



TSE Code : 4585

# Supplementary Documents of Business Results for Fiscal Year 2015 Ended Dec.31, 2015

Tatsuyoshi Hirano  
Chairman & CEO

February 24, 2016



*Addressing Unmet Medical Needs*  
UMN Pharma Inc.

- Business Results for FY 2015
  - Financial Results
  - Business Progress
  
- Business Plan for FY 2016
  
- Mid-Term Business Plan: FY2016—FY2019
  - Growth Strategy & Action Plan

- Business Results for FY 2015
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# Consolidated Financial Results for FY2015 ended Dec.31, 2015 vs FY2014



Sales: Income from Contract Manufacturing (¥202 Mil)

Expenses: Costs Decreased for Review Process for Approval & Other Related Costs at Gifu Plant

(Millions of yen) Except for per share data fractions dropped	FY2014 (Consolidated)	FY2015 (Consolidated)	Change		Major factors of the change
Net sales	1,108	202	(905)	(81.7)%	Milestone received (1,000), Income from contract manufacturing +94
Cost of sales	173	52	(121)	(69.7)%	Royalty payment to PSC (160) COS of contract manufacturing +38
R&D expenses	4,270	2,933	(1,337)	(31.3)%	Supplies expenses (865), Outsourcing expenses (382) Depreciation (138)
Other SG & A expenses	607	424	(182)	(30.1)%	Property tax (140), Salaries (21),
Operating Income	(3,942)	(3,207)	+735	-	
Ordinary Income	(4,249)	(3,390)	+859	-	(Non-operating income / expense) Income from grants (73) Interest / stock issuance fees +45
Net Income	(3,961)	(3,390)	+570	-	Governmental grants, net (247)
Net income per share	¥(452.34)	¥(354.16)			
Net Assets per share	¥387.74	¥34.84			

# FY2015 Financial Results : Actual vs Forecasts disclosed on Feb.13,2015 & Oct.30, 2015



– Changes from Feb.13 Forecasts : Substantial decline in sales due to delay in obtaining approval

– Changes from Oct.30 Revised Forecasts : The results almost as projected

(Millions of yen) fractions dropped	FY2015 Forecasts Disclosed Feb.13 (Consolidated)	<b>FY2015 Actual (Consolidated)</b>	Change		Major factors of the change
Net sales	5,224	<b>202</b>	(5,021)	(96.1)%	Unachieved milestone income (2,200) Lesser income from contract manufacturing (2,556)
Operating Income	(878)	<b>(3,207)</b>	(2,328)	-	Cost of Sales decreased +4,189 R&D expense increased due to delay in commercial production (1,914) SG&A costs decreased +419
Ordinary Income	(1,025)	<b>(3,390)</b>	(2,364)	-	
Net Income	(1,033)	<b>(3,390)</b>	(2,356)	-	

(Millions of yen)	FY2015 Forecasts Disclosed Oct. 30 (Consolidated)	<b>FY2015 Actual (Consolidated)</b>	Change (fractions dropped)		Major factors of the change
Net sales	222	<b>202</b>	(19)	(8.9)%	
Operating Income	(3,224)	<b>(3,207)</b>	+17	-	
Ordinary Income	(3,404)	<b>(3,390)</b>	+14	-	
Net Income	(3,405)	<b>(3,390)</b>	+15	-	

# Consolidated Balance Sheets as of Dec.31, 2015 vs. Dec.31, 2014



— Total assets decreased ¥1,073 Mil to ¥11,808 Mil on Dec. 31, 2015

— Raw materials and supplies increased ¥1,336 Mil, as the preparation for commercial production proceeded

Account	FY2014 (as of Dec.31,2014)	FY2015 (as of Dec.31,2015)	Change	Remarks
Assets	(Millions of yen*)	(Millions of yen*)		*fractions dropped
Current assets				
Cash and deposits	2,080	<b>842</b>	(1,238)	Due to losses incurred
Raw materials / supplies	348	<b>1,685</b>	+1,336	Materials for commercial production
Other	768	<b>776</b>	+7	
Total current assets	3,197	<b>3,303</b>	+106	
Fixed assets				
Property, plant & equip.				
Buildings & structures (net)	5,120	<b>4,680</b>	(440)	Depreciation
Machinery, & equipment (net)	3,410	<b>2,555</b>	(855)	
Lease assets (net)	533	<b>426</b>	(107)	
Others	105	<b>474</b>	(368)	Preparatory costs for additional capacity investment at Gifu plant
Intangible fixed assets	245	<b>171</b>	(73)	
Investments & others	268	<b>196</b>	(72)	
Total fixed assets	9,685	<b>8,504</b>	(1,180)	
Total assets	12,882	<b>11,808</b>	(1,073)	



