



TSE Code : 4585

# Financial Results for First half of FY 2014 Ending Dec. 31, 2014



*Addressing Unmet Medical Needs*  
UMN Pharma Inc.

Tatsuyoshi Hirano  
Chairman & CEO

July 31, 2014

- Financial Results for the First half of FY2014
- Business Progress for the First half of FY2014
- FY2014 - FY2017 Mid-Term Business Plan

- **Financial Results for the First half of FY2014**
- Business Progress for the First half of FY2014
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# Summary of Consolidated Financial Results for the 1<sup>st</sup> half of FY2014

(From January 1 through June 30, 2014)



— Comparison to the corporate forecast disclosed on Feb. 14, 2014 —

- Sales: In line with the initial forecast
- Expenses: \*PV expenses at Gifu plant will be partly recognized in the 2<sup>nd</sup> half of FY2014, resulting in smaller than expected losses reported during the 1<sup>st</sup> half.

(Millions of yen) Except for per share data	1 <sup>st</sup> half FY2014 - Forecasts ※ - (Consolidated)	1 <sup>st</sup> half FY2014 - Actual - (Consolidated)	Change		Major factors of the change
Sales	1,105	<b>1,078</b>	(26)	97.7%	
Operating income	(2,167)	<b>(1,796)</b>	+370	82.9%	Timing of recognition changed for part of PV expenses at Gifu plant
Ordinary income	(2,292)	<b>(1,967)</b>	+324	85.8%	ditto.
Net income	(2,079)	<b>(1,677)</b>	+402	80.7%	ditto.
Net income per share	¥(246.74)	<b>¥(198.63)</b>			

※ Financial forecasts disclosed on Feb. 14, 2014

\* PV (Process Validation) : The collection and evaluation of data, from the process design stage through commercial production, which establishes scientific evidence that a process is capable of consistently delivering quality products.

## Degree of Current Progress of Full Year Financial Forecasts for FY2014



- Committed to achieve our full year goal of Sales for FY2014
- Seeking for operational efficiency to further reduce costs and make the budget under control

(Millions of yen) Except for per share data	FY2014(Full Year) - Forecasts ※ - (Consolidated)	1 <sup>st</sup> half FY2014 - Actual - (Consolidated)	Progress on Full Year Forecasts	Remarks
Sales	2,186	<b>1,078</b>	49.4%	Achieve our sales goal by realizing strategic alliance in East Asian markets during FY2014
Operating income	(3,210)	<b>(1,796)</b>	56.0%	Costs, including PV expenses, are under control and will result within our budget
Ordinary income	(3,424)	<b>(1,967)</b>	57.5%	ditto.
Net income	(2,436)	<b>(1,677)</b>	68.9%	ditto.
Net income per share	¥(289.11)	<b>¥(198.63)</b>		

※ Financial forecasts disclosed on Feb.14, 2014

# Summary of Consolidated Financial Results for the 1<sup>st</sup> half of FY2014

(From January 1 through June 30, 2014)



– Comparison to the previous year (1<sup>st</sup> half of FY2013) –

(Millions of yen) Except for per share data	1 <sup>st</sup> half FY2013 - Actual - (Consolidated)	1 <sup>st</sup> half FY2014 - Actual - (Consolidated)	Change		Remarks
Sales	24	<b>1,078</b>	+1,055	4434.0 %	Received a milestone payment from Astellas for submission of NDA for approval of UMN-0502 (May 30, 2014)
Cost of sales	4	<b>166</b>	+163	4067.1 %	Royalty payable to Protein Sciences Corporation with regard to the above mentioned reception of a milestone payment
R&D expenses	1,218	<b>2,431</b>	+1,212	199.5%	Mainly due to execution of PQ/PV trial operation at Gifu plant (Posting depreciation 927, supplies expenses 664 outsourcing expenses 322, salaries 222 etc.)
Other SG&A expenses	299	<b>277</b>	(21)	92.9%	Administrative expenses decreased mainly due to reduction of labor cost
Operating income	(1,497)	<b>(1,796)</b>	(299)	120.0%	Increase of costs for PQ/PV trial operation at Gifu plant overwhelmed increase of revenue
Ordinary income	(1,641)	<b>(1,967)</b>	(326)	119.9%	
Net income	(1,166)	<b>(1,677)</b>	(511)	143.8%	Mainly due to decrease of loss charged to minority interest

## Consolidated Balance Sheets as of June30, 2014 vs. Dec.31, 2013

– Total assets decreased to ¥13,081 Mil from ¥19,001 Mil due to partial repayment of syndicated loan & reduction entry of related assets upon the receipt of grant from METI



Account	FY2013 (as of Dec.31,2013)	1 <sup>st</sup> half FY2014 (as of June30,2014)	Change*	Remarks
Assets	(Millions of yen)	(Millions of yen)		*fractions dropped
Current assets				
Cash on hands/banks	4,267	<b>1,612</b>	(2,655)	Partial repayment of syndicated loan
Raw materials/supplies	106	<b>421</b>	315	Materials for trial operation (Gifu plant)
Accrued consump. tax recv.	789	<b>10</b>	(779)	
Others	233	<b>326</b>	94	
Total current assets	5,396	<b>2,371</b>	(3,025)	
Fixed assets				
Property, plant & equip.				
Buildings & structures	6,054	<b>5,368</b>	(686)	Reduction entry of related assets upon the reception of “Subsidy for Domestic Location Promotion Projects” of the Ministry of Economy, Trade and Industry
Machinery, & equipment	5,968	<b>3,980</b>	(1,988)	
Others	803	<b>709</b>	(94)	
Intangible fixed assets	411	<b>283</b>	(128)	
Investments & others	367	<b>368</b>	1	
Total fixed assets	13,605	<b>10,710</b>	(2,895)	
Total assets	19,001	<b>13,081</b>	(5,921)	

