

# Supplementary Documents of Business Results for Fiscal Year 2018 ended December 31, 2018

# February 14, 2019

Addressing Unmet Medical Needs UMN Pharma Inc.



# Business Results for FY 2018

# On the Progress of the Business Policy in FY2018

- Capital and Business Alliance with Shionogi & Co., Ltd.
- Development of In-House Next-Generation Bio-Pharmaceuticals
- Other Policy Related

# Business Plan for FY 2019

- Capital and Business Alliance with Shionogi & Co., Ltd.
- Business Performance Related



## Business Results for FY 2018

# On the Progress of the Business Policy in FY2018

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### Summary of Financial Results of FY2018 (Non-Consolidated)

- Net Sales: 103 M yen->Achieved as planned, Net Loss: (728) M yen->Landing within the plan

- Net Asset: 382 M ven, Cash deposit: 1,018 M ven-> Both landing within the plan





Non-Consolidated Financial Results for FY2018 vs Forecasts on February 14, 2018

- Net Sales: Achieved as planed

- Under operating income: Improved from the initial forecasts



(Round down to less than M yen)	FY2018 FCST (Announced On Feb 14, 2018)	FY2018	Change	Remarks
Net Sales	102	103	100.7%	<ul> <li>Achieved milestones based on alliance with Shionogi &amp; Co. as planned</li> </ul>
Cost of sales	-	1	-	
R&D expenses	657	469	71.5%	<ul> <li>Reduced expenses, mainly consumables and personnel</li> <li>Partial expenses moved to 1Q of FY2019</li> </ul>
SG&A expenses	249	238	95.7%	<ul> <li>Reduced recruitment fee</li> <li>Achieved cost reduction by thorough cost control</li> </ul>
Operating income	(803)	(606)	75.5%	Significantly Improved net loss comparing with the initial forecast
Ordinary income	(809)	(609)	75.3%	Same as above
Net income	(810)	(728)	90.0%	Absorbed impairment loss due to cost reduction and movement of partial cost to 1Q of FY2019, and improved net loss comparing with the initial forecast
EPS (yen)	(63.31)	(55.12)		





CB Partial Conversion by Shionogi & Co. Ltd.

- 745 M yen (2500K shares 298yen/share) converted to common stock on October 31, 2018 - Ratio of share holding of Shionogi Co., Ltd. after CB conversion: 20.27%



- Capital stock: 679 M yen, Capital surplus: 679 M yen; increased 372 M yen each after CB conversion  $\succ$
- Net assets : 382 M yen; maintain the same level as FY2017
- CB unconverted balance at the end of FY2018: 715 M yen (2,400 K shares, 298 yen/share)



#### Trends in quarterly net assets of FY2018

Disclosed on February 14, 2018; Conversion Scenario of 1<sup>st</sup> Unsecured Convertible Bond of the Bonds with Stock Options (CB issue amount = 1,460 Mil. yen) ,anticipated from Business Performance of FY2018 - Point : Status of the 1<sup>st</sup> phase, the Company's stock price trend, and forecasts of net assets for FY2018 and FY2019

- Shionogi decides conversion policy in consideration on the progress of the 1<sup>st</sup> phase, stock price trend, and forecasts of net asset value of FY2018 and FY2019
- Consult with Shionogi on conversion policy and aim for steady CB conversion after FY2018, in order to prevent excessive debt situation





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#### Disclosed on February 14, 2018; Business Directions for FY2018

Concentrate resources on development of core technology and fundamental research on development candidates with Shionogi & Co., Ltd.
 Secure sales by steady achievement of milestones



Partnership of the 1 <sup>st</sup> Phase with Shionogi & Co., Ltd.	<ul> <li>Steady achievement of development of core technology along with milestone conditions (= realization of sales strategy)</li> <li>Improvement reliability of transition to the 2<sup>nd</sup> phase by promoting fundamental research on development candidates products</li> <li>Steady promotion of CB conversion policy</li> </ul>
Development of In-House Pipeline of Next-Generation Bio-Pharmaceuticals	<ul> <li>Steady promotion of fundamental research on development candidates from existing in-house pipeline</li> <li>Expand the possibility of selecting development candidates through fundamental research on new candidates</li> <li>Active review and introduction of novel adjuvants and formation technology</li> </ul>
Contract Manufacturing Business of Biopharmaceuticals etc.	<ul> <li>Avoid dispersal of management resources</li> <li>Accept contract business from only academia that can be candidates for future development pipeline</li> </ul>
Enhancement of R&D Bases	<ul> <li>Maintenance of Yokohama laboratory and re-launch of Akita plant</li> <li>Enhancement of each site</li> <li>Strengthen R&amp;D organization by active adoption of personnel for R&amp;D and manufacturing</li> </ul>

