019.

In addition to the six main products in the field of women's healthcare, we have positioned GABAPEN®, which we inherited from Pfizer last year, as our core product. These seven products generated 5 billion yen in the fiscal year ended September 30, 2019, which we plan to double to 10 billion yen by the fiscal year ending September 30, 2024.

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## 女性医療領域の主な新薬開発パイプライン

- ✓ 女性医療領域の新薬は、2022/9期以降に順次上市予定
- ✓ 新薬の上市により、女性医療領域の売上高を2024/9期目途に約2倍に

開発コード（一般名）	地域	予定適応症	開発段階	備考
FSN-011-01 (プロゲステロン)	日本	更年期障害	Phase III	Besins Healthcare社から導入
FSN-013 (エストロール/ ドロスピレノン)	日本	月経困難症	Phase II 試験終了	Mithra社から導入 用途特許取得（～2037年）
FSN-013 (エストロール/ ドロスピレノン)	ASEAN	避妊	欧米 申請準備中	同上
FSN-014 (エストロール)	日本	更年期障害	Phase I	同上
FSN-014 (エストロール)	ASEAN	更年期障害	欧米 Phase III開始	同上



21

Next, I would like to explain the pipeline of our new drugs from the top of this list. First, regarding FSN-011-01, this is a treatment for menopausal disorders that uses progesterone. The development is proceeding smoothly and Phase III is scheduled to be completed this month. After the completion, we plan to file it in September next year, so we will make steady progress in completing it.

Next, regarding FSN-013, this is one of our promising new drugs that uses the new estrogen component E4. The Phase II has been smoothly completed. We are planning to commence POC tests before entering Phase III, and we will proceed with Phase III while observing the results. In addition, drug's patents extend until 2037, so we would like to grow it steadily after it is put on the market.

In addition to the two new drugs that I have just mentioned, the seven strategic products I have just mentioned currently generate total sales of about 10 billion yen and we intend to double sales in the women's healthcare field in Japan by the fiscal year ending September 2024.

On the other hand, regarding the status of development in Asia, the Phase III trial has been completed for FSN-013 as described here, and the application is currently being prepared in Europe and the US. Basically, we will apply in ASEAN using data from Europe and the United States, so as soon as approval is obtained in Europe and the United States, the application will be made as soon as possible. We will focus first on Thailand, then Indonesia and the Philippines, which are markets with large populations.

As for FSN-014, this is already in Phase III at Mithra. As it may take a while, we will prioritize the development of FSN-011-01 described in the top row, and the stage for FSN-014 is currently Phase I.

These are the developments of new drugs in women's healthcare.

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## 抗体薬バイオシミラー取組状況

- ✓ 2018年11月、日本におけるバイオシミラーの商業化に関する独占的パートナーシップにつき Alvotech hf.社と合意
- ✓ 自己免疫疾患、悪性腫瘍性疾患等に対する治療薬7品目（国内市場規模合計2,500億円）について協議を開始、うち1品目について合意済
- ✓ Alvotechのグローバルデータを基に国内申請2023/9期から順次日本国内にて上市
- ✓ 自社販売又は他社との販売提携にて、販売額300億円を目指す

### Alvotechトピックス

- 独STADA社とバイオシミラー7品目の欧州等での独占販売権につき合意（2019年11月）
- UAE Yas Holding社とバイオシミラー3品目のMENA地域での独占的パートナーシップにつき合意（2019年11月）
- 印Cipla社とバイオシミラー1品目の一部新興市場での独占的パートナーシップにつき合意（2019年8月）

【日本国内における商業化スキーム】



22

On the next page, I would like to talk a little about biosimilars. The Company's initiatives with Alvotech are as explained in the financial results briefing for the second quarter back in May. Currently, we have begun discussions on biosimilars for seven therapeutic antibodies in the areas of autoimmune diseases and cancer. We have already agreed on one therapeutic agent. Therefore, we are in the process of preparing for the application in Japan.

Regarding our efforts with Alvotech, our basic policy is to apply for approval in Japan based on global data including Japanese people, so it is possible to greatly reduce steps for clinical trials in Japan.

