



TSE Code : 4585

Financial Results for Fiscal Year 2013



Addressing Unmet Medical Needs
UMN Pharma Inc.

Tatsuyoshi Hirano
Chairman & CEO

February 17, 2014

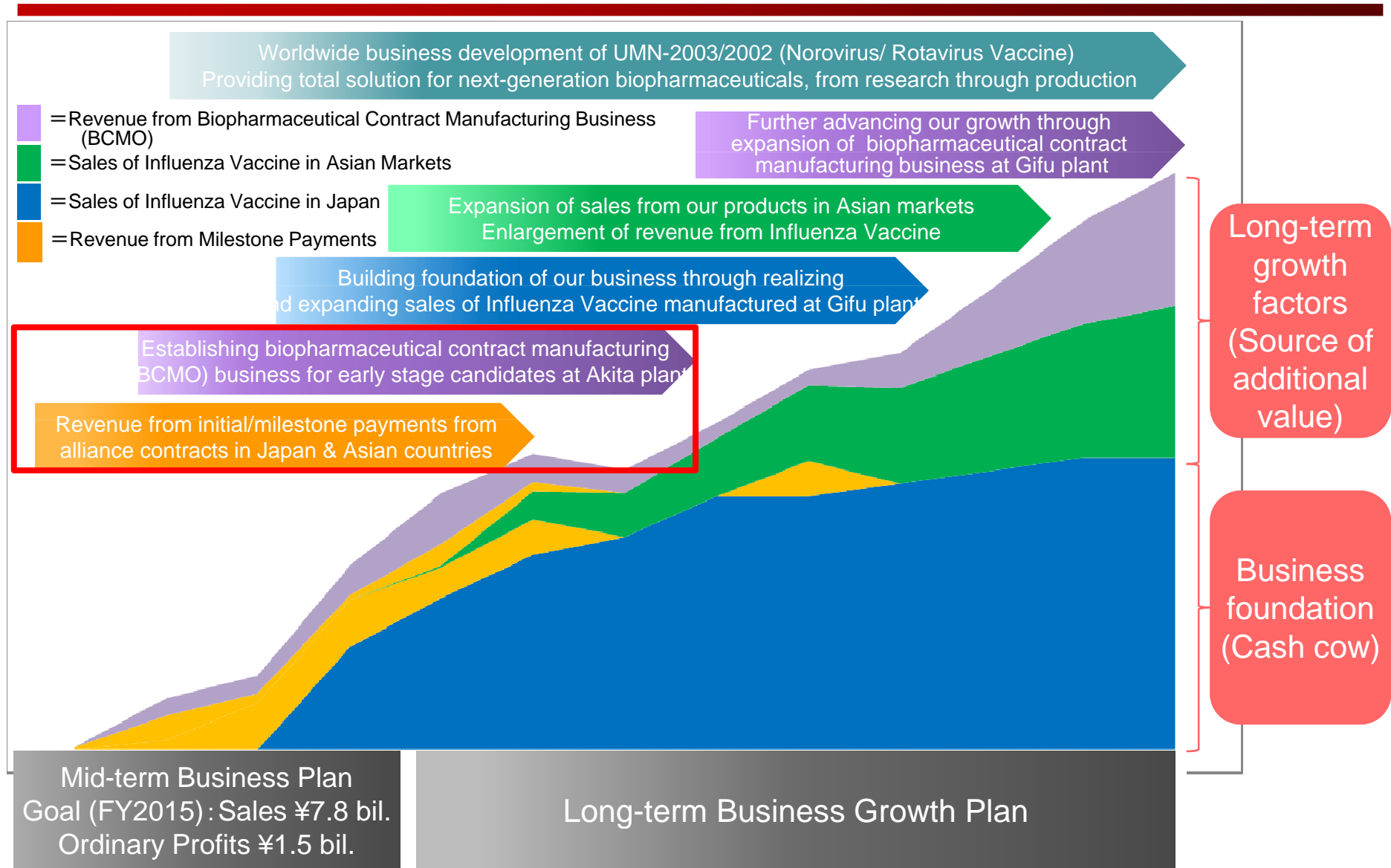
- Business Results of Fiscal Year 2013
 - Financial Results
 - R&D Activities
 - Business Development
(In-house Pipeline)
 - Business Development
(Biopharmaceutical Contract Manufacturing Organization Business)

- Business Plan for Fiscal Year 2014

- Mid-Term Business Plan : FY2013 - FY2015
 - Growth Strategy & Action Plan
 - Financial Goals

Progress Review of Our Growth Plan

- Sales shortage from our FY 2013 plan due to delay in development in Asian markets and BCMO
- UMN-0502 on schedule for application for approval (NDA) in Japan planned in FY2014



Analysis: Unmet Factors for FY 2013 Compared to the Initial Plan

- Delayed business development in China and establishment of BCMO



Establishing
biopharmaceutical contract
manufacturing (BCMO) business
for early stage candidates
at Akita plant

【Plan】

- Obtaining several contracts.

【Results】

- Signed an agreement with Yakult Honsha Co., Ltd. and API Co., Ltd. to co-develop and commercialize bio-similars on oncology, but still staying in study phase.
- Obtained several orders from National Institute of Infectious Diseases and other pharmaceutical companies, but the volume remained low.

Revenue from
initial/milestone payments from
alliance contracts
in Japan & Asian countries

【Plan】

- Broad ranged alliance activities, resulting in accumulation of initial/milestone payments from contracts.
- Sign alliance contract for Chinese markets during FY 2013.

【Results】

- Signed first refusal rights with Taiwan's Adimmune Corporation for marketing in Taiwan and China.