# Consolidated Balance Sheets as of Dec. 31, 2015 vs. Dec.31, 2014 (continued)

- Repayment of syndicated loan for the construction of Gifu plant started from 4Q of FY2015
- Total liabilities amounted to ¥11,474 Mil as short-term loan for working capital under commitment line increased

Account	FY2014 (as of Dec.31,2014)	FY2015 (as of Dec.31,2015)	Change	Remarks
Liabilities	(Millions of yen*)	(Millions of yen*)		*fractions dropped
Current liabilities				
Short-term loan	600	<b>3,600</b>	+3,000	Loan for working capital under commitment
Long-term loan due within one year	336	<b>1,119</b>	+783	Transferred from long-term a/c, repayment of syndicated loan
Account Payable	607	<b>425</b>	(182)	Procurement of materials for trial production at Gifu plant decreased
Other	255	<b>185</b>	(69)	
Total current liabilities	1,798	<b>5,330</b>	+3,531	
Long-term liabilities				
Long-term loan	6,329	<b>5,210</b>	(1,119)	Transfer to current liabilities a/c
Lease obligations	457	<b>351</b>	(106)	
Other	591	<b>582</b>	(8)	
Total long-term liabilities	7,377	<b>6,144</b>	(1,233)	
Total liabilities	9,176	<b>11,474</b>	+2,297	

# Consolidated Balance Sheets as of Dec. 31, 2015 vs. Dec.31, 2014 (continued)



- Net assets decreased to ¥333 Mil due to net loss incurred during the period
- Shareholders' equity ratio stood at 2.8% at the end of FY2015

Account	FY2014 (as of Dec.31,2014)	FY2015 (as of Dec.31,2015)	Change	Remarks
Net assets	(Millions of yen*)	(Millions of yen*)		*fractions dropped
Shareholders' equity				
Common stock	8,688	<b>8,697</b>	+9	Exercise of stock option
Capital surplus	8,357	<b>8,366</b>	+9	
Retained earnings	(13,340)	<b>(16,730)</b>	(3,390)	Due to net loss incurred
Treasury stock	(0)	<b>(0)</b>	–	
Total Shareholders' equity	3,705	<b>333</b>	(3,371)	
Accumulated other comprehensive income				
Unrealized holding gains on securities	–	–	–	
Total accumulated other comprehensive income	–	–	–	
Stock subscription rights	–	–	–	
Minority interests	–	–	–	
Total net assets	3,705	<b>333</b>	(3,371)	
Total liabilities & net assets	12,882	<b>11,808</b>	(1,073)	



# Consolidated Cash Flows for FY2015 ended Dec.31, 2015 vs FY2014



— Free cash flows during FY2015 was ¥(3,792) Mil due to cash outflow for procurement of raw materials and supplies for future commercial production and capital investment at Gifu plant

(Consolidated, millions of yen, fractions dropped)	FY2014	FY2015	Change	Remarks
<b>Cash flows from operating activities</b>				
Net loss before income taxes & minority interests (-)	(4,002)	<b>(3,390)</b>	+612	
Depreciation	1,873	<b>1,524</b>	(348)	
Income from grants	(2,213)	<b>(76)</b>	+2,137	
Advanced depreciation deduction	1,966	—	(1,966)	
Other	637	<b>(1,401)</b>	(2,038)	Raw materials & supplies
Subtotal	(1,738)	<b>(3,343)</b>	(1,604)	
Grants received	2,316	<b>176</b>	(2,140)	
Other	(263)	<b>(227)</b>	+36	
Net cash provided by (used in) operating activities	314	<b>(3,393)</b>	(3,708)	
<b>Cash flows from investing activities</b>				
Purchase of tangible fixed assets	(5)	<b>(407)</b>	(402)	Preparatory investment for additional capacity of Gifu plant
Purchase of intangible fixed assets	(3)	<b>(2)</b>	+0	
Other	(0)	<b>11</b>	+11	
Net cash provided by (used in) investing activities	(8)	<b>(398)</b>	(389)	
<b>Free cash flows</b>	<b>305</b>	<b>(3,792)</b>	<b>(4,098)</b>	