### Disclosed on February 14, 2018; R&D Targets in Alliance with Shionogi & Co,. Ltd

- Development of fundamental core technology: Construction of new worldwide fundamental technology

- Fundamental research on development candidates: Create optimal logical next-generation vaccine for each infectious disea

Development of Fundamental Core Technology	<ul> <li>Establish new technology platform for biopharmaceuticals including vaccine for preventing human infections         <ul> <li>Create collaborative platform of new fundamental technology that can be deployed worldwide</li> </ul> </li> </ul>			
Fundamental Research on Development Candidates	<ul> <li>Promote research, development, application, launch (product supply) of next-generation logical vaccine, combined by adjuvant and drug/drug delivery technology based on established new fundamental technology</li> <li>Development of next-generation vaccines with higher efficacy and safety</li> <li>UMN is mainly in charge of production, and Shionogi is in charge of development, application and sales.</li> <li>* Development candidates consists of part of existing in-house development pipelines and new development candidates targets</li> </ul>			
Partnership of the 1	<sup>st</sup> phase (This time) Partnership of the 2 <sup>nd</sup> phase (Schedule in FY2019)			

### Partnership of the 1<sup>st</sup> phase (This time)

<ul> <li>Improvement of fundamental technology rerated to vaccine drug production, and comprehensive construction including adjuvants and formulations</li> <li>In parallel promoting fundamental R&amp;D candidates</li> <li>UMN has an obligation for establishment of fundamental core technology</li> <li>Until FY2019, accept certain milestones every six month according to the development progress</li> <li>Capital alliance (1.63 billion yen) aimed at supporting RD, capital investment, and working capital required during the 1<sup>st</sup> phase</li> <li>*Secure business funds until December 2019</li> </ul>	<ul> <li>Select official development candidates and promote joint development, application and marketing after GLP exam</li> <li>Conclude an exclusive license agreement of official development of pipelines and marketing, and agreement of cooperation by other forms, when shifting to the 2<sup>nd</sup> phase</li> <li>Required development financing contribution scheme after the 2<sup>nd</sup> phase will be discussed later</li> </ul>
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### Disclosed on February 14, 2018; R&D Targets in Alliance with Shionogi & Co,. Ltd

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On the Progress of Capital and Business Alliance with Shionogi & Co., Ltd. -Achieved the 1<sup>st</sup> and 2<sup>nd</sup> milestones related to development of fundamental core technology as planed 1. -Steadily progress of fundamental research and of development candidates selection for the 2<sup>nd</sup> phase



### Disclosed on February 14, 2018; Upcoming Research and Development Direction Company

- Development of fundamental core technology: Construction of new worldwide fundamental technology

- Fundamental research on development candidates: Create optimal logical next-generation vaccine for each infectious disease

Development	<ul> <li>Development of a set of core technology required for development and supply of biopharmaceuticals including vaccines worldwide</li> <li>Respond to regulations in each country for approval</li> <li>Competitive with productivity and cost</li> </ul>
of Fundamental Core Technology	Development of our own core technology reflecting latest knowledge and technology
	<ul> <li>Apply established fundamental technology to development candidates sequentially</li> </ul>
	<ul> <li>Creation of logical vaccines</li> <li>Create vaccines that induce optimal immune responses for each</li> </ul>
Fundamental	target infection by combining of adjuvant and drug delivery technology
Research on Development	<ul> <li>Create more effective next-generation vaccines</li> <li>Universal Vaccine</li> </ul>
Candidates	- Vaccines to prevent infection, that are not prevention of severity
	Includes novel vaccines for infectious diseases in which vaccine market has not been introduced

Disclosed on July 31, 2017; Accelerating Development of Logical Vaccine

- Integrate new adjuvant and drug delivery system with recombinant protein antigen from our technology





# due to integration of above technology

### Disclosed on July 31, 2017; Start Joint Research with NIBIOHN

- Cutting edge pharmaceuticals, ex. novel vaccine, with high value added and high productivity using synergy both new adjuvant of NIBIOHN and manufacturing technology of UMN





# **Target of Next-Generation Logical Vaccine**





Fundamental Research on Development Candidates for Creation of Next-generation Logical Vaccine

- Create by joint research with NIBIOHN and application of various technology
- Examine multiple new candidates in addition to in-house development pipeline





