## **M**Others

**TSE Code** : 4585

## Supplementary Documents of **Business Results for First Six Months** of Fiscal Year 2018

## July 31, 2018

**Market Medical Needs UMN Pharma Inc.** 



### Business Results for First Six Months of 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

## Major Action from the third quarter of FY2018

- Research and Development
- Convertible Bond Conversion



#### Business Results for First Six Months of FY 2018

### On the Progress of the Business Policy in FY2018

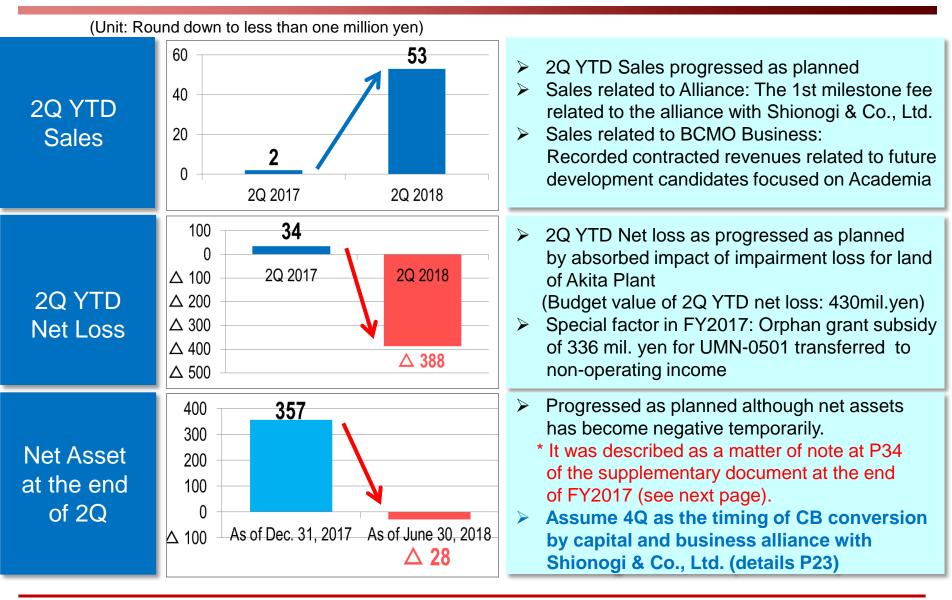
- Capital and Business Alliance with Shionogi & Co., Ltd.
- Development of In-House Next-Generation Bio-Pharmaceuticals
- Other Policy Related

### Major Action from the third quarter of FY2018

- Research and Development
- Convertible Bond Conversion

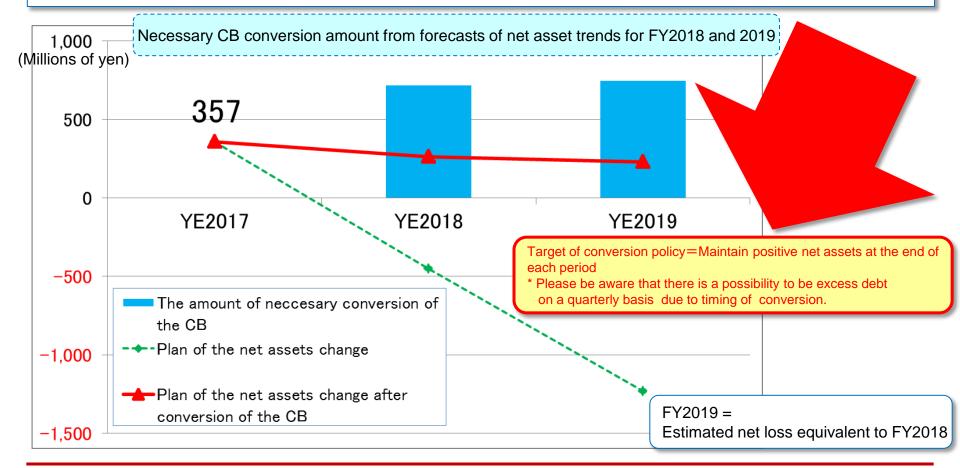
#### Summary of Financial Results for First Six Months of FY2018 (Non-consolidated)