Consolidated Financial Results for FY2013 ended Dec.31, 2013 vs FY2012



- Sales: Shortage of plan due to delay in business development in Asia & BCMO
- Expenses: Increased due to starting trial operation at Gifu plant

(Millions of yen) Except for per share data	FY2012 (Consolidated)	FY2013 (Consolidated)	Change (fractions dropped)		Major factors of the change
Net sales	108	93	(15)	86.3%	Contract money / Milestones (36) BCMO sales +21
Cost of sales	17	27	+ 10	157.3%	Royalty payment to PSC (9) Cost of sales of BCMO +19
R&D expenses	1,649	3,925	+ 2,276	238.0%	Outsourcing expenses (247) Depreciation +1,267 Supplies expenses +928
Other SG&A expenses	514	562	+ 48	109.5%	Salaries (40) Professional Fee Consideration +40 Tax +13
Operating income	(2,072)	(4,421)	(2,349)	213.4%	
Ordinary income	(2,652)	(4,147)	(1,495)	156.4%	Non-operating income / expenses Subsidy Income +513 Commission for syndicated loan (488) Interest expenses (189)
Net income	(1,996)	(3,717)	(1,721)	186.1%	Adjustment for tax +52 Minority interests +155
Net income per share	¥(420.61)	¥(491.59)			
Net assets per share	¥599.10	¥498.74			

Consolidated Balance Sheets as of Dec.31, 2013 vs. Dec.31, 2012

- Total assets at ¥19,001 million, increased due to additional investments in Gifu plant
- Upon completion of Gifu plant, account title changed from construction in process



Account	FY2012 (ended Dec.31,2012)	FY2013 (ended Dec.31,2013)	Change*	Remarks
Assets	(Millions of yen)	(Millions of yen)	*fractions dropped	
Current assets				
Cash on hands/banks	3,882	4,267	384	
Raw materials/supplies	33	106	72	
Other	273	1,022	749	Accrued consumption tax receivable due to completion of construction
Total current assets	4,190	5,396	1,206	
Fixed assets				
Property, plant & equip..				
Buildings & structures	424	6,054	5,629	Transferred from in-progress A/C
Machinery, & equipment	81	5,968	5,886	Same as above
Construction in progress	8,781	1	(8,780)	Transferred to other A/C
Other	307	802	495	Increase of leased assets
Intangible fixed assets	39	411	371	Production management system
Investments & others	206	367	160	Increase of Long-term receivable
Total fixed assets	9,841	13,605	3,764	
Total assets	14,031	19,001	4,970	

Consolidated Balance Sheets as of Dec.31, 2013 vs. Dec.31, 2012 (continued)



- Short-term & Long-term Loans at ¥13,069 million, increased due to payments related to Gifu plant
- Total Liabilities at ¥14,748 million, increased ¥5,085 million

Account	FY2012 (ended Dec.31,2012)	FY2013 (ended Dec.31,2013)	Change *	Remarks
Liabilities	(Millions of yen)	(Millions of yen)	*fractions dropped	
Current liabilities				
Short-term loan	—	1,484	1,484	For operation
Long-term loan due within one year	1,100	2,710	1,610	Part of syndicated loan payable within 1 year (Upon receipt of subsidy from METI)
Account Payable	136	382	246	Supplies for Gifu
Other	79	151	71	
Total current liabilities	1,316	4,728	3,411	
Long-term liabilities				
Long-term loan	7,810	8,875	1,065	Syndicated loan
lease obligations	165	549	383	Lease obligation/machinery at Gifu
Other	370	596	225	Asset retirement obligation
Total long-term liabilities	8,346	10,020	1,674	
Total liabilities	9,662	14,748	5,085	

Consolidated Balance Sheets as of Dec.31, 2013 vs. Dec.31, 2012 (continued)

- Common Stock & capital surplus increased due to investment & exercise of warrants by Astellas
- Equity capital ratio at 22.1%, decreased due to increase of loans



Account	FY2012 (ended Dec.2012)	FY2013 (ended Dec.2013)	Change*	Remarks
Net assets	(Millions of yen)	(Millions of yen)		*fractions dropped
Shareholders' equity				
Common stock	5,152	6,956	1,804	Common stock & capital surplus increased due to investment by Astellas & exercise of warrants
Capital surplus	4,821	6,625	1,804	
Retained earnings	(5,662)	(9,379)	(3,717)	Due to Net loss incurred
Treasury stock	—	(0)	(0)	
Total Shareholders' equity	4,311	4,202	(109)	
Accumulated other comprehensive income				
Unrealized holding gains on securities	5	—	(5)	Sales of Investment security
Total accumulated other comprehensive income	5	—	(5)	
Stock subscription rights	—	6	6	
Minority interests	52	44	(7)	
Total net assets	4,369	4,253	(115)	Equity capital ¥4,202 (FY2013)
Total liabilities & net assets	14,031	19,001	4,970	

FY2013 Progress in R&D Activities : In-House Pipeline

- UMN-0502(ASP7374) positive top-line results from two phase III studies
- Planned to file in FY2014 in Japan



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 (1 arm)
Number of subjects : 55
Primary endpoint : Immunogenicity