Therefore, compared to conducting clinical trials from scratch in Japan, we can significantly reduce the cost of obtaining approval.

We are currently in discussions with Alvotech regarding the other six products and we are planning to launch them in Japan in stages starting in 2023.

We consider biosimilars for antibody drugs to be new modalities for our company, so our basic policy is to sell biosimilars on a stand-alone basis. However, depending on the field of the target product, we will not insist on this stance, but will prioritize raising the value of our products with a view to forming sales alliances with other companies.

As a reference, the blue box on the right with the white text are topics at Alvotech. The news is that STADA, a major German generics company and Alvotech have agreed to exclusive sales rights in Europe for seven biosimilars.

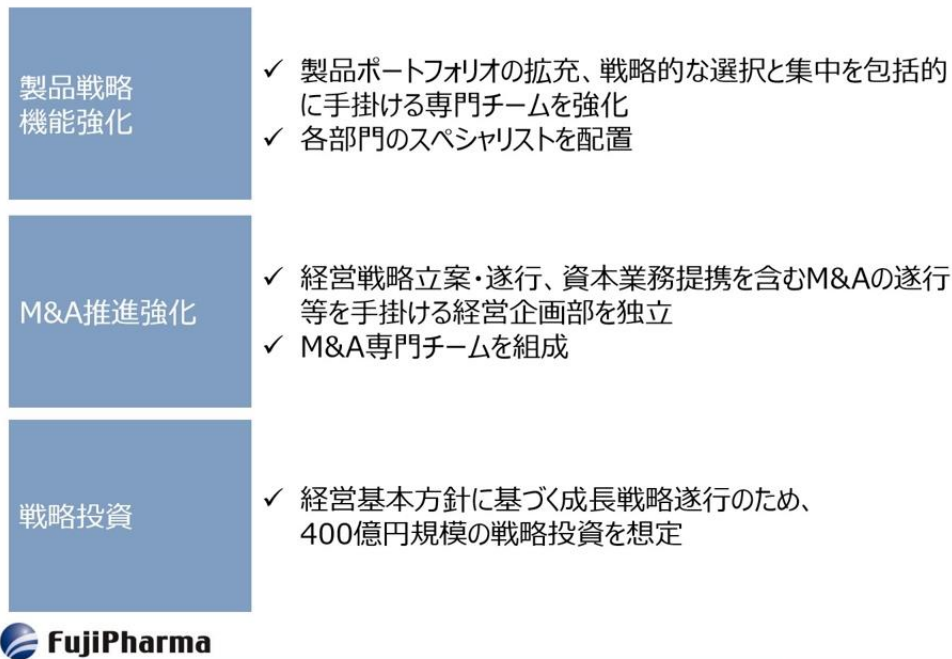
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## 成長戦略実行に向けた取組



Moving on to the last page about our organizational structure going forward: in order to accelerate the initiatives for the growth strategy I have just mentioned, we will first formulate a product strategy with clear priorities, and then proceed with the listing of the products that are essential for us in the future, as well as the acquisition of business portfolios.

To carry this out, the Corporate Planning Department was established independently on October 1, within which we have a specialized team to conduct mergers and acquisitions. I will work together with the Product Strategy Department and the M&A Team to expand the product portfolio of our core businesses and, in some cases, to strengthen our technological base. We will also pursue strategic M&A to expand into North America.

To achieve these goals, we will make strategic investments over the next five years or so, with a scale of around 40 billion yen in mind. I'll finish the presentation here.

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## Question & Answer

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**Moderator:** Thank you for the presentations. Now, we would like to move on to a question-and-answer session.

Today's briefing is scheduled to be transcribed in full. Therefore, if you mention your company or name when asking questions, it will be disclosed as is. If you wish to remain anonymous, please do not mention your company or name when asking questions.

So, if you have any questions, raise your hand.

**Yoshida:** I am Yoshida from Ichiyoshi Research Institute. Thank you for your explanation.

This is the first financial briefing following the appointment of Mr. Iwai as President. I understand this change happened suddenly, with the former President Takemasa's intention to resign in order to speed up various initiatives. I'd like to know about the background in more detail.