#### Progress of Fundamental Research on Development Candidates for Creation of Next-generation Logical Vaccine

- Certain results in multiple development pipelines->Transition to development candidate products



- Consultation with Shionogi & Co., Ltd. for development and commercialization

Fundamental Research on Development Candidates	<ul> <li>Certain results in creating of next-generation logical vaccine in multiple in-house development pipelines         <ul> <li>Realized high efficiency and high productivity by combination of adjuvant and formulation/drug delivery technology</li> <li>Implementing application of fundamental core technology to in-house development pipelines sequentially</li> <li>in progress to intellectual property related assuming commercialization</li> </ul> </li> </ul>
Consultation with Shionogi & Co., Ltd.	<ul> <li>Both companies considering prioritizing development candidates, and reviewing for selection of development drug formulation as next-generation logical vaccine</li> <li>Both companies considering development plans for development candidates</li> <li>Both companies considering development candidates in multiple new candidates</li> </ul>

### Disclosed on July 31, 2017; What is Adjuvant?

- Chemicals enhancing the effectiveness of vaccine

- As an origin, "adjuvare" in Latin meaning "help"



- How to choice optimal adjuvant is along a good path by more deeply understanding immune response
- Adding adjuvant is an important option to vaccines against emerging infectious diseases as well as vaccines against RNA virus with easy mutation
- Adjuvant is a key to research and development of vaccine beyound infectious diseases



### On the Progress of Strengthening Functions at R&D Sites

- Yokohama Lab.: Developing mainly fundamental research on development candidates aiming for the 2<sup>nd</sup> phase - Akita Plant: Completed re-launch for milestone achievement, and continuing maintenance of GMP system



R	Yokohama Lab.: Maintenance of Experimental Environment Akita Plant: Re-Launch	<ul> <li>Completed maintenance to promote multiple projects at Yokohama Lab.</li> <li>Completed re-launch of equipment at Akita Plant, and progressing to prepare for trial manufacture</li> </ul>					
Reinforcement of	Enhancement at Each Site	<ul> <li>Yokohama Lab. and Akita Lab.:         <ul> <li>Promoting fundamental R&amp;D of development candidates</li> </ul> </li> <li>Akita Plant:         <ul> <li>Promoting R&amp;D related to fundamental core technology</li> <li>Establishing structure for GMP operation</li> <li>*Strengthening effective GMP system through support by Shionogi &amp; Co., Ltd.</li> </ul> </li> </ul>					
R&D Sites	Strengthen R&D Organization by Positive Adoption of Human Resources of R&D/Manufacturing	<ul> <li>Accelerated further adoption of personnel related to R&amp;D/manufacturing; a total of 28 members after an of 16 at Yokohama lab and Akita plant</li> <li>R&amp;D personnel FY2017 FY2018</li> <li>Yokohama Lab. 3</li> <li>Akita Lab. 5</li> </ul>				Difference 5 -1 11 <b>15</b>	



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### **Business Direction for FY2019**

- The first year toward full-scale development: Completion of the 1<sup>st</sup> phase and shift to the 2<sup>nd</sup> phase agreement
- Enhancement of financial resources, and strengthening training of R&D human resources to prepare for full-scale development

# FY2019 = The first year toward full-scale development

<Matters to be achieved>

- Achievement for the 3<sup>rd</sup> and 4<sup>th</sup> milestones
- Selection of development pipelines
- Agreement for transition to the 2<sup>nd</sup> phase

<Consultation key points of the 2<sup>nd</sup> phase>

- Maximization of business value from collaboration
- Making mid-long term WIN-WIN relationship by utilizing each strength

Source of potential growth >
Establishment of fundamental technology

- related to biopharmaceutical drug production
- Optimizing portfolio of development pipelines
- Aggressive expansion to application of fundamental technology

To realize the above;

- Enhancement of financial resources
- Expansion and improvement of R&D personnel

# Realization of sustainable growth of enterprise value

Plan to disclose figures in mid-term management plan after transition to the 2<sup>nd</sup> phase



### Major Action of FY2019: Research development and transition to the 2<sup>nd</sup> phase

- 1<sup>st</sup> phase: Steady achievement of the 3<sup>rd</sup> and 4<sup>th</sup> milestone conditions, which is progressing as planed

- 2<sup>nd</sup> phase: Advance preparatory work ahead of schedule by promoting fundamental research on development candidates



R&D and Intellectual Property Strategy on Selection of Development Candidates in F2019

- Selection of formulation for development as a next-generation logical vaccine and decision of development plan