## Consolidated Balance Sheets as of June 30, 2014 vs. Dec.31, 2013 (continued)

- Interest-bearing debt decreased to ¥8,196 Mil due to repayment of syndicated loan due and ahead of schedule
- Total liabilities decreased by ¥4,217 Mil to ¥10,531 Mil at June 30, 2014, compared to that of the end of FY2013



Account	FY2013 (as of Dec.31,2013)	1 <sup>st</sup> half FY2014 (as of June30,2014)	Change*	Remarks
Liabilities	(Millions of yen)	(Millions of yen)		*fractions dropped
Current liabilities				
Short-term loan	1,484	<b>1,500</b>	16	For operation
Long-term loan due within one year	2,710	<b>75</b>	(2,635)	Paying back part of syndicated loan payable within 1 year upon receipt of subsidy from METI
Account Payable	382	<b>1,093</b>	711	Procurement of materials for trial operation at Gifu plant
Other	151	<b>148</b>	(3)	
Total current liabilities	4,728	<b>2,816</b>	(1,911)	
Long-term liabilities				
Long-term loan	8,875	<b>6,621</b>	(2,254)	Payment of syndicated loan due
Lease obligations	549	<b>500</b>	(49)	Analytical instruments (Gifu plant)
Long-term deposits	340	<b>340</b>	—	
Other	255	<b>252</b>	(3)	
Total long-term liabilities	10,020	<b>7,714</b>	(2,306)	
Total liabilities	14,748	<b>10,531</b>	(4,217)	



## Consolidated Balance Sheets as of June 30, 2014 vs. Dec.31, 2013 (continued)



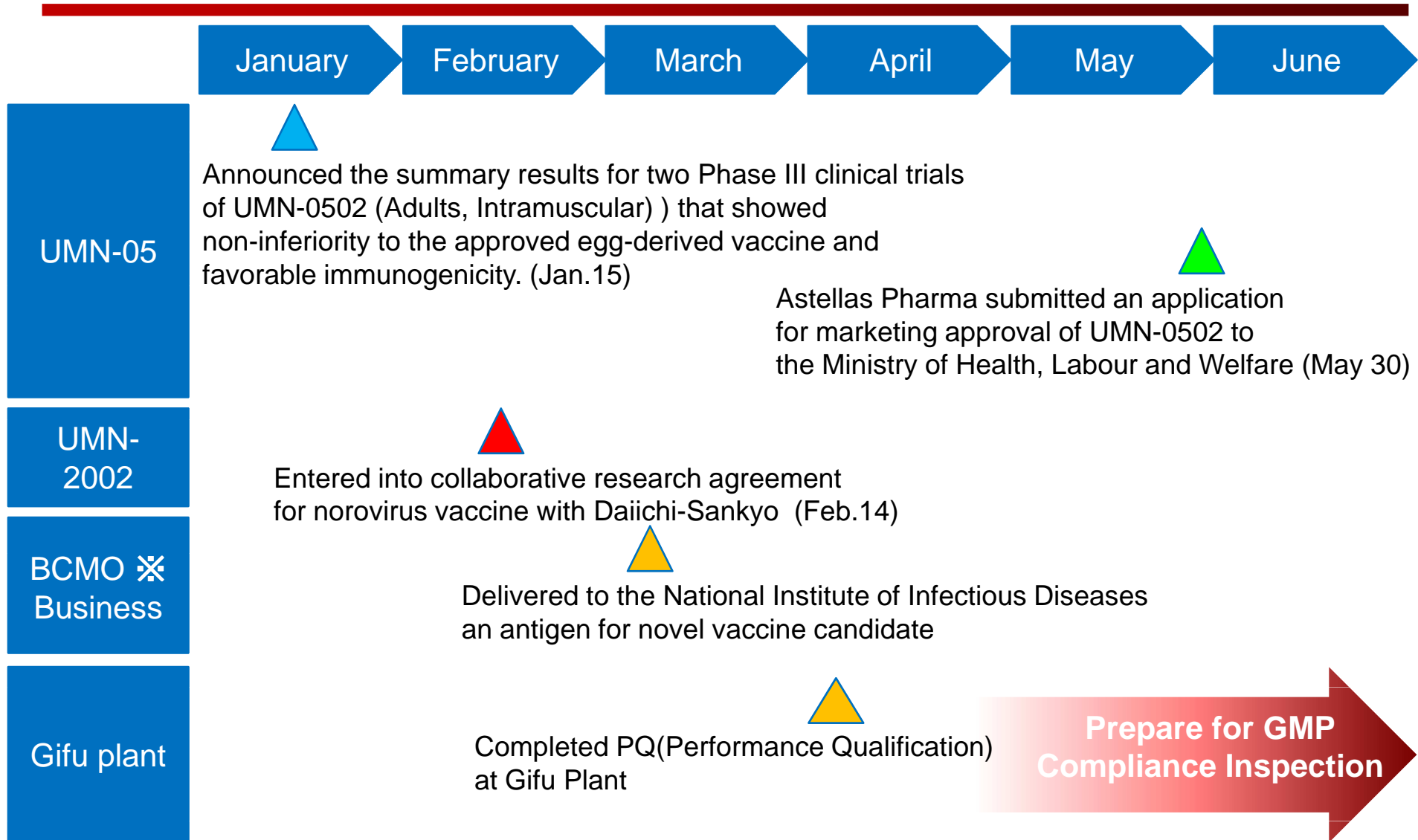
- Common stock & Capital surplus increased due to exercise of stock option
- Shareholders' equity ratio stands at 19.4% at June 30, 2014