I understand that Mr. Iwai was involved with Fuji Pharma in his previous role at the US consumer business of Mitsui & Co., Ltd. until last year. I would like you to explain your recent activities and how you are catching up, to help my understanding about the transition.

**Imai:** Regarding the background, honestly speaking, I worked with Iwai when he was seconded from Mitsui & Co. to our company in 2007 and 2008 and since then we had been approaching him to continue helping us with management. We had the opportunity to discuss things further from the spring of this year, and the decision has been made by himself.

Under such circumstances, we needed to respond in a flexible manner, and the previous president proposed that he hand over to Iwai and reorganize the system. It was a little sudden, but this is how we decided to replace the president.

In fact, he has always supervised our business as the leader of Mitsui's healthcare business and thanks to his experience of being seconded in the past, he has been catching up relatively quickly. Iwai will explain his own background.

**Iwai:** In the last two years, I was at Mitsui & Co. (U.S.A.) as General Manager of the US Consumer Service Business Unit from July 2017 to September of this year. I covered four major business areas: healthcare centered on North America, which includes not only medicine but healthcare in general; the real estate business; fashion and textiles; and the South American trading business.

North America is the largest healthcare market in the world and the market is expanding as the population grows. I shouldn't be talking so much about the situation at that time, but in the field of healthcare, one of our focuses was to export the latest business models developed in the United States to Asia, including Japan.

Another focus was based on my experience as general manager of the Pharmaceuticals Division in the medical business unit before going to the United States. I oversaw the medical business in the United States as well, namely the production of raw materials for pharmaceuticals. This was not a personal but an organizational effort that I was involved in. Those were my main activities.

**Yoshida:** I see. To confirm, do you mean that you were nominated by former President Takemasa?

**Imai:** Yes.

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**Iwai:** Yes.

**Yoshida:** I see. Second, regarding new fields including 505(b)(2), are you talking about entering these fields based on Mr. Iwai's experience? Or did you have such discussions from before? As Mr. Iwai assumed his post this time, what changes can we expect and what are promising areas, if any?

**Iwai:** Previously, the idea existed within the Company that we needed to pursue 505(b)(2) in this way. But in terms of expanding in the US with 505(b) (2), after I joined the company, I said that we should take more efforts given our technology, so we have just begun to accelerate.

One starting point for thinking when that if the ingredients are the same, it is sometimes difficult to secure high drug prices in Japan. I believe that this reflects a lack of appreciation for technology. Therefore, our approach is to enter the North American market, in which technologies are valued fairly, and establish this as one of our pillars.

**Yoshida:** I see. On a related note, you've got approval for IOPAQUE® in Thailand so far. I understand that you had a global strategy centered on Thailand, but what is your view on this direction? In this context, I wonder if there is a little change in the way of talking about refining technology in Toyama. Also despite the approval in Thailand, it seems to be taking time to launch, so could you tell us how long it will take for the product to be launched?

**Iwai:** Is your question about selling in ASEAN?

**Yoshida:** Yes, selling in ASEAN.

**Iwai:** Basically, the ASEAN's sales policy has not changed. The North America policies are in addition to that. Regarding the ASEAN business, the CMO business with OLIC continues to be our main activity, and there is no change in the policy of changing this business to a production and sales business.

Accordingly, in addition to contrast media that I have mentioned, we will put even more effort into the production and sales business of Esterol using E4, development code FSN-13, in ASEAN including Thailand. This is one point.

In addition to this, when we consider good ways to expand in North America, one approach is to manufacture products in Asia and the other is to capitalize on technology. For North America, our basic approach is to differentiate ourselves with our technologies.

**Yoshida:** I see. This will be my last question. I think the medium-term management plan for the next five years was originally planned to be announced this time or this autumn. What should we expect in terms of how you will deal with this: are you preparing a new plan to be announced?

**Imai:** As we refreshed management, we are now formulating the new plan based on the already prepared medium-term management plan. We plan to complete the new medium-term management plan under the new management next spring when the new president will announce it again.