- Discussion for use of other companies' IP related to creation of logical vaccine, and study on aggressive IP conversion of candidates

R&D	<ul> <li>Selection of final formulation as a next-generation logical vaccine of preferred development candidates         <ul> <li>Application of fundamental technology</li> <li>Selection of combination of antigen/adjuvant formulation/drug delivery technology, and selection of formulation for development</li> <li>Evaluation of effectiveness and productivity</li> </ul> </li> <li>Drawing up of non-clinical and clinical development plans of priority development candidates</li> </ul>
Strategy of Intellectual Property	<ul> <li>Discussion on utilization of external intellectual property related to creation of next-generation logical vaccine</li> <li>Positive discussion to make intellectual property related to commercialization of development candidates</li> </ul>

### FY2019 Financial Forecasts (Non-Consolidated)

- Reflect only the 1st phase R&D activities

- Plan to disclose promptly a revision plan after the 2<sup>nd</sup> phase agreement, if necessary



(Unit: M yen)	FY2018 Results (Non-consolidated)	FY2019 Forecasts (Non-consolidated)	Enrecasts Prerentiisites			
Net Sales	103	100	Sales of milestone achievement related to the 1 <sup>st</sup> phase			
Cost of sales	1	-	Cost of sales related to contracted business as R&D expenses			
R&D expenses	469	737	Promoting R&D focused on test manufacturing and establishment of manufacturing process mainly at Akita Plant, and absorb transition expenses from FY2018			
Other SG&A expenses	238	250	Increase mainly for IP and recruitment expenses anticipated * Consideration of increase in corporate tax rerated to CB conversion			
Operating Income (Loss)	(606)	(887)	Loss expansion compared to FY2018 due to strengthening of R&D activities with Shionogi anticipated			
Ordinary Income (Loss)	(609)	(891)	Bond interest and CB conversion related expenses on non-operating expenses			
Net Income (Loss)	(728)	(893)	CB conversion policy as an important point in order to maintain the net asset value positive at the end of Dec, 2019.			
Net Income (Loss) per share	(55.12)	(58.36)				
<ul> <li>The above forecasted figures that are based on information currently acquired, that can be determined to be reasonable and based on certain assumptions, however that are not intended to promise realization.</li> <li>There is a possibility that forecasts may differ due to various uncertain factors.</li> </ul>						

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Financial Forecasts for FY2019 : Cost of sales, R&D expensed, Other SG&A expenses

- R&D expenses: Record expenses only related to the 1<sup>st</sup> phase of alliance with Shionogi & Co.

- Other SG&A expenses : Estimate increase R&D personnel recruitment expenses



Account items (Unit: M yen)	FY2016 Results (Consolidated)	FY2016 Results (Non-consolidated)		FY2017 Results (Non-consolidated)	FY2018 Results (Non-consolidated)	FY2019 Forecasts (Non-consolidated)		
Cost of sales	39	51		51		3	1	-
R&D expenses	3,151		279	380	469	737		
Other SG&A expenses	444	273		219	238	250		
SG&A expenses	3,596		553	599	708	987		
Depreciation expense within the above			25 ee	*** * Fixed asset acquisition expenses are expensed by lump-sum dep				
	Points			Details				
R&D Expenses	<ul> <li>Full-scale test manufacturing of Akita plant, and development of candidates</li> <li>Full-scale CMC development using 600L of Akita plant</li> <li>Continue recruitment of R&amp;D and manufacturing personnel</li> <li>Add facility investment to support Data Integrity</li> <li>Incorporate elements of expenses shifted out of FY2018</li> </ul>					ing personnel ty		
Other SG&A Expenses	Increase in expense of intellectual prope and recruitment		$\rightarrow$ Plan to introduce expenses to intellectual property and					
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Conversion Scenario of the1st Convertible Bond-Type Bonds with Subscription Rights to Shares(CB) in FY201

- Promote steady conversion of unconverted 715M yen (2400K shares, 298 yen/share)

- Assume conservatively 4Q of FY2019 as a conversion timing , as in that of FY2018



- In parallel steady achievement of milestones related to the 1<sup>st</sup> phase, promote conversion to the 2<sup>nd</sup> phase through talks of alliance
- By realizing conversion of unconverted 715M yen in FY2019, maintain positive net assets value at the end of FY2019

### Trends in quarterly net assets and assumption for the timing of CB conversion in FY2019



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Finally:

- To the Stage of Full-scale Development as Re-challenge-

We hope to contribute to health of people around the world by bringing innovative biopharmaceuticals to the world.