# Consolidated Cash Flows for FY2015 ended Dec.31, 2015 vs FY2014 (continued)

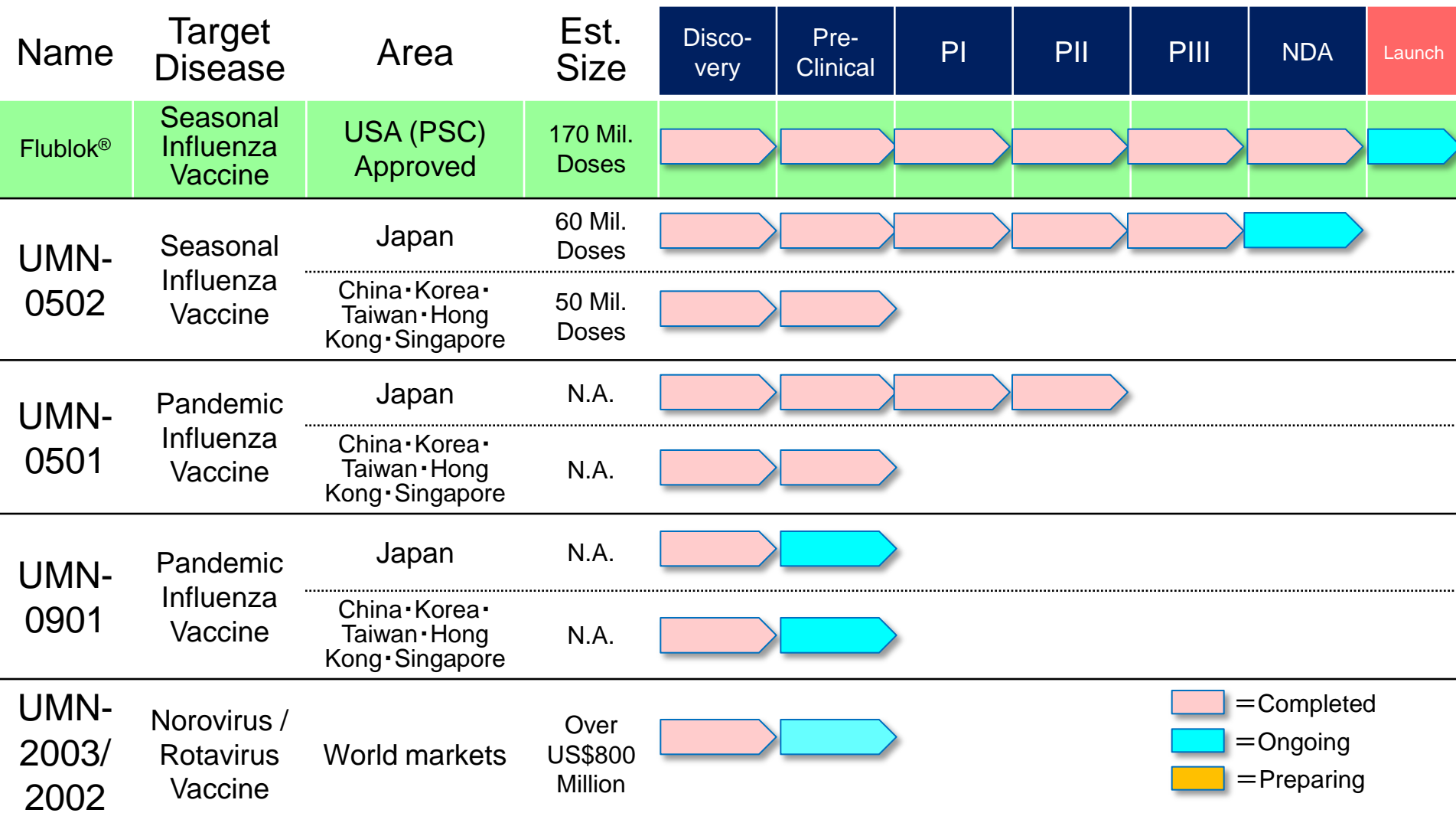


- Net short-term loan increased by ¥2,972 Mil under commitment line for working capital
- Repayment of syndicated loan started from 4Q / FY2015

(Consolidated, millions of yen, fractions dropped)	FY2014	FY2015	Change	Remarks
<b>Cash flows from financing activities</b>				
Net increase (decrease) in short-term loan	(914)	<b>2,972</b>	+3,886	Under commitment line for operation
Net increase (decrease) in long-term loan	(4,920)	<b>(336)</b>	+4,584	Repayment of syndicated loan
Proceeds from issuance of common stock	3,441	<b>18</b>	(3,423)	
Repayments of lease obligations	(94)	<b>(100)</b>	(6)	
Other	(6)	<b>—</b>	+6	
<b>Net cash provided by (used in) financing activities</b>	<b>(2,493)</b>	<b>2,554</b>	<b>+5,047</b>	
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>(2,187)</b>	<b>(1,238)</b>	<b>+949</b>	
<b>Cash and cash equivalent at beginning of the period</b>	<b>4,267</b>	<b>2,080</b>	<b>(2,187)</b>	
<b>Cash and cash equivalent at end of the period</b>	<b>2,080</b>	<b>842</b>	<b>(1,238)</b>	

# Status of R&D pipeline (as of December 31, 2015)

– Continuously going through regulatory process with Pharmaceutical & Medical Agency (PMDA) for the approval of UMN-0502 (ASP7374)