Account	FY2013 (as of Dec.31,2013)	1 <sup>st</sup> half FY2014 (as of June30,2014)	Change*	Remarks
Net assets	(Millions of yen)	(Millions of yen)		*fractions dropped
Shareholders' equity				
Common stock	6,956	<b>6,965</b>	9	Due to exercise of stock option
Capital surplus	6,625	<b>6,634</b>	9	
Retained earnings	(9,379)	<b>(11,056)</b>	(1,677)	Due to net loss incurred
Treasury stock	(0)	<b>(0)</b>	–	
Total Shareholders' equity	4,202	<b>2,543</b>	(1,659)	
Accumulated other comprehensive income				
Unrealized holding gains on securities	–	<b>–</b>	–	
Total accumulated other comprehensive income	–	<b>–</b>	–	
Stock subscription rights	6	<b>6</b>	–	
Minority interests	44	<b>–</b>	(44)	
Total net assets	4,253	<b>2,549</b>	(1,704)	Due to net loss incurred
Total liabilities & net assets	19,001	<b>13,081</b>	(5,921)	

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# Business Development during First Six Months of FY2014

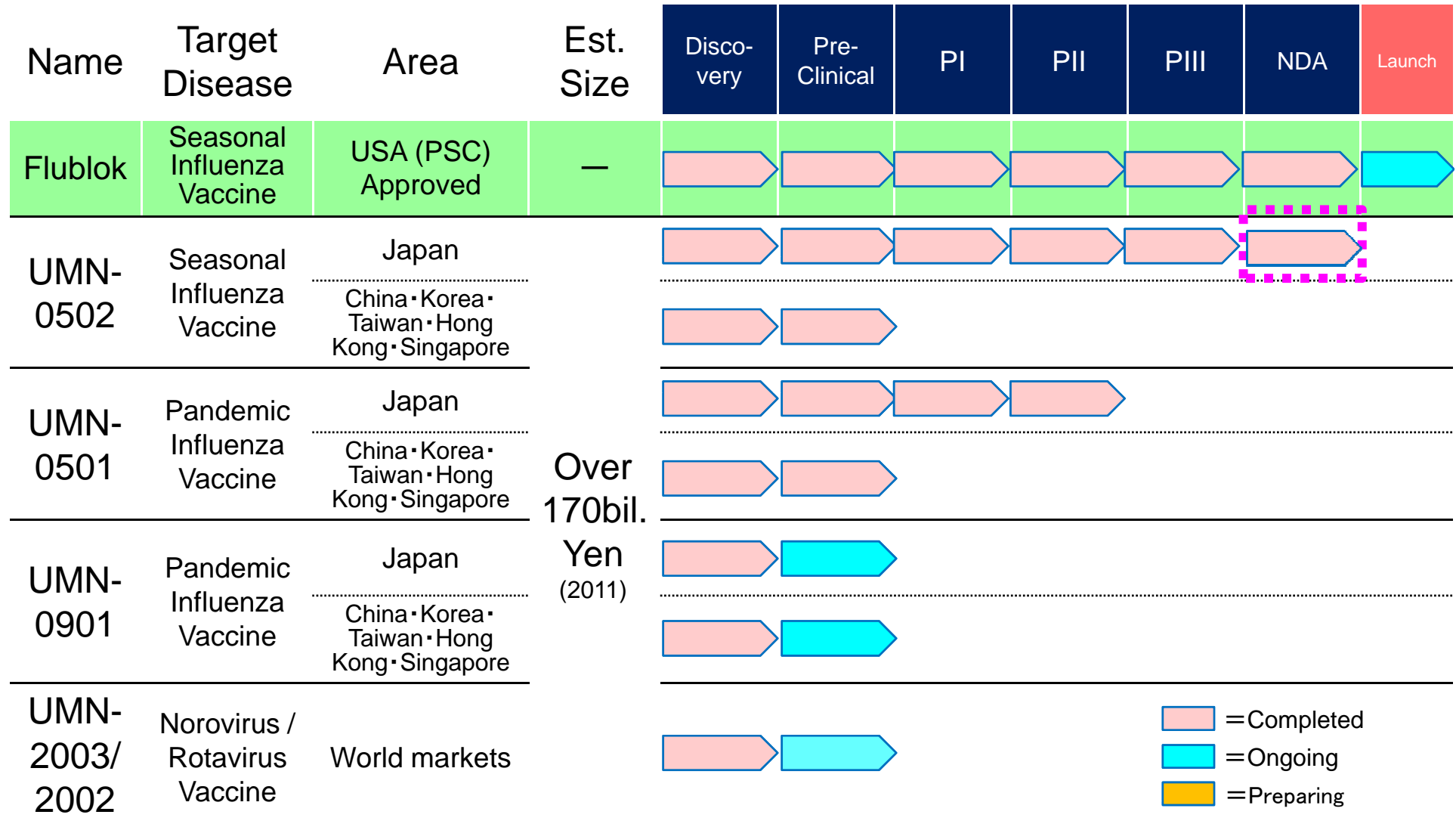
– Submitted an application for marketing approval of UMN-0502 as scheduled



※ BCMO = Biopharmaceutical Contract Manufacturing Organization

# Current Progress of In-House Pipeline (as of June 30, 2014)

–UMN-0502 : Step forward, filed NDA for approval in Japan



## Features of UMN-0502

– First-in-class, next-generation recombinant seasonal influenza vaccine



First-in-class, next-generation recombinant seasonal influenza HA vaccine, produced by a cell-culture manufacturing method employing the Baculovirus Expression Vector System (BEVS), a next-generation technology platform for manufacturing biopharmaceutical products.