We hope to reward stakeholders through the realization of commercialization by making full use of our accumulated technology, know-how, and past failures.

In FY2019, we will expand the alliance with Shionogi & Co., Ltd. to the stage of the 2<sup>nd</sup> phase

= We will take the first step to biotechnology business by full-scale development

	People: Secure necessary personnel>Focus on improving quality by training					
Management Resource Policy	Goods: Achieve milestones of the 1 <sup>st</sup> phase >Go to full-scale development through the 2 <sup>nd</sup> phase					
	Money: Strengthen mid- to long-term financial base >Secure R&D funds + Continue cost reduction					



# Appendix

# Financial Results for FY2018

### Financial Results for FY2018 vs FY2017 (Non-Consolidated)

-Revenue: In line with the same period of FY2017 by 1<sup>st</sup> and 2<sup>nd</sup> milestones revenue -Each profit and loss stage: Increase in loss due to an increase in R&D expenses, extraordinary loss, and influence of factors of FY17

(Million yen)	FY2017	FY2018	Cha	ange	Main Factors for Change		
Net Sales	104	103	(0)	(0.4%)	Equivalent to the previous fiscal year		
Cost of sales	3	1	+1	-			
R&D expenses	380	469	+90	+23.7%	Increase in R&D expenses related to alliance with Shionogi, experimental environment fee of Yokohama lab, reinstatement fee of Akita plant, and recruitment fee of R&D personnel.		
Other SG&A expenses	219	238	+19	+8.8%	Increase in recruitment fee and tax related to CB conversion		
Operating Income (Loss)	(498)	(606)	(108)	-	Increase loss due to R&D expenses related to collaboration with Shionogi		
Ordinary Income (Loss)	(158)	(609)	(451)	-	In FY2017, transferred 336 M yen of UMN-0501 orphan grant to non-operating income		
Net Profits (Loss)	(159)	(728)	(569)	-	In addition to the above factors, recorded extraordinary loss of 116 M yen in FY2018		
Net Income (Loss) per share	(12.96)	(55.12)					
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### Balance Sheets for FY2018 (Non-Consolidated) vs FY2017

- Total assets: 1,018 M yen of cash and cash equivalents stayed within the plan in FY2018

- Net Assets: Capital and capital surplus increased due to CB conversion, and net assets remained at he same level of FY2017

(Million yen)	FY2017	FY2018	Change	Remarks
Cash and deposits	1,734	1,018	(715)	Cash flow balance within the plan
Other current assets	102	58	(43)	
Total current assets	1,836	1,077	(759)	
Non-current assets	-	80	+80	Recorded land acquisition of Akita plant
Other non-current assets	54	19	(34)	Decreased due to refund of land guarantee of Akita plant
Total non-current assets	54	100	+45	
Total assets	1,891	1,177	(713)	
Current liabilities	46	52	+6	
Non-current liabilities	1,487	742	(744)	Decreased due to partial CB conversion by Shionogi
Total liabilities	1,533	795	(738)	
Capital stock & capital surplus	613	1,358	+745	Increased due to CB conversion
Retained earnings	(256)	(984)	(728)	
Others	(0)	8	+8	21 <sup>st</sup> stock subscription right related to SO
Total net assets	357	382	+25	Maintained the same level as FY2017
Total liabilities & net assets	1,891	1,177	(713)	
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### Cash Flows for FY2018 (Non-Consolidated)

- Operating cash flow: (578) M yen

- Cash and cash equivalents: Decreased 715 M yen from FY2017 as planned



(Million yen)	FY2018	Remarks
Cash flows from operating activities		
Net loss before income tax (-)	(726)	
Adjustment for non-cash activities	132	Adjustment of impairment loss etc.
Others	19	
Sub total	(575)	
Income tax payment etc.	(3)	
Cash flows from operating activities	(578)	
Cash flows from investing activities	(133)	Payment related to land acquisition of Akita plant, etc.
Cash flows from financing activities	(3)	
Net increase (decrease) in cash and cash equivalents (-)	(715)	
Cash and cash equivalents at beginning of period	1,734	
Cash and cash equivalents at the end of period	1,018	Already secured business funds until the end of FY2019



- This material and information provided in this presentation include so-called "forward-looking statements", based on assumptions with current expectations, projection and risks. It contains uncertainty that can lead to practically different results.
- These risks and uncertainties include general domestic and international economic conditions, such as general industry and market conditions and fluctuation of interest rate and currency exchange.
- Even if there are new information and events in the future, the Company is not obligated to update or modify "forward-looking statements" included in this announcement.