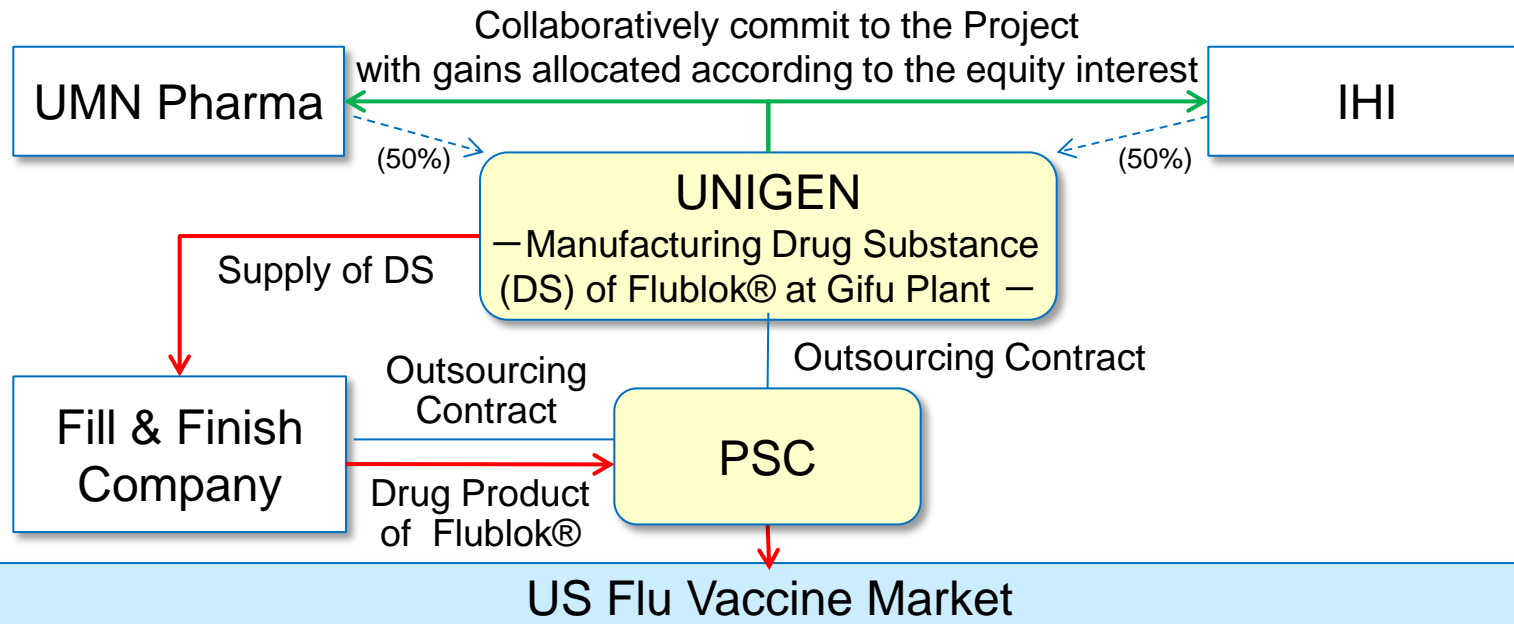
# PSC and UNIGEN Reached Agreement to Source Flublok® (※1) from Japan for the US Market (February 12, 2016)



## Summary of Agreement

- Scheme : UNIGEN to Supply Drug Substance of Flublok® to PSC
- Terms : Unit Price to be adjusted by Yield & Volume (risk aversion)
- Commitment term : At least 10 Years
- Licensure : PSC to apply FDA licensure of Gifu plant
- Terms on Risk factors : Market / material prices, foreign exchange, etc.

## Business Structure of the Project



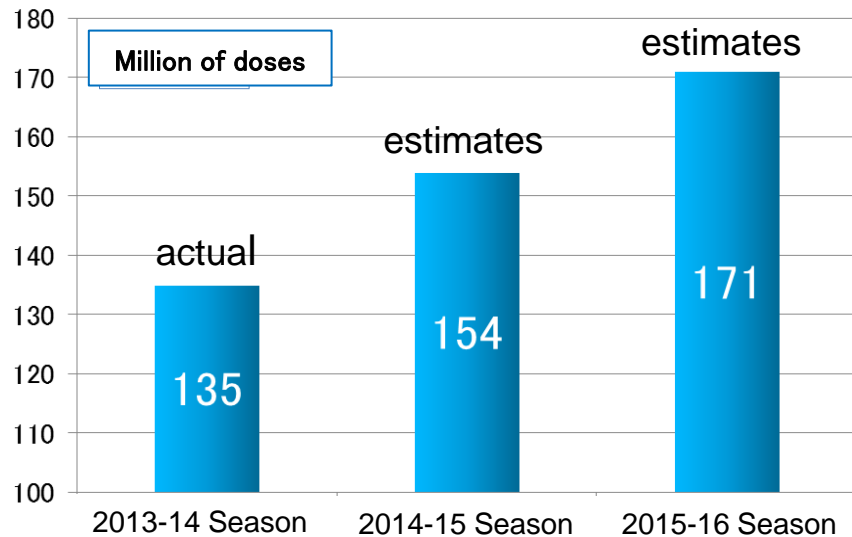
(※1) Flublok® : The world's first recombinant protein-based vaccine for the prevention of seasonal influenza developed by PSC, which was approved by FDA in January 2013. UMN-0502 is copy of Flublok® and the license for Japan obtained by UMN