【Immunogenicity】

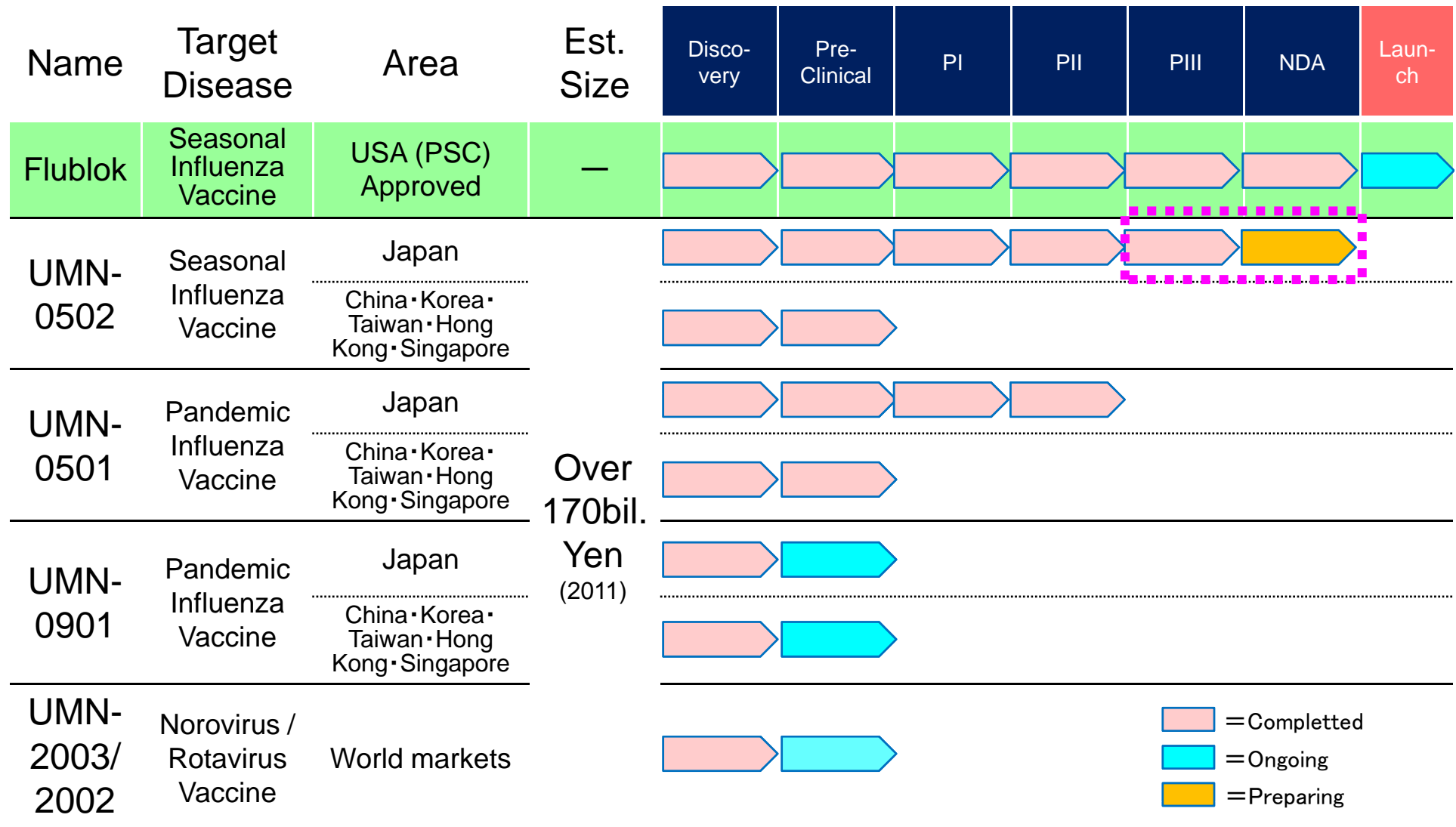
The study showed favorable immunogenicity of intramuscularly-administered UMN-0502(ASP7374)

【Safety】

No major safety problem was observed.

Current Progress of In-House Pipeline

- UMN-0502: Preparing for NDA filing during FY2014 in Japan



FY2013 Progress in Partnership ① : Business Development in Asia

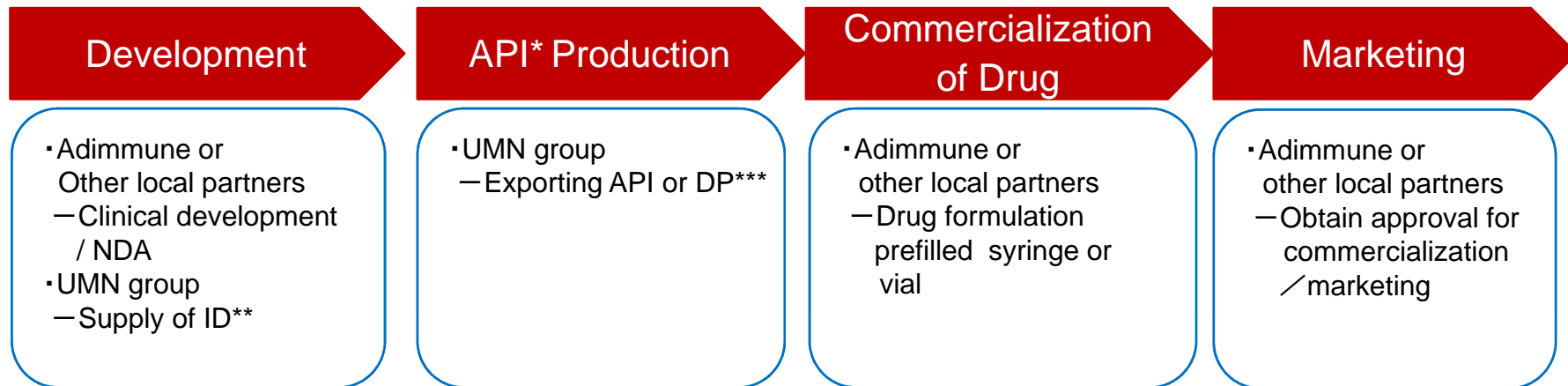


- Agreed with Adimmune Corporation to provide the first refusal right for Commercialization of UMN-0502, UMN-0501, and UMN-0901 in Taiwan and China

Terms of Agreement

- First refusal right for Commercialization of UMN-0502, 0501 and 0901 in Taiwan and China
- Consultation of clinical development in Taiwan & China to provide
- Formulation process for prefilled syringe at Adimmune's plant to cooperate in the future

Scheme of Collaboration



*API = Active Pharmaceutical Ingredient

**ID = Investigational Drug

***DP=Drug products

Adimmune Corporation

Head office: Taichung, Taiwan Representative: 董事長 詹啓賢
Net sales: TWD 387.2 million (US\$ 12.78 million) No. of employees: 284
Business description: , Development, manufacturing and marketing of vaccines & biological products