Possibly manufactured for 6 to 8 weeks, at the earliest, after obtaining target gene information, a fraction of the time required for traditional influenza vaccines.

Could contain completely concordant HA\* of strain of influenza virus going around.

100% egg-derived-protein-free influenza vaccine.

Both subcutaneous injection and intramuscular injection available.

Phase III clinical trial conducted for adults aged from 20 to 64 / aged 65 and over showed non-inferiority of UMN-0502 compared to the approved egg-derived vaccine in terms of immunogenicity.

No major safety problem was observed for UMN-0502, as the safety profile was about the same as that of the approved egg-derived vaccine.

\* HA = Hemagglutinin protein, constituent of influenza vaccine

UMN-0502 : Completed Three Phase III Clinical Trials Successfully  
– Showed non-inferiority compared to the approved egg-derived vaccine / favorable immunogenicity of UMN-0502 (ASP7374)



### Double-blind study in subjects aged 65 and over (released March, 2013)

**【Study overview】**

Population : Healthy volunteers aged 65 and over  
Design, Arms : Double-blind study  
(Egg-derived vaccine, UMN-0502(ASP7374))  
Number of subjects : 1,060  
Primary endpoint : Immunogenicity

**【Immunogenicity】**

The study showed non-inferiority of ASP7374 compared to the approved egg-derived trivalent inactivated vaccine in Japan.

**【Safety】**

No major safety problem was observed.

### Double-blind study in subjects aged from 20 to 64 years (released January 2014)

**【Study overview】**

Population : Healthy volunteers aged from 20 to 64 years  
Design, Arms : Double-blind study  
(Egg-derived vaccine, UMN-0502(ASP7374))  
Number of subjects : 900  
Primary endpoint : Immunogenicity

**【Immunogenicity】**

The study showed non-inferiority of ASP7374 compared to the approved egg-derived trivalent inactivated vaccine in Japan.

**【Safety】**

No major safety problem was observed.

### Open-label study of intramuscularly-administered UMN-0502 (ASP7374) in subjects aged 61 and over (released January 2014)

**【Study overview】**

Population : Healthy volunteers aged 61 and over  
Design, Arms : Open-label study (One arm)  
Number of subjects : 55  
Primary endpoint : Immunogenicity

**【Immunogenicity】**

The study showed favorable immunogenicity of intramuscularly-administered UMN-0502(ASP7374)

**【Safety】**

No major safety problem was observed.

## Review Schedule for NDA of UMN-0502

- Ministry of Health, Labor and Welfare has noticed Standard Review Timeline for NDA, aiming at median time of 12 months for standard review products



Administrative Notice

March 30, 2012

To: Division of Pharmaceutical Affairs,  
Prefectural Health Department (Bureau)

From: Evaluation and Licensing Division,  
Pharmaceutical and Food Safety Bureau,  
Ministry of Health, Labour and Welfare

### **On the Standard Review Timeline for New Drug Applications**

The Mid-term Plan of the Pharmaceuticals and Medical Devices Agency (authorized under MHLW-PFSB No. 0331002 dated March 31, 2009) sets a target for the total review time for new drugs, aiming at a median time of 12 months for standard review products. The target needs to be achieved through efforts by both the regulatory authorities and applicants.

Source : [http://www.pmda.go.jp/english/service/pdf/notifications/PFSB-ELD\\_20120330.pdf](http://www.pmda.go.jp/english/service/pdf/notifications/PFSB-ELD_20120330.pdf)

# UMN-2002 : Collaborative Research Agreement with Daiichi-Sankyo

– Daiichi-Sankyo is conducting basic research with recombinant norovirus VLP antigen provided by UMN



## Collaborative Research Agreement with Daiichi Sankyo

### 【Summary of terms】

- UMN will provide Daiichi-Sankyo with recombinant norovirus VLP\* antigen exclusively
- Daiichi Sankyo will conduct basic research to determine the possibility of developing the vaccine
- UMN grants Daiichi Sankyo the right to negotiate exclusively further partnership during the collaborative research agreement period

\* VLP = Virus Like Particle

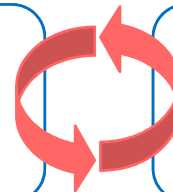
### Scheme of Collaboration



Passion for Innovation. Compassion for Patients.™



- Conduct research to determine possibility to develop norovirus vaccine with VLP antigen
- Conduct preliminary tests for development



- Provide recombinant norovirus VLP antigen produced by BEVS
- Conduct process development for manufacturing

### 【Progress situation as of June 30, 2014】

- Daiichi Sankyo is conducting basic research to determine the possibility of developing the vaccine with recombinant norovirus VLP antigen provided by UMN



## Gifu Plant

– Advance to the stage of PV (※) for UMN-0502(ASP7374), as scheduled



### Current Stage

- ◆ Conducting PV(※) , preparing for GMP Compliance Inspection
  - Required for each product
- ◆ Applying for Manufacturer's Licence
  - Required for each plant



(※)PV (Process Validation) : The collection and evaluation of data, from the process design stage through commercial production, which establishes scientific evidence that a process is capable of consistently delivering quality products.