# US Flu Vaccine Market is On Steady Growth

– Supply of 170 Mil doses estimated for 2015-16 Season in US

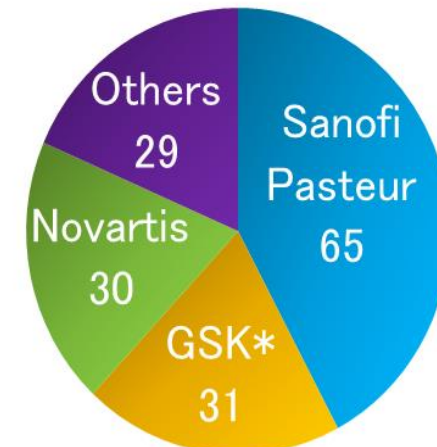
- Oligopoly : 3 Big Players Dominate the Current US Flu Vaccine Market
- US Flu Vaccine Market has realized Steady Growth for past 10 years (CAGR 8%)
- Accelerated Growth observed during the past few years (CAGR 13%)

## US Flu Vaccine Market (No. of Supply)



## Major Players in US Flu Vaccine Market

(Unit : Million doses, 2014-15 season)



In July 2015, the influenza vaccines of Novartis joined CSL, a global specialty biotherapeutics company

Approximately 1 million doses of Flublok® were manufactured by PSC during 2015-16 season, which is almost the upper limit of PSC's capacity

Marketing strategy to increase market share of Flublok® is currently under consideration by PSC

Source : <http://www.cidrap.umn.edu/news-perspective/2014/07/us-flu-vaccine-supply-expected-top-150-million-doses>  
<http://www.cidrap.umn.edu/news-perspective/2015/10/us-flu-levels-low-new-seasons-reporting-starts>

# Business Potential : Supplying Flublok® to US Market



— Business value could exceed that of Japan

	Japan	US
Market Size (Annual Supply)	60 Mil Doses	150 Mil ~ 170 Mil Doses
Unit Price (Egg-based, Quadrivalent,	@¥1,500 (※1)	Private Sector @US\$16~18 (※2) Government(CDC) @US\$12~13 (※2)
Cost Structure	<u>Supplying Drug Products</u> Cost Structure: <ul style="list-style-type: none"><li>— Cost of Manufacturing</li><li>— Filling Cost</li><li>— Royalty payment to PSC</li></ul>	<u>Supplying Drug Substances</u> Cost Structure <ul style="list-style-type: none"><li>— Cost of Manufacturing</li></ul>

(※1) Source : <http://mainichi.jp/articles/20151025/ddm/041/040/065000c>

(※2) Source : CDC (US) HP [http://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/index.html?s\\_cid=cs\\_000](http://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/index.html?s_cid=cs_000)