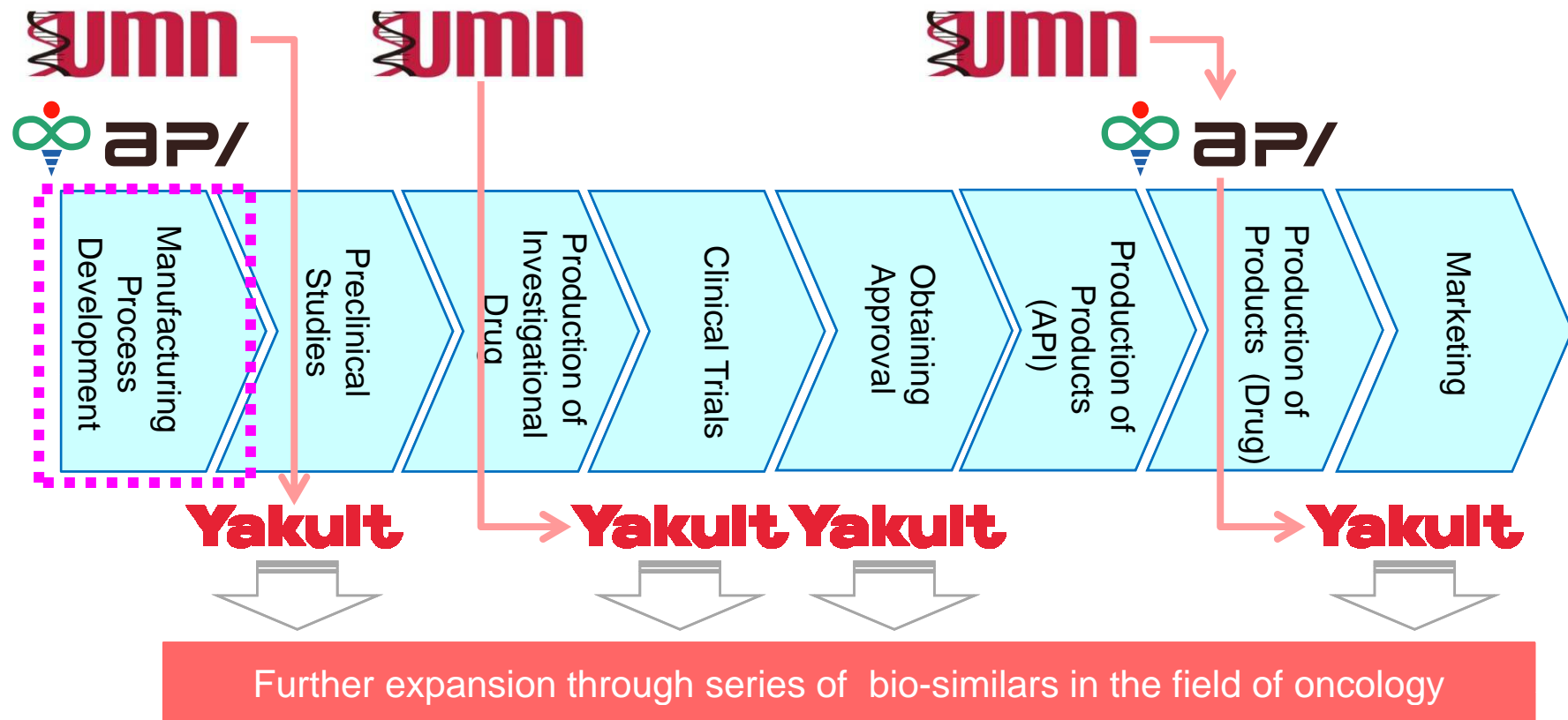
FY2013 Progress in Partnership ② : BCMO Business

- Reached agreement with API & Yakult Honsha to co-develop and commercialize bio-similars in the field of oncology (June, 2013 & Dec. 2013 for different candidates)



To Take advantage of the strength of each company, planning to establish competitive value-chain

- UMN and API will be in charge of process development and manufacturing of the drug substances and drug products
- Yakult Honsha will be responsible for development and marketing, taking advantage of its strong presence in the field of oncology





FY2013 Progress in Partnership ③ : Steps Forward to Next Seeds

- Obtained orders from NIID (※) to produce candidate antigens for novel vaccines
- Obtained another order to produce candidate protein for novel drug



To obtain orders by leveraging our capacity

- Focus on obtaining orders leveraging BEVS platform, which could maximize our value
- Drive collaboration with research institutions from early stage for development of future seeds

		Platform Technology	
		BEVS	Non-BEVS (CHO / other cell)
Business Model	Joint R&D	To maximize our value by BEVS platform 	 Yakult Accumulation of track records for stable source of earnings
	Fee for Service	NIID* : Antigens for novel vaccine Company X : Production of protein as candidate for novel drug	To obtain orders of production by leveraging our state of the art manufacturing facilities

*NIID = National Institute of Infectious Diseases

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Business Plan For 2014 : Actions To Be Accomplished