# Major Activities for Achieving Financial Goals of FY2014 (Full Year)

– Chinese market and BCMO (※) business



<b>Chinese Market</b>	<p>Potential partners has been contacting with Chinese authority for the regulation / condition of approval of influenza vaccines in Chinese market.</p>
<b>BCMO (※) Business</b>	<p>As an outcome of above mentioned action by the potential partners, we have now seen some possibilities to establish mutually beneficial business scheme in Chinese market. So we think it possible to proceed to next stage of negotiation, talk of terms and other details, with the companies.</p> <p>Already obtained one order for the second half of FY2014, and making other final negotiations with 3 customers. As for the 4 customers under contact, 3 of which are repeaters, and 1 of which is a new customer.</p>

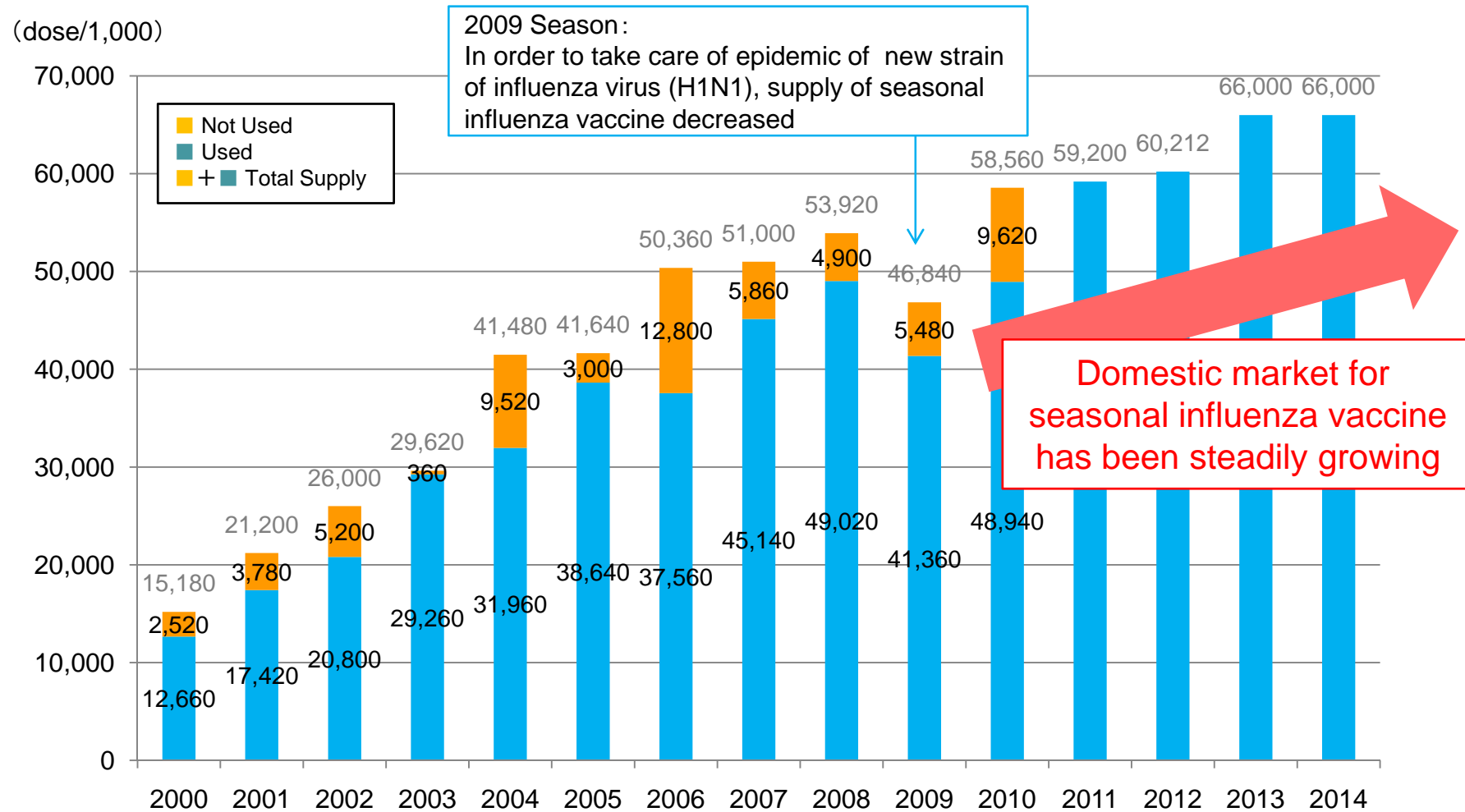
(※) BCMO : Biopharmaceutical Contract Manufacturing Organization

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# Market Volume of Seasonal Influenza Vaccine in Japan