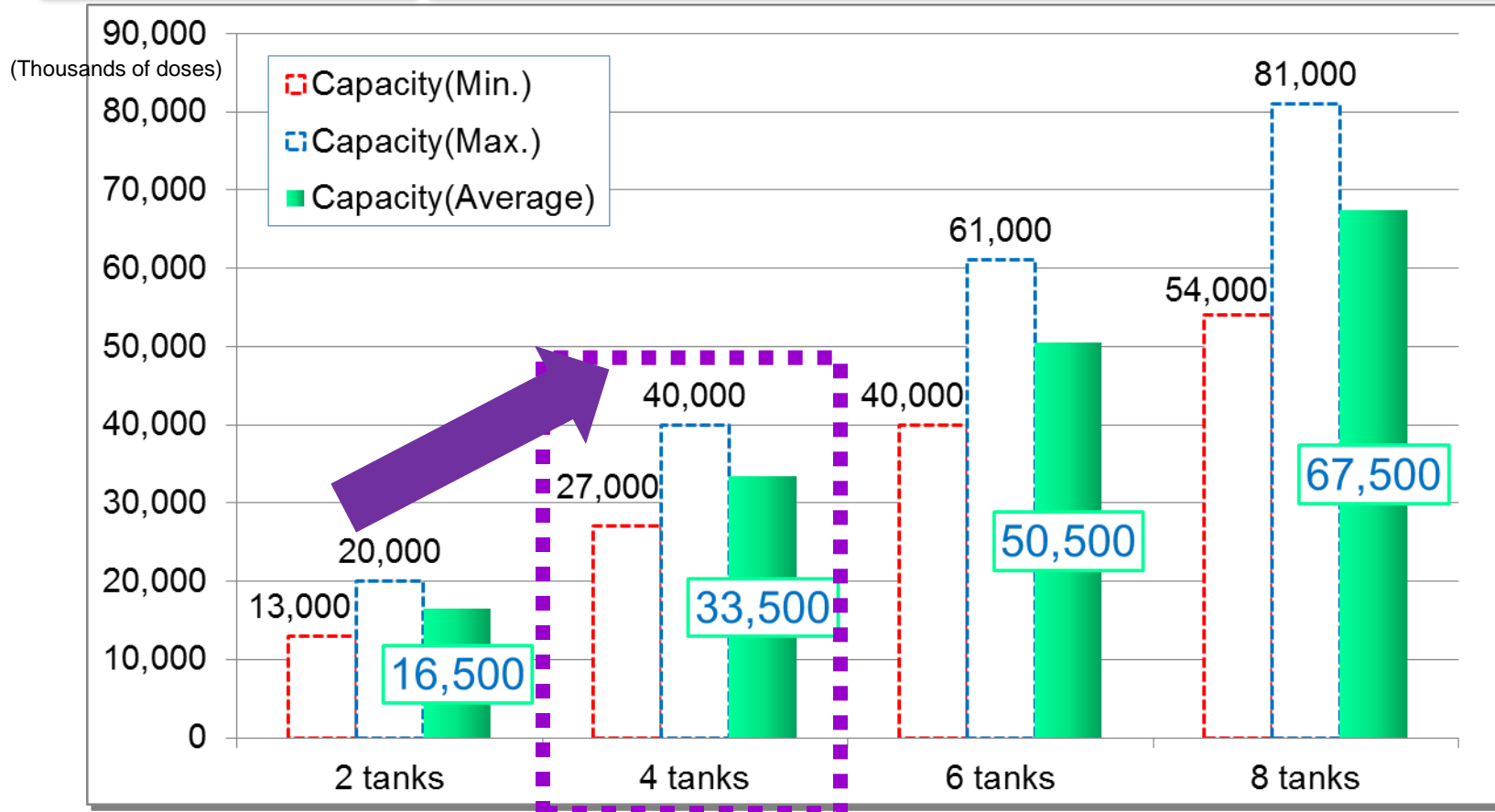
# Manufacturing Capacity of Gifu Plant : Additional Expansion Decided



- Decided to enhance capacity of Gifu plant to four 18,000L tanks, up from current two, in order to meet projected US demands

## Details

- ◆ Amount of Investment : ¥2.6 billion (tax excluded)
- ◆ Completion of Construction : December, 2016



➤ Actual manufacturing volume depends upon such factors as yield of strains, period of operation, specifications of drug., etc. The expected manufacturing capacity takes such variable factors into account, but the actual figures could be different

- UMN : Provided VLP antigen produced by refined process
- Daiichi-Sankyo : Conducted basic research using the VLP antigen



## 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

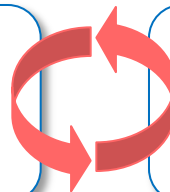
### Scheme of Collaboration



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 as of Dec.31, 2015】

- Provided Daiichi-Sankyo with VLP antigen produced by refined process
- Established more refined process for VLP antigen, conducting nonclinical antigenicity test



– Obtained additional 2 contracts during FY2015

- The projects are to be concluded for the clients' acceptance during FY2016 or later
  - Sales are expected to be posted after their acceptance

Contracts for  
Leveraging  
BEVS Platform

Leading to Future  
Full-fledged Contracts  
Out of Seeds for  
Novel Drugs

- NIID\*\*
  - Accumulation of Further Contracts
- University A
  - Taken over NIID Contract
- Company A
  - **Evaluation for Applicability of BEVS Platform**

Contracts for  
Making Full Use of  
Facilities & Resources

Leading to Future  
Advanced Contracts for  
R&D & Larger-scale  
Manufacturing

- Company B
  - **Feasibility Study for Contract Manufacturing : Taking care of a part of manufacturing process for the existing drug**

\* BCMO : Biopharmaceutical Contract Manufacturing Organization

\*\*NIID : The National Institute of Infectious Diseases

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Upon obtaining approval for UMN-0502 and after successfully commencing the commercial production, we will receive a certain amount of milestone payments pursuant to the agreement with Astellas of September 2010, and thus realize revenue from sales of UMN-0502 product.

As the approval has not yet been obtained nor we have enough information and assurance for it, the receipt of the milestone payments and booking of the revenue during this fiscal year are uncertain at this point. Therefore, the related sales could fluctuate considerably.