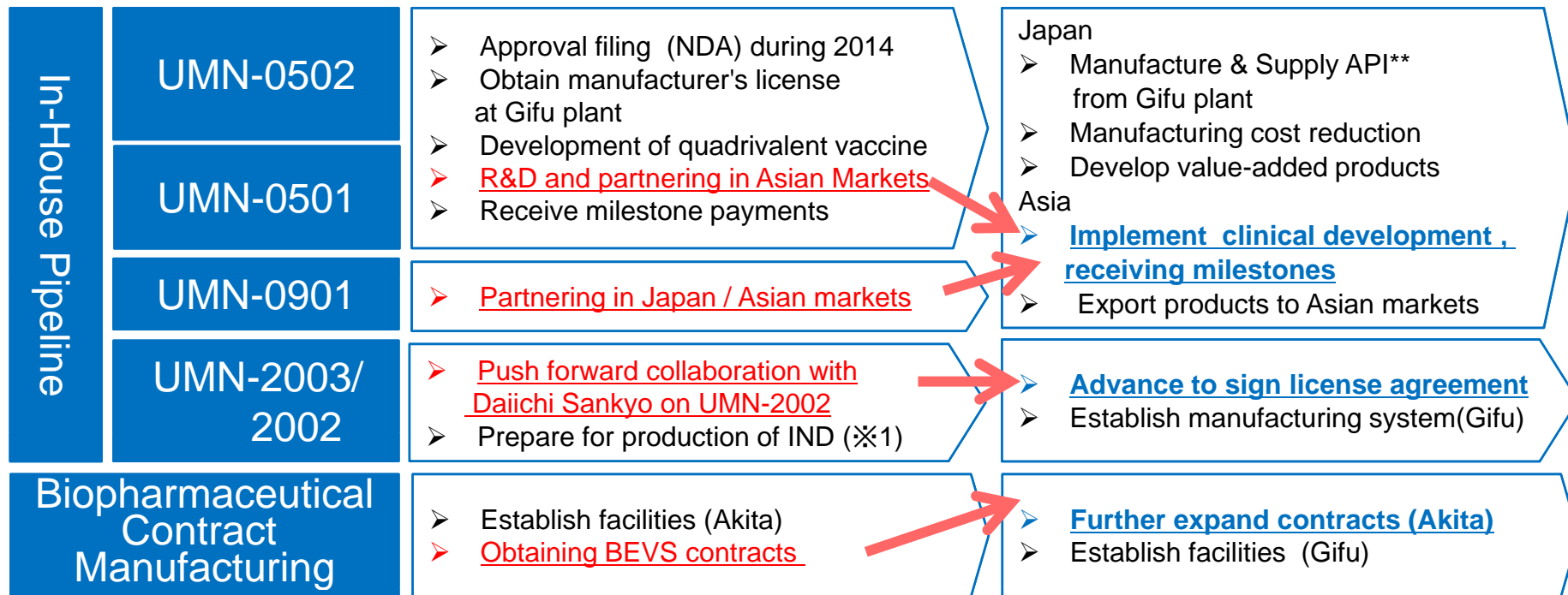
- In-house pipeline: UMN-0502 NDA , development in Asia, and collaborative research for norovirus project
- BCMO : additional contracts mainly on BEVS and collaboration with Yakult Honsha



Focus on following 3 Major actions to recover the delayed plan during FY2013

- ① Chinese market (UMN-0502,0501,0901) : Drive alliance negotiation
- ② Norovirus vaccine (UMN-2002) : Push forward collaboration with Daiichi Sankyo
- ③ BCMO business : Obtain additional contracts (on existing projects / new projects)

FY2013 – FY2015 Action plan for our mid-term business plan



*IND = Investigational New Drug

**API = Active Pharmaceutical Ingredient

Forecast for FY2014 Consolidated Financial Results (Conservative forecast)



- Sales: Aim at upside sales instead of conservative forecast for sales
- Expenses: Increase costs for establishing manufacturing system at Gifu, development of quadrivalent vaccine

(Millions of Yen)	FY2013 Actual(Cons.)	FY2014 Forecast(Cons.)	Change (Fractions dropped)		Major factors of the change
Net sales	93	2,186	+2,092	2,341.0 %	Contract money / Milestones 1,840 BCMO sales 346
Cost of goods	27	361	+333	1,326.2 %	Royalty payment to PSC 294 Cost of sales of BCMO 66
R&D expenses	3,925	4,474	+549	114.0%	Depreciation 1,919(Including lease) Supplies expenses 954 Salaries 457 Energy expenses 251
Other SG&A Expenses	562	560	(2)	99.6%	Salaries 210 Taxes 156 Consideration 51
Operating income	(4,421)	(3,210)	+1,211	72.6%	
Ordinary income	(4,147)	(3,424)	+724	82.5%	Interest expenses 214
Net income	(3,717)	(2,436)	+1,281	65.5%	Subsidy income 2,213 Loss of reduction entry 1,986 Minority interests Δ794
Net income per share	¥(491.59)	¥(289.11)			

Forecast for FY2014 Consolidated Financial Results : Sales



- Partnership : Receipt of milestone payment on UMN-0502 NDA, and partnership contracts in China
- BCMO Business : Revenues regarding collaborative agreement for UMN-2002 & new BCMO orders

Breakdown of sales (Millions of yen)	FY2011 Actual(Cons.)	FY2012 Actual(Cons.)	FY2013 Actual(Cons.)	FY2014 Forecast(Cons.)	FY2014 (Initial plan)
UMN-0502	—	—	—	—	—
Sales of product					
Milestone payment /Contract money	1,000	108	72	1,840	2,400
BCMO business	—	—	20	346	744
Total net sales	1,000	108	93	2,186	3,144

		Point	Details
In-House Pipeline	Milestone payment / contract money	Astellas Pharma, business development in China	Japan : ➤Receipt of milestone payment from Astellas Pharma, Inc. upon filing for regulatory approval (NDA) based upon the agreement dated September 21, 2010 East Asia : ➤Contract money on partnership agreement in China
	Biopharmaceutical contract manufacturing business	Revenues from collaborative agreement for UMN-2002, orders obtained for BCMO(BEVS)	UMN-2002 : ➤Revenues regarding Collaborative Agreement with Daiichi Sankyo BCMO Business : ➤Obtaining BCMO orders leveraging BEVS technology ※Revenues from Agreement with Yakult Honsha and API for co-development & commercialization of biosimilars in the fields of oncology will start booking from FY2015

Forecast for FY2014 Consolidated Financial Results : SG&A



- Process Validation (PV) at Gifu Plant following application of Pharmaceutical Manufacture, and Inspection of Japan FDA
- Preparation for quadrivalent flu vaccine