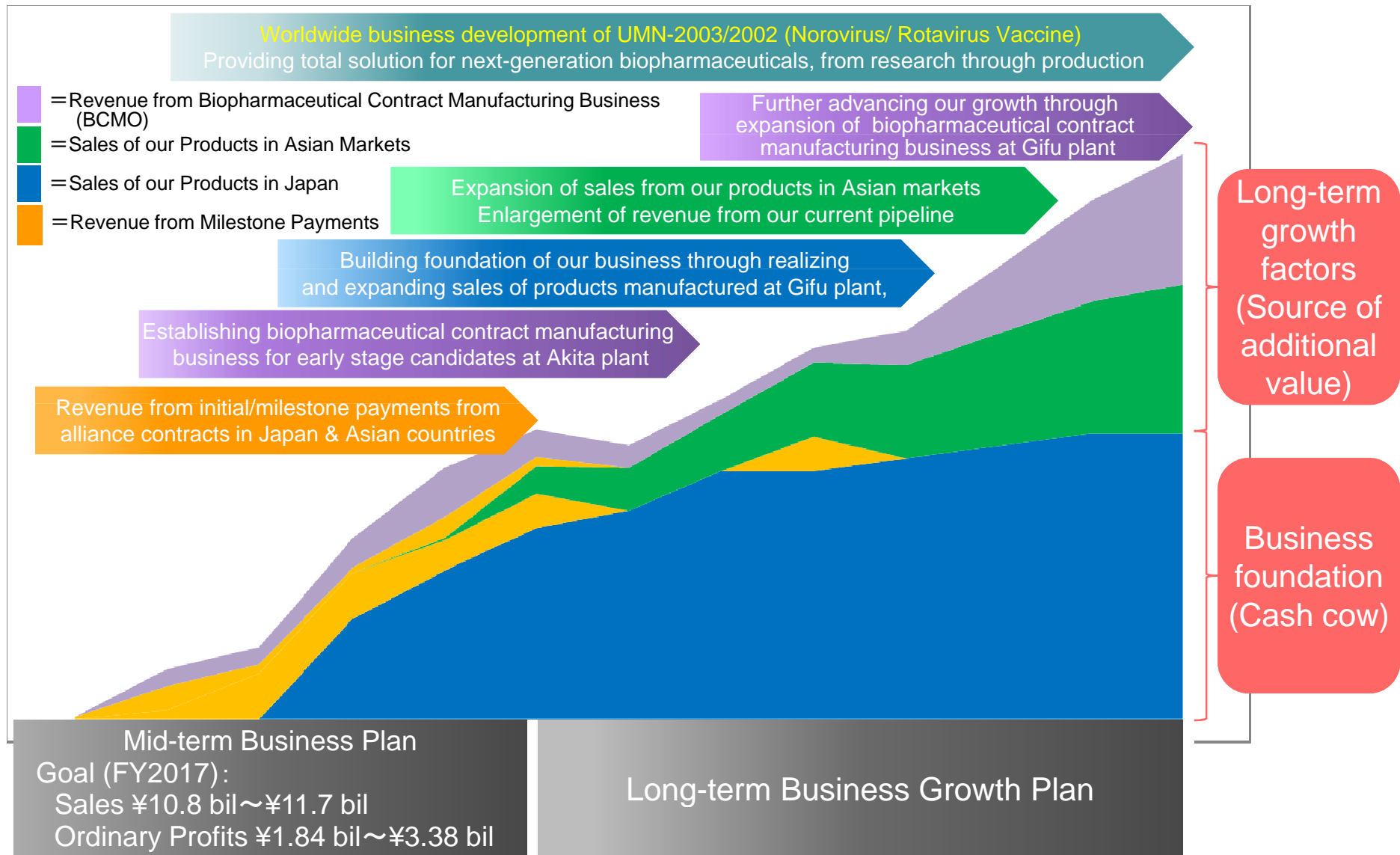
- Domestic market for seasonal influenza vaccine has been growing steadily since 2000
- Supply of the vaccine for current season estimated to have reached as much as 66 million doses



Source: 2000-2011: Ministry of Health, Labour and Welfare, Materials of 14<sup>th</sup> Commission for Demand of Seasonal Influenza Vaccine (July 29, 2011)  
 2012: Article of Nikkei Medical (July 31, 2012)  
 2013-2014: Estimated figure by UMN Pharma Inc.

# Our Growth Strategy

- Establish revenue base on UMN-0502 in Japan, growth expansion via development in Asia,
- Additional growth expected on UMN-2002 project, sustainable steady growth with BCMO business



# FY2014 - FY2017 Action Plan

- Establish & strengthen core business to build robust profit base
- Exploiting new area to create future additional value



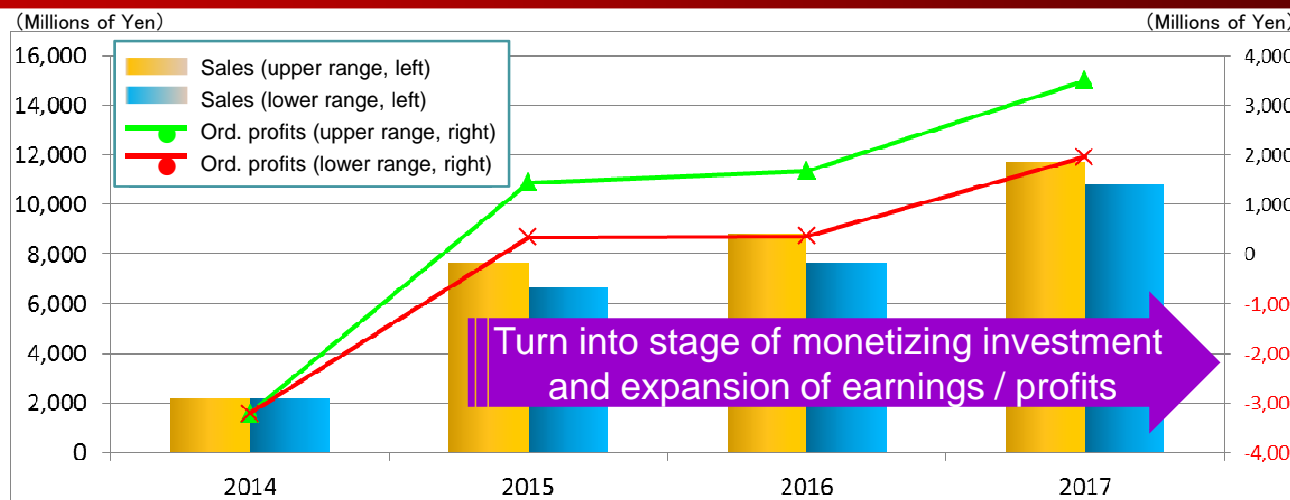
## Action Plan for Our Mid-Term Business Plan FY2014 — FY2017