Among the other pipelines, we will accelerate UMN-2002, which is the joint research with Daiichi Sankyo, so as to receive proceeds based on the research contract, and expand furthermore the biopharmaceutical contract manufacturing business.

We will also engage in absolute cost-control activities in order to further reduce expenses. However, some R&D expenses are projected as we will continue to collect necessary data to obtain approval for marketing of UMN-0502, conduct R&D activities for better production efficiency at Gifu plant and further accelerate activities for the project of exporting Flublok® drug substances from Gifu plant to the US market.

As reasonable forecasts of consolidated net sales, operating income, ordinary income, and net income for Fiscal Year ending December 31, 2016 (FY2016) cannot be made at this point, the forecasts for FY2016 will be disclosed as soon as it becomes available.

# Growth Strategy: Paths & Goals to be Achieved through FY2020

—Establish Position as Global Bio-Pharma by Leveraging BEVS Platform



## Critical Challenges to be Addressed in order to Achieve our Strategic Goals by FY2020

- Expansion of manufacturing capacity and enhancement of manufacturing efficiency at Gifu plant in order to meet expected future demands of UMN-0502 in Japan / Flublok® in the US
- Global deployment of our in-house pipeline
- Aggressively seek for promising seeds, technologies and IP's for our sustainable and accelerated Growth

## Establish Revenue Base on UMN-0502 in Japan

### Concentrate All the Resources on the following

Accommodate Review Process for Approval of UMN-0502 by MHLW / PMDA

Accommodate GMP Compliance Inspection at Gifu Plant by MHLW / PMDA

# FY2016 Top Priority : Overseas Development

– Accelerate actions so as to start exporting Flublok® to US from 2017-18 Season



## Export UMN-0502 (Flublok®) Drug Substances Manufactured at Gifu Plant to U.S. and Asian Markets, making full use of Capacity

Goal : Start exporting Flublok® to US from 2017-18 Season

		Current status	Important issues to be addressed	
U.S. Market	UNIGEN	PSC's Gifu plant audit finished, cGMP literacy training & preparation for FDA inspection at Gifu plant under way	Preparation for FDA pre-(Type C) meeting & FDA inspection of Gifu plant, further enhancement of practical cGMP literacy	Regulatory inspection of Gifu plant by FDA
	PSC	Preparing for submission of FDA licensure application, gap analysis of manufacturing process in progress, submitted application for FDA pre-(Type C) meeting	FDA Type C meeting expected during April 2016	Regulatory inspection of Gifu plant by FDA , submission of application for the licensure to FDA
	Coacting	Reached agreement on basic terms such as production schedule, logistics, commercial terms, etc.	PSC and UNIGEN shall enter into; 'Supply Agreement for Drug Substance of Flublok®' and 'Quality Agreement'	

## Preparing for Documents / Investigational drug for PIII clinical study in Korea

- Planning to provide Ildong Pharmaceutical Co., Ltd. with related documents
- Preparing for supply of investigational drug for expected PIII clinical study

Develop Novel Vaccines, including UMN-2002, by Further Leveraging BEVS Platform,  
so as to Address Unmet Medical Needs

Continuing to carry out the research to verify the possibility  
with Daiichi Sankyo under the joint research agreement

UMN-  
2002

- Continuing to carry out the research to verify the possibility of UMN-2002 development using Daiichi Sankyo's device for new administration.
- Provided Daiichi-Sankyo with VLP antigen produced by refined process and Daiichi Sankyo conducted basic research using the VLP antigen.
- Further advance is being under consideration between the two companies.

Pursuing possibilities to make existing contracts advance to alliance

BCMO

- Further progress on existing contracts are under consideration
  - Possibilities of stepping forward to the next stage / IP licensing
- Assessing business values, seeking possibilities of forming alliance