Breakdown costs (Millions of yen)	FY2011 Actual(Cons.)	FY2012 Actual(Cons.)	FY2013 Actual(Cons.)	FY2014 Forecast(Cons.)	FY2014 Initial plan(Cons.)
Cost of sales	160	17	27	361	742
R&D expenses	1,474	1,649	3,925	4,474	3,140
Other SG&A expenses	441	514	562	560	571
Total of SG&A expenses	1,915	2,163	4,488	5,035	3,711
Depreciation	156	124	1,404	1,935	1,738

	Point	Details
R&D expenses	PV manufacturing, development of quadrivalent flu Vaccine	R&D expenses expected to increase during FY2014 due to incurring R&D costs at Gifu plant throughout the year. UMN-0502 : <ul style="list-style-type: none"> ➤ Process validation (PV) manufacturing for GMP Inspection ➤ Acquisition of various quality data for development of quadrivalent flu vaccine
Other SG&A expenses	Lower than FY2013, covering increase of fixed asset tax	<ul style="list-style-type: none"> ➤ Fixed asset tax at Gifu plant of ¥110 Million is to be charged starting FY2014 ➤ Reduction in other costs resulted in less total administrative expenses for FY2014 than FY2013 despite fixed asset tax

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Mid-term business plan for on & after FY2016 will be released after ongoing talks with Astellas regarding sales plan for UMN-0502

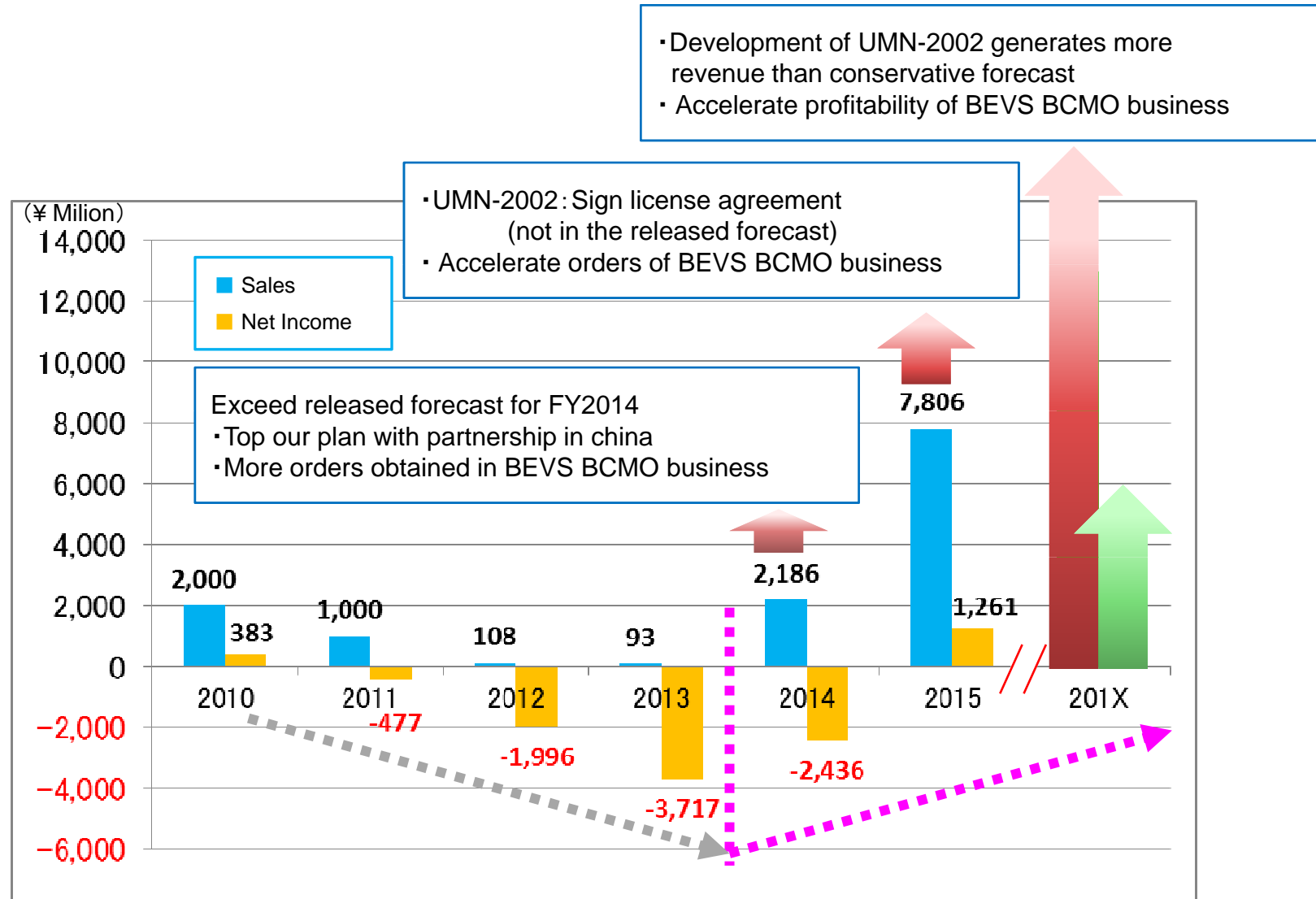


➤ Based upon the summary results in PIII clinical trials of UMN-0502 (ASP7374), released on January 15, 2014, UMN and Astellas Pharma Inc. have started talks regarding profile of the drug and sales plan after the regulatory approval for commercialization.

➤ As the outcome of the talks will seriously influence our future financial conditions, our mid-term business plan starting FY2016 will be disclosed soon after finishing the talks with Astellas Pharma Inc.