In-House Pipeline	UMN-0502	<p>Japan</p> <ul style="list-style-type: none"> <li>➤ Increase manufacturing capacity at Gifu plant</li> <li>➤ Strengthen cost competitiveness – Reduction of costs / Improve yield efficiency</li> <li>➤ Consider possibility of additional indication of UMN-0502 into the age under 20</li> <li>➤ Product development to increase value, achieving sales milestones</li> </ul> <p>East Asia &amp; Other markets</p> <ul style="list-style-type: none"> <li>➤ Realize business alliance in China &amp; other East Asia markets</li> <li>➤ Implement clinical development, receiving milestones, start exporting to Asian markets</li> <li>➤ Seeking for the chance to supply API (※) to other markets outside Asia</li> </ul>
	UMN-0501	
	UMN-0901	
	UMN-2003/ 2002	
Biopharmaceutical contract manufacturing	<ul style="list-style-type: none"> <li>➤ Obtain BEVS contracts / advance to alliance</li> <li>➤ Increase clinical development productivity &amp; speed for bio-similar projects and monetize them as early as possible</li> </ul>	
Development of human resources	<ul style="list-style-type: none"> <li>➤ Enhance recruiting function</li> <li>➤ Strengthen HR development / Ensure world-class HR</li> </ul>	
Management foundation	<ul style="list-style-type: none"> <li>➤ Strengthen operating foundation for global business expansion</li> <li>➤ Enhance Investors Relations function</li> </ul>	

※ API : active pharmaceutical ingredient

# FY2014 - FY2017 Mid-Term Business Plan : Financial Targets

- Turn into profitability through launching UMN-0502 drug product from FY2015 onward
- Further expand earnings / profits by development in overseas markets and taking off BCMO business



Consolidated (Millions of yen)	FY2013 (Dec.31,2013) Actual	FY2014 (Dec.31,2014) Forecast	FY2015 (Dec.31,2015) Mid-term Plan	FY2016 (Dec.31,2016) Mid-term Plan	FY2017 (Dec.31,2017) Mid-term Plan
Sales	93	2,186	6,660 ~ 7,663	7,649 ~ 8,850	10,834 ~ 11,735
Operating income	(4,421)	(3,210)	337 ~ 1,438	358 ~ 1,672	1,961 ~ 3,499
Ordinary income	(4,147)	(3,424)	161 ~ 1,263	214 ~ 1,529	1,846 ~ 3,384
Net income	(3,717)	(2,436)	118 ~ 950	153 ~ 1,145	1,461 ~ 2,611

<Disclosure of Mid-term Financial Target figures in a form of 'range'>

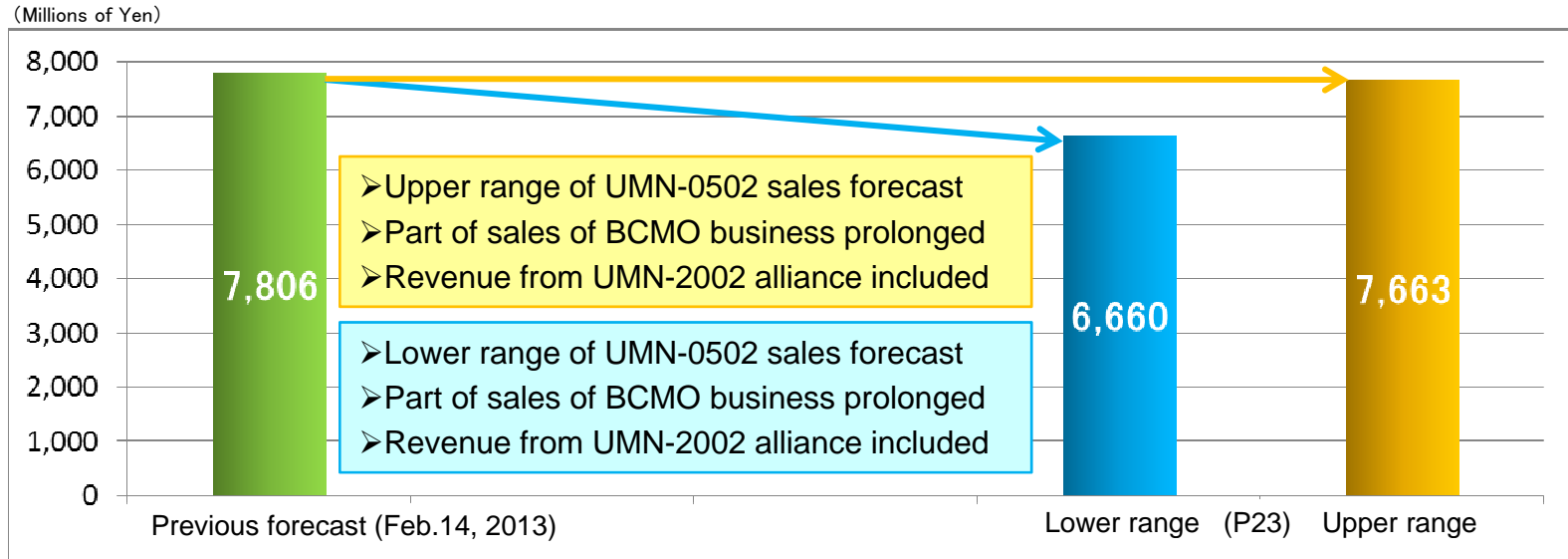
UMN and Astellas are still discussing future sales plan of UMN-0502. Astellas is supposed to provide UMN with more committed sales plan after market research Astellas is now preparing. So we have decided to disclose 'Mid-Term Financial Targets' mainly base upon our own analysis and forecast in a form of range. UMN would quickly disclose revised figures after receiving more precise sales plan from Astellas, if necessary.

# Variance Analysis of FY2015 Financial Targets against Previous Forecast

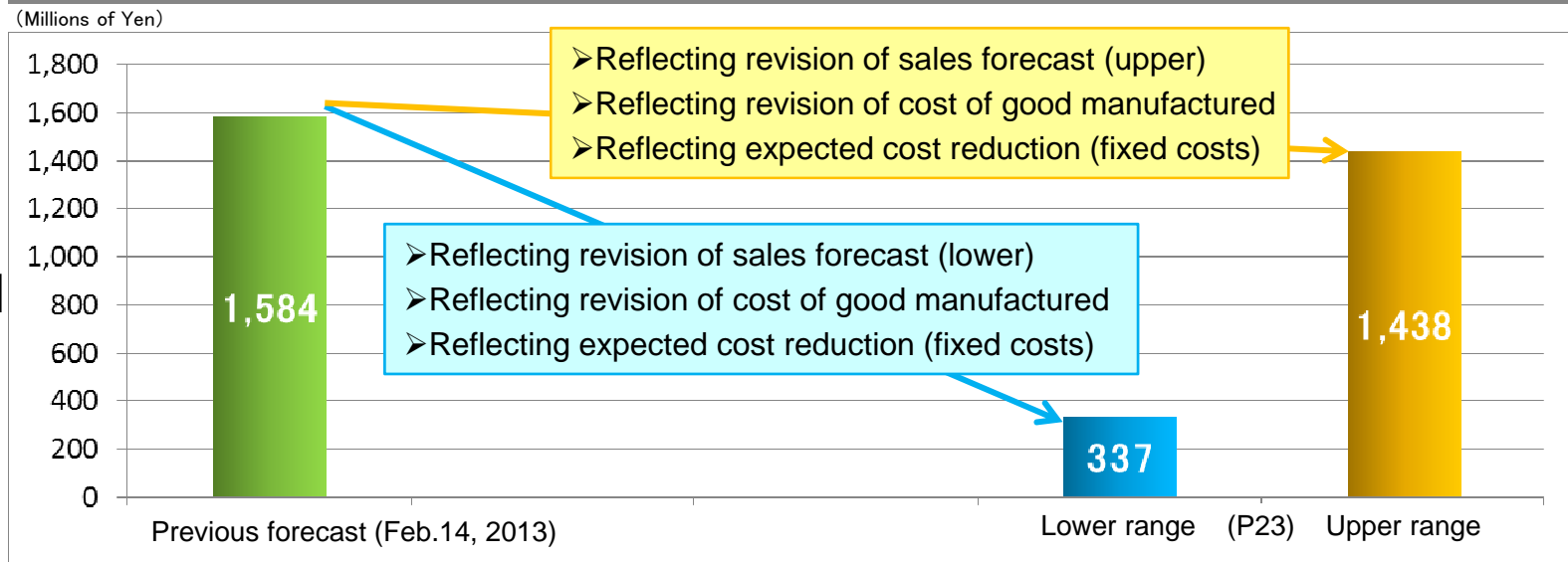


- Sales : Reflecting upper & lower range of UMN-0502 sales forecast
- Operating income : Reflecting a range of UMN-0502 sales forecast and revised costs of good manufactured

## 【Sales】



## 【Oper. income】





# FY2014 – FY2017 Mid-Term Business Plan

– Prospects / Assumptions for sales planning (consolidated)



		Point	Details
In-House Pipeline	Sales of products	<ul style="list-style-type: none"> <li>Mainly based upon our own market analysis/forecast.</li> <li>Disclosed in a form of range</li> </ul>	<p>Japan :</p> <ul style="list-style-type: none"> <li>Upon several discussion with Astellas about marketing analysis &amp; strategy of UMN-0502,UMN made our own sales forecast, in a form of range, taking into following variable factors into account:                             <ul style="list-style-type: none"> <li>Demand / supply of seasonal influenza vaccine for past 10 years (P20)</li> <li>Launch timing of other pharmaceutical companies' cell-based influenza vaccine</li> <li>Speed of penetration of novel cell-cultured vaccine from traditional egg-based vaccine</li> <li>Consider possibility of additional indication of UMN-0502 into the age under 20</li> <li>Anticipated price range</li> </ul> </li> </ul> <p>(Attention) Sales forecast of UMN-0502 could change during the course of further talks with Astellas. We will disclose it promptly in such a case.</p>
	Upfront / milestone payment	<ul style="list-style-type: none"> <li>Receipt of milestone payments with regard to UMN-05 projects, both in Japan and Asia.</li> <li>Receipt of upfront fee and milestone payments with regard to UMN-2002 project.</li> </ul>	<p>Japan :</p> <ul style="list-style-type: none"> <li>Receipt of milestone payments from Astellas based upon the agreement dated Sept.21,2010 are included.</li> </ul> <p>East Asia :</p> <ul style="list-style-type: none"> <li>South Korea : Receipt of milestone payments from Ildong Pharmaceutical based upon the agreement dated Dec.18, 2012 are included.</li> <li>China : As we are working to reach partnership agreement during FY2014, expected receipt of milestone payments are included.</li> </ul> <p>UMN-2002</p> <ul style="list-style-type: none"> <li>Receipt of upfront fees and milestone payments are included for the expected area / agreement</li> </ul>
BCMO Business		<ul style="list-style-type: none"> <li>Business expansion expected from 2nd half of FY2015</li> </ul>	<p>Revenue from providing investigational drug for early-stage investigation &amp; clinical trials of bio-similar candidates, receipt of order for various kind of evaluation test Services, are counted.</p>

This material includes forward-looking statements based on assumptions and beliefs in light of the information currently available to management and subject to significant risks and uncertainties.

Actual financial results may differ materially depending on a number of factors including adverse economic conditions, currency exchange rate fluctuations, adverse legislative and regulatory developments, delays in new product launch, pricing and product initiatives of competitors, the inability of the company to market existing and new pipelines effectively, interruptions in production, infringements of the company's intellectual property rights and the adverse outcome of material litigation.

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