- 2Q YTD Sales: Progressed as planned 2Q Net loss: Progressed within plan
- Net assets at the end of June: (28) mil. yen; Cash balance at the end of June: 1,312 mil. yen; both as planned



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 1<sup>st</sup> Phase, Company's Stock Price Trend, and Forecast of Net Assets for FY2018 and 2019

- Shionogi decides conversion policy in consideration of 1<sup>st</sup> Phase progress, stock price trend, and forecasts of net asset value of FY2018 and 2019
- Consult with Shionogi on conversion policy and aim for steady CB conversion after FY2018, in order to prevent excessive debt situation

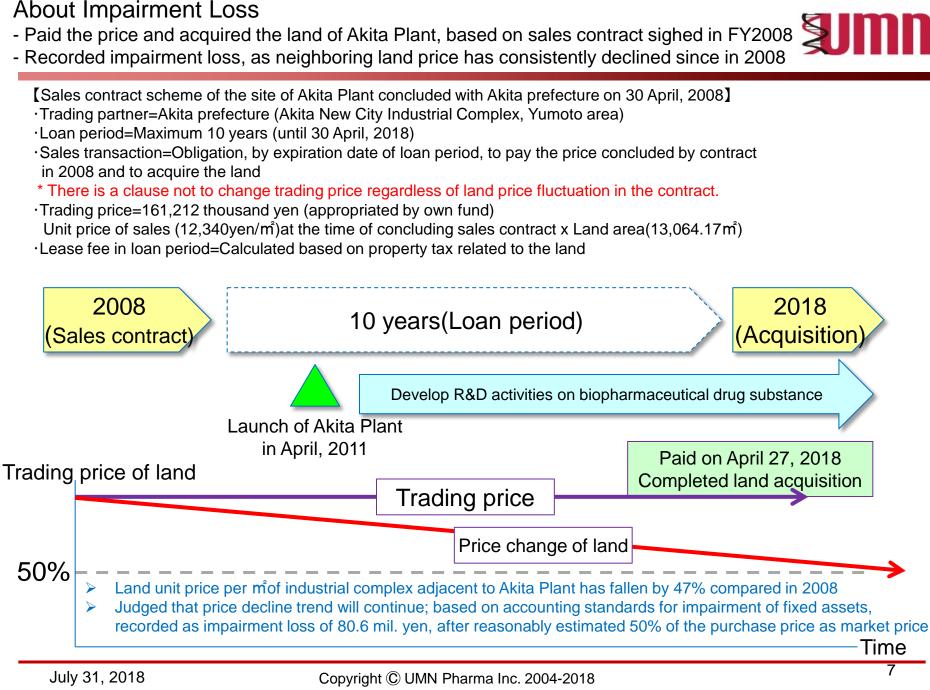


#### Non-consolidated Financial Results for 2Q in FY2018 vs Financial Forecast in FY2018

- Sales: Progressed as planned at 2Q, and anticipate achieving the plan for the full year
- Below operating income: Made progress within the plan, as the impact of impairment loss was absorbed at the stage of net loss

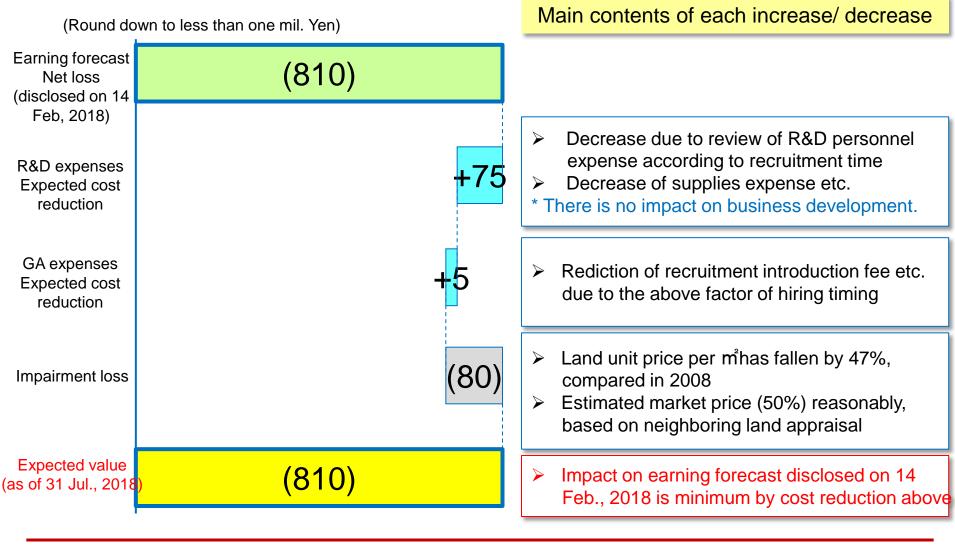
(Million of yen)	Financial Forecast for FY2018	2Q YTD Results for FY 2018	Progress Rate against Full-year Forecast	Remarks		
Net Sales	102	53	52.1%	<ul> <li>Achieved as planned at 2Q</li> <li>Anticipate achieving full-year plan by the 2<sup>nd</sup> milestone achievement</li> </ul>		
Cost of Sales	-	1	-			
R&D Expenses	657	234	35.7%	<ul> <li>Progressed within the plan against 2Q budget of 342 M yen</li> <li>Assume landing in the plan at the end of FY2018</li> </ul>		
General and Administrative Expenses	249	122	49.2%	<ul> <li>Progressed within the plan against 2Q budget of 137 M yen</li> <li>Assume landing in the plan at the end of FY2018</li> </ul>		
O p e r a t i n g Income(Loss)		(305)	38.0%	<ul> <li>Assume landing in the plan at the end of FY2018</li> </ul>		
Ordinary Income(Loss)	I XIIUI	(307)	38.0%	Same as above		
Quarterly Net Income(Loss)	(810)	(388)	47.9%	<ul> <li>Impact of impairment loss was absorbed by cost reduction</li> <li>Assume landing as planned at the end of FY2018, according to the forecast of FY2018 as disclosed on 14 Feb., 2018</li> </ul>		
Quarterly Net Income(Loss) per share (Yen)	(63.31) yen	(30.34)yen				
July 31, 2018	July 31, 2018 Copyright © UMN Pharma Inc. 2004-2018 6					

All Rights Reserved.



Analysis of impact on the full-year financial forecast at the ending December 2018

- Expect to decrease 80 mil. yen of R&D and GA expenses for the full year
- Recorded impairment loss of land of 50%, however impact on earning forecast is minor by cost reduction above





### **Business Results for First Six Months of 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

#### Major Action from the third quarter of FY2018

- Research and Development
- Convertible Bond Conversion

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

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



Partnership 1 <sup>st</sup> Phase with Shionogi & Co., Ltd.	<ul> <li>Steady achievement of development of core technologies along with milestone conditions (= realization of sales strategy)</li> <li>Improvement reliability of transition to 2<sup>nd</sup> Phase by promoting basic 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 basic 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>			
July 31, 2018	Copyright © UMN Pharma Inc. 2004-2018 10			

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

- Development of core technologies Construction of new worldwide basic technologies
- Fundamental research on development candidates: Create optimal logical next generation vaccine for each infectious diseas

development of core technologies	<ul> <li>Establish new technology platform for biopharmaceuticals including vaccine for preventing human infections         <ul> <li>Create collaborative platform of new basic technologies 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 1 <sup>st</sup>	Phase (This time) Partnership 2 <sup>nd</sup> Phase(Schedule in FY2019)				
<ul> <li>Improvement of fundamental rerated to vaccine drug pro- and comprehensive constru- including adjuvants and form</li> <li>In parallel promoting fundation</li> <li>UMN has an obligation for basic technology</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</li> </ul>				

- •Until 2019, accept certain milestones every six month according to the development progress
- Capital alliance (1.63 billion yen) aimed at supporting RD, capital investment, and working capital required during 1<sup>st</sup> Phase

\*Secure business funds until December 2019

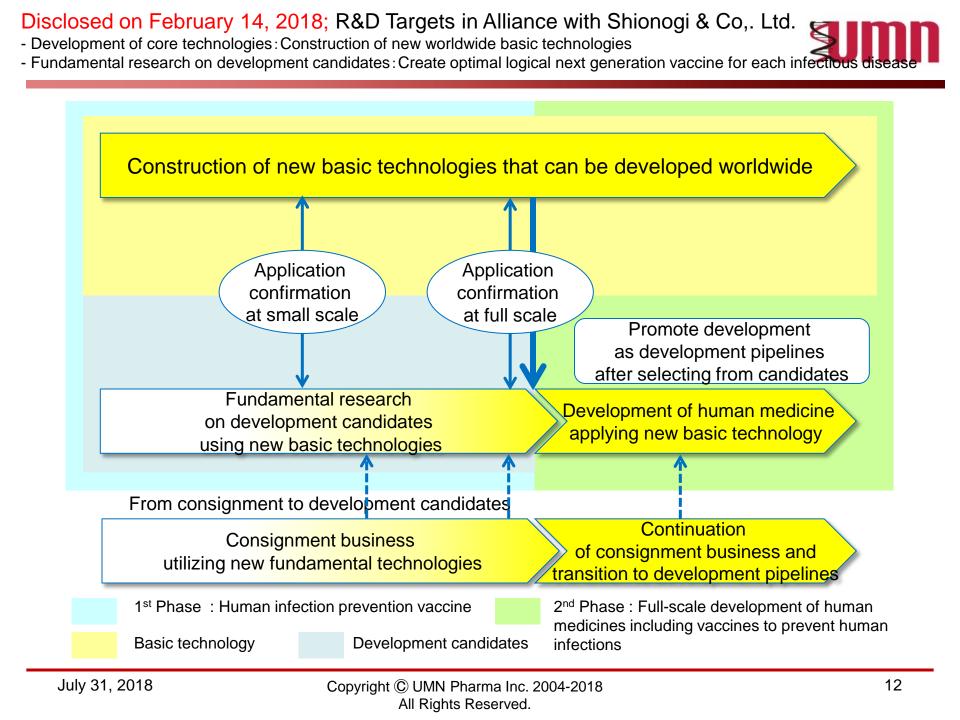
later

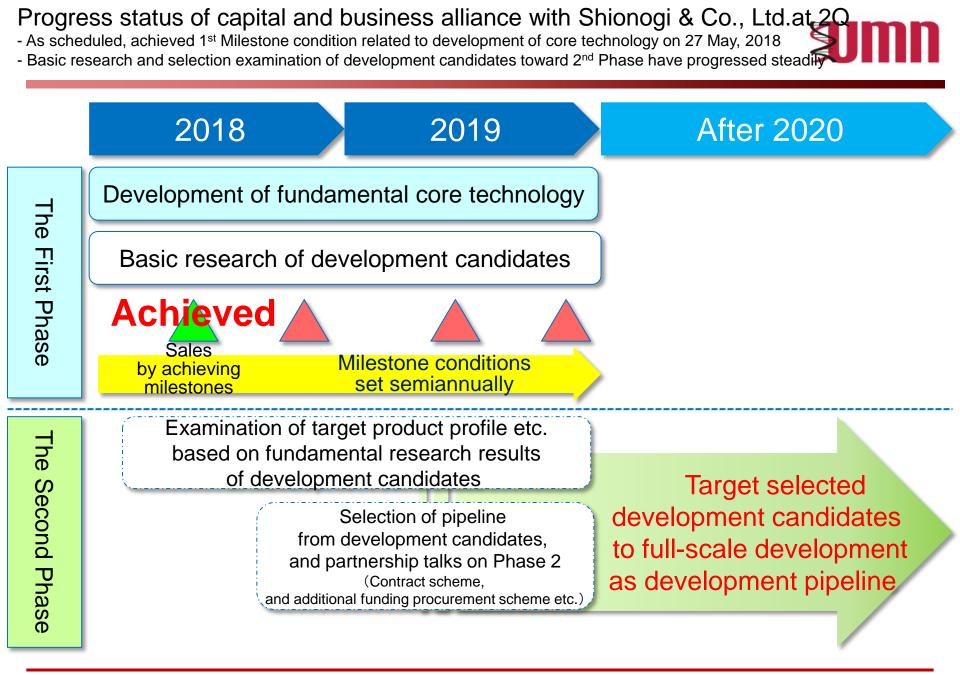
and agreement of cooperation by other forms,

Required development financing contribution

scheme after the 2<sup>nd</sup> phase will be discussed

when shifting to the 2<sup>nd</sup> phase