Catch Up Plan : From FY2014 and After

- UMN-2002 : Advance to sign license agreement, increase future flows of revenues
- BCMO business : Obtain additional contracts, mainly on BEVS (on existing projects / new projects)



FY2013 -2015 Mid-Term Business Plan's Goal



Not only realizing profits in FY 2015, but setting stable foundation for sustainable growth after FY2016 while monetizing initial investments

FY2013 – FY2015 Action Plan for Our Mid-Term Business Plan

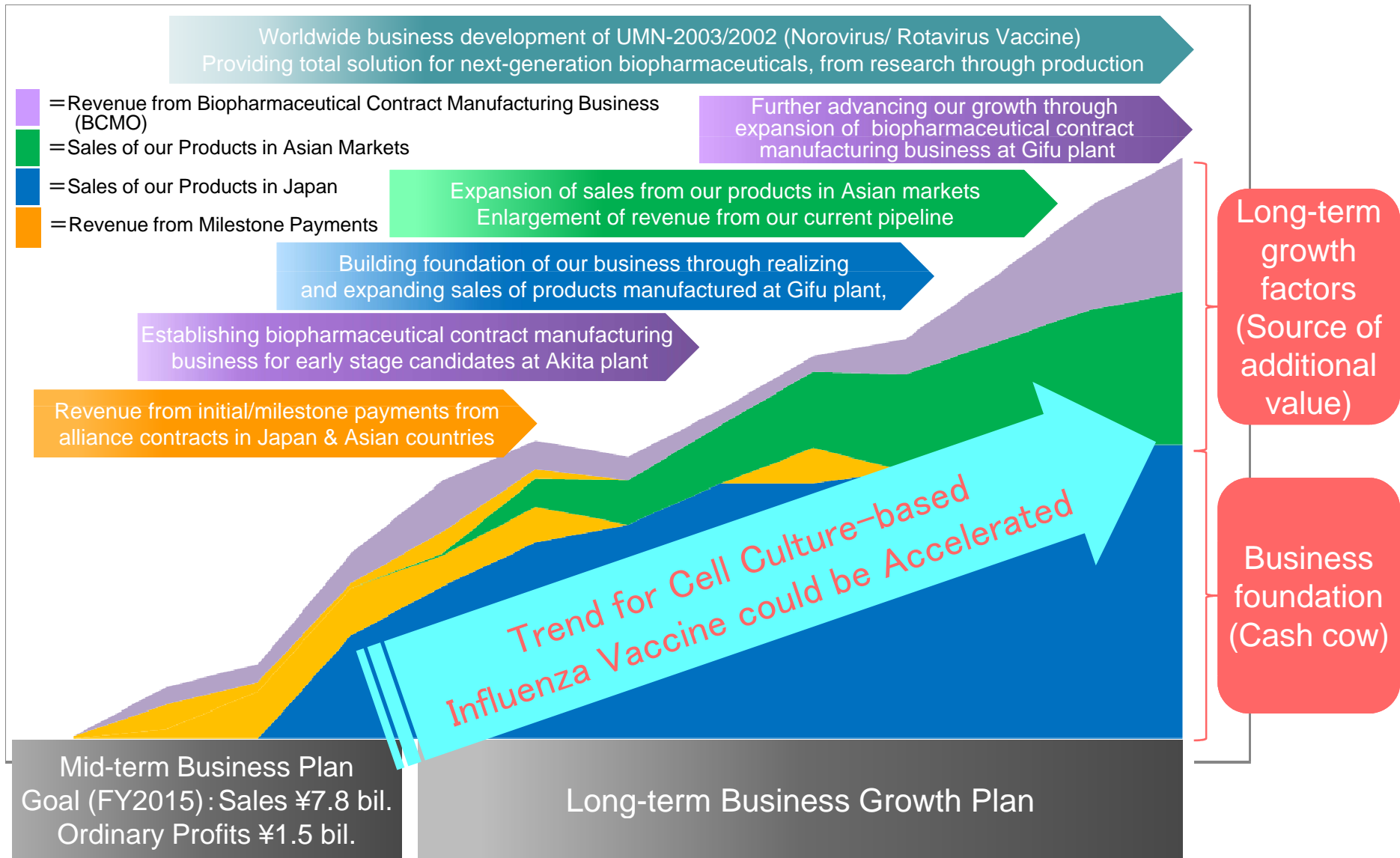
In-House Pipeline	UMN-0502	<ul style="list-style-type: none"> ➤ Approval filing (NDA) during 2014 ➤ Obtain manufacturer's license at Gifu plant 	<p>Japan</p> <ul style="list-style-type: none"> ➤ Manufacture & supply API* from Gifu plant ➤ Manufacturing cost reduction ➤ Develop value-added products <p>Asia</p> <ul style="list-style-type: none"> ➤ Implement clinical development , receiving milestones ➤ Export DS / DP to Asian markets
	UMN-0501	<ul style="list-style-type: none"> ➤ Development of quadrivalent flu vaccine ➤ R&D and partnering in Asian markets ➤ Receive milestone payments 	
	UMN-0901	<ul style="list-style-type: none"> ➤ Partnering in Japan / Asian markets 	
	UMN-2003/2002	<ul style="list-style-type: none"> ➤ Push forward collaboration with Daiichi Sankyo on UMN-2002 ➤ Establish manufacturing system 	
Biopharmaceutical contract manufacturing	<ul style="list-style-type: none"> ➤ Obtain BEVS contracts ➤ Increase clinical development Productivity & speed for bio-similar 	<ul style="list-style-type: none"> ➤ Further expand contracts ➤ Monetize bio-similar projects 	
Development of human resources	<ul style="list-style-type: none"> ➤ Enhance recruiting function ➤ Strengthen HR development** 	<ul style="list-style-type: none"> ➤ Abundance of world-class HR 	
Organizational efficiency	<ul style="list-style-type: none"> ➤ Promote organizational efficiency ➤ Enhance IR function 	<ul style="list-style-type: none"> ➤ Strengthen organizational efficiency for global business expansion 	

* API = Active Pharmaceutical Ingredient

**Renewed Personnel-system will start from April 2014

Our Growth Plan (Released on Dec.11, 2012)

- 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



Focus on obtaining orders leveraging BEVS platform to maximize our value



Establishing biopharmaceutical contract manufacturing business for early stage candidates at Akita plant

Further advancing our growth through expansion of biopharmaceutical contract manufacturing business at Gifu plant