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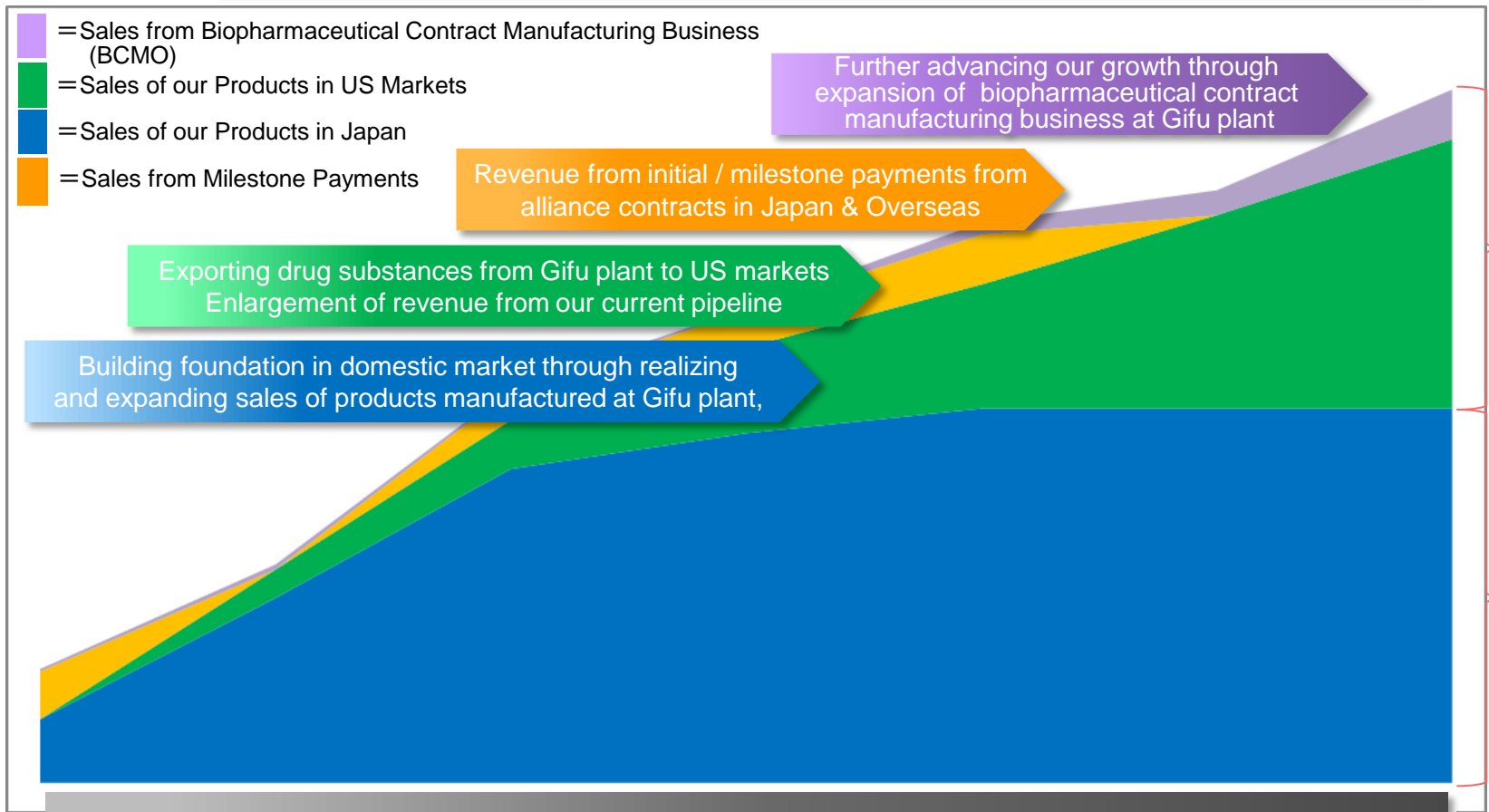


# Growth Strategy: Update

- Sales base establishes on UMN-0502 in Japan & exporting drug substances from Gifu to US
- Additional growth expected on UMN-2002 project, sustainable steady growth through BCMO business



Worldwide business development of UMN-2003/2002 (Norovirus/ Rotavirus Vaccine)  
 Providing total solution for next-generation biopharmaceuticals, from research through production



Long-term growth factors (Source of additional value)

Business foundation (Cash cow)

Mid to Long-term Business Growth 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 FY2016 — FY2019

In-House Pipeline	UMN-0502	<p>Japan</p> <ul style="list-style-type: none"> <li>➤ Obtaining marketing approval for UMN-0502 &amp; start commercial production at Gifu plant</li> <li>➤ Increase manufacturing capacity in order to meet projected future demands</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> </ul> <p>Overseas</p> <ul style="list-style-type: none"> <li>➤ Start exporting Flublok® to US from 2017-18 Season</li> <li>➤ Implement clinical development in South Korea, leading to start exporting DS from 2018</li> </ul>
	UMN-0501	
	UMN-0901	
	UMN-2003/ 2002	
Biopharmaceutical contract manufacturing	<ul style="list-style-type: none"> <li>➤ Achieve satisfactory results on the existing contracts</li> <li>➤ Make the existing contracts up to form an alliance, further up to future in-house pipeline</li> </ul>	
Development of human resources	<ul style="list-style-type: none"> <li>➤ Strengthen HR function in order to secure future management qualified personnel</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 / Secure timely disclosure function</li> </ul>	

# Disclosure of Financial Targets of Mid-term Business Plan from Fiscal Year 2016 to Fiscal Year 2019 ending December 31



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As for the financial targets of mid-term business plan from fiscal year 2016 (FY2016) to fiscal year 2019 (FY2019) ending December 31, reasonable forecasts cannot be made at this point as well. The forecasts for the financial targets of mid-term business plan from FY2016 to FY2019 will be disclosed as soon as it becomes available.

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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