**Yoshida:** Thank you.

**Moderator:** Thank you. Do you have any other questions?

**Otsuka:** My name is Otsuka from Nikkan Yakugyou. I would like to ask about biosimilars. You said that you are preparing for the application for one product, but what is the specific schedule for the application?

In addition, as for the other six items, I would like to ask what we should expect as an overall image?

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**Iwai:** This is a very difficult question and due to the confidentiality agreement with Alvotech, we are unable to disclose the details. As described here, there are specific time periods for each product, but I cannot say when they will be launched for each product. The current approach is to successively launch the products over a period of several years from 2023 onwards.

As I mentioned at the beginning, we should partner with other companies for some of the products, so we are considering a sales joint venture in order to maximize the value of these products.

**Otsuka:** I see. Perhaps it's difficult to say now, but do you think it's more like all items at once rather than one item at a time? Rather than aiming to launch one product at a time, do you think it will be all at once?

**Iwai:** The registration must be done one item at a time, so in that sense, it is one by one. In terms of partnerships, there may be several partnerships, but not for all of them. I can't say for sure.

**Otsuka:** Do you mean we can imagine things will accelerate considerably?

**Iwai:** Yes. That's right.

**Moderator:** Anything else?

**Akahane:** This is Akahane from Tokai Tokyo Research Center. I have several questions, so I'll go one at a time.

First, I would like to acknowledge your business performance. The NHI drug price was revised due to the consumption tax hike and there might be some temporary demand surge, but I think the basic response is refraining from purchasing drugs. What is the current situation? This is the first point.

**Sato:** Regarding the impact on purchase behavior due to the revision of the consumption tax, as you know, the Ministry of Health Labour and Welfare issued a guidance in August to avoid stockpiling or avoiding purchases. They have not had a significant impact on our business.

**Akahane:** Do you feel there is almost no impact?

**Sato:** Right. There is no significant impact.

**Akahane:** I see. Then, you gave us the results and forecast, and it's not in too much detail about individual products, but first about contrast media: given that there is no temporary increase or restraint on buying, has the contrast media market itself performed well enough for the last fiscal year?

Regarding biosimilars, in addition to development, they have been in the market for a considerable time. What do you feel about biosimilars, on whether medical institutions have become less reluctant to use them?

**Iwai:** Contrast media have been increasing on a volume basis, although they are affected by the NHI drug price reductions in October. There are still about 200 hospitals preparing for DPC, and within the DPC, they have begun to consider how to combine it with outpatient treatment. Therefore, we currently recognize that the contrast media market will continue to grow on a quantitative basis.

As for biosimilars, given the need to address high-cost medical treatment, the development of biosimilars will be needed from the clinical practitioners going forward, especially for patients who are in a vulnerable situation. We also expect the government will promote the introduction of biosimilars, so our current understanding is that this market is sure to grow.

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**Akahane:** I see. Looking at individual products, I understand that LUNABELL® is struggling because of various competitors and I was convinced of the results and expectations, and OPTIRAY® is facing an expiration, but Filgrastim performed well, right? There might be the drug price, but how come the forecast is a little stringent?

**Sato:** As you just mentioned, it is fair to say that the impact of the NHI drug price is significant.

**Akahane:** Are the effects largely explained by drug prices?

**Sato:** Yes.

**Akahane:** I see. The president also mentioned joint ventures and in the case of biosimilars, new drug makers tend to take the lead, and major generic manufacturers like Sawai and Toa are not as active. Hearing their recent briefings, they are saying that they may have no choice but to do it. Do you also consider these companies? With biosimilars, alliances are forming with new drug makers and competition over market share is happening. How do you consider alliances, including this aspect?

**Iwai:** When considering an alliance, one of our key points is the area: we consider strong positions or capturing the KOL in certain areas. From this perspective, rather than considering generic manufacturers or new drug makers, our basic idea is to form partnerships with companies that are strong in certain area and have a firm control over KOL in that area.