Focus on accumulating orders leveraging BEVS platform, develop partnership

		Platform	
		BEVS	Non-BEVS (CHO / other cell)
Business Model	Joint R&D	<p>Strengthen</p> <p>Focus on obtaining orders leveraging BEVS platform, which could maximize our value</p>	<p>Yakult</p> <p>↓</p> <p>Source of stable earnings</p>
	Fee for Service	<p>↑</p> <p>Develop small orders up to big collaborative projects</p>	<p>Obtain orders which meet profitability requirements</p>

Mid-Term (FY2013 – FY2015) Business Plan : Income Statement

- FY2014 : Realizing sales goal is minimum, further tighten cost control
- FY2015 : Profitability will be achieved, with upside potential by Asian development & UMN-2002



As UMN and Astellas Pharma are now discussing sales plan of UMN-0502, financial figures for FY2015 are left same as the Mid-Term Plan released on Feb.2013. Renewed financial plan for FY2015-6 will be disclosed soon after finishing the discussion

Consolidated Income Statement

(Millions of Yen)	FY2012 Actual	FY2013 Actual	FY2014 Forecast	FY2015 Initial plan
Net sales	108	93	2,186	7,806
Operating income	(2,072)	(4,421)	(3,210)	1,584
Ordinary income	(2,652)	(4,147)	(3,424)	1,500
Net income	(1,996)	(3,717)	(2,436)	1,261

Mid-Term (FY2013 – FY2015) Business Plan

– Breakdown of Sales (Consolidated)



Breakdown of sales (Millions of yen)	FY2012 Actual(Cons.)	FY2013 Actual(Cons.)	FY2014 Forecast(Cons.)	Fy2015 Initial plan(Cons.)
UMN-0502	—	—	—	4,348
Sales of products				
Upfront/ Milestone payment	108	72	1,840	2,200
BCMO business	—	20	346	1,258
Total net sales	108	93	2,186	7,806

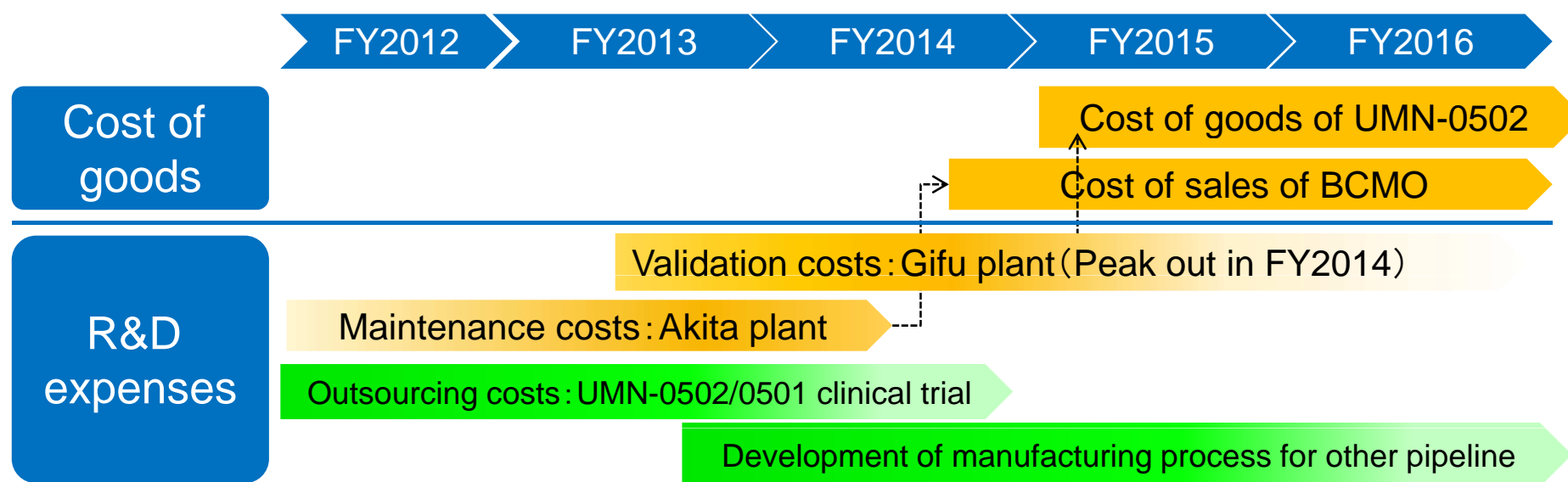
		Point	Details
In-House Pipeline	Sales of products	Recording sales from FY2015	Japan: • Plan to start commercial manufacturing & shipping of UMN-0502 from FY2015.
	Upfront/ Milestone payment	Receipt of milestone payments from Astellas, Ildong, expected partner for China are counted	Japan : • Receipt of milestone payments from Astellas Pharma based upon the agreement dated Sept.21,2010 are included. • Revenue from agreement on UMN-2002 will be counted in view of progress on collaborative research agreement with Daiichi Sankyo. East Asia: • South Korea: Receipt of milestone payments from Ildong Pharmaceutical based upon the agreement dated Dec.18, 2012 are included. • China: As we are working to reach partnership agreement during FY2014, expected receipt of milestone payments are included.
BCMO business		Business expansion of BCMO(BEVS)	Revenue from providing investigational drug for early-stage investigation & clinical trials of bio-similar candidates, receipt of order for various kind of evaluation test Services, are counted.

Mid-Term (FY2013 – FY2015) Business Plan



— Breakdown of cost of sales, R&D expenses, other SG&A expenses (Consolidated)

Details of SG&A (Millions of yen)	FY2012 Actual(Cons.)	FY2013 Actual(Cons.)	FY2014 Forecast(Cons.)	FY2015 Forecast(Cons.)
Cost of sales	17	27	361	4,467
R&D expenses	1,649	3,925	4,474	1,074
Other SG&A expenses	514	562	560	681
Total of SG&A expenses	2,163	4,488	5,035	1,754
Depreciation	124	1,404	1,935	1,322





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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