**Akahane:** I see. Lastly, the Ministry of Health, Labour and Welfare has recently made a proposal to review and consolidate about 30% of public hospitals and that the same is true of private hospitals. You sell contrast media, so you cater to hospitals rather than pharmacies, so what impact should this consolidation have on your business?

**Iwai:** The consolidation of hospitals?

**Akahane:** Yes.

**Iwai:** Basically, we do not believe that consolidation and decommissioning will have a major impact on us in areas where we excel. Currently, in our field of gynecology and then in terms of formulation, we are talking about the use of hormone or injection drugs. We do not believe that the consolidation of hospitals will directly lead to less consumption of these products.

**Akahane:** Do you mean that even if a customer hospital is consolidated, for example, you can secure business with the next hospital? The number of hospitals that use injections or generics are not very limited, but they are not all. That's why I think it's unclear how the market share will change if one hospital was using it but was consolidated with another hospital that is not using them.

**Iwai:** I think we must consider the number of patients and from this perspective, it is unlikely to lead directly to the shrinkage of the pharmaceutical market for us.

**Akahane:** Understood well. Thank you very much.

**Moderator:** Thank you. Do you have any questions?

**Participant:** Thank you for your explanation. Sorry if you have already disclosed this information, but I would like to ask about the 40 billion yen strategic investment. In the materials, the figures for new products and new drugs are cut off at the fiscal year ending September 2024. However, in the material on strategic investment, it says this investment will be made towards 2030. I would like to ask whether the 40 billion yen is planned be spent by the fiscal year ending September 2024.

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And I would like to confirm whether this includes R&D expenditure. That's all.

**Iwai:** First, as the period will be for the next five years, so we are considering a strategic budget of this scale by the fiscal year ending September 2024. This is the first point.

Second, it does not include research and development.

**Moderator:** Do you have any other questions?

**Yoshimizu:** Thank you. This is Yoshimizu from the Chemical Daily.

Regarding the North America business, is it correct to understand that it will materialize in the next five years or so?

**Iwai:** We would like to see concrete results within five years.

**Yoshimizu:** Understood. And how do you envision the scale of this business in five years?

**Iwai:** I think how to enter is quite difficult. Sorry that I don't have a direct answer, but for example, it is unlikely that we acquire a company that already has a substantial amount of sales, such as 10 billion yen, as it will require a considerable amount of money compared to our scale.

Therefore, I have mentioned 505(b)(2). We currently believe that the appropriate way for a company our scale to enter North America is perhaps by forming a business alliance at the entry point with a development-driven company capable of carrying out 505(b)(2) by leveraging our drug formulation technologies, which can be followed by a capital alliance.

Therefore, although we do not have an indicator for the percentage of our total sales in the fiscal year ending September 2024, our current approach is to spend a considerable amount of money over the next five years to build a solid base to generate sales in the five years beyond.

**Yoshimizu:** For example, would you like to enter through licensing or in various forms?

**Iwai:** Yes, for the entrance.

**Yoshimizu:** Understood. What are the strengths of your company's formulation technology that enables you to differentiate yourself from competitors?

**Iwai:** As you know, most of our drug formulation technologies are for injections, so one thing we need to do is to build up technologies in the field of injections.

The other is that we have been conducting various research on oral formulations. For example, we are working on a way to convert oil-based products into regular tablets. Normally, it is like a soft capsule, but there is a technology to make it into tablets. Toyama is in the process of developing such products.

We are developing such technologies for practical application and we are now at the stage of exploring whether it can be used for other formulations as well.

**Yoshimizu:** Lastly, when do you expect to achieve sales of 30 billion yen in biosimilars?

**Iwai:** It's a bit ahead in the future. I'm sorry.

**Yoshimizu:** I understand. Thank you very much.

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**Moderator:** Do you have any other questions?

Now that we have no additional questions, we will close Fuji Pharma Co., Ltd.'s financial results briefing for the fiscal year ended September 30, 2019. Thank you very much for your participation.

[END]

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**Document Notes**

1. *Portions of the document where the audio is unclear are marked as follows: [Inaudible].*
2. *This document has been translated by SCRIPTS Asia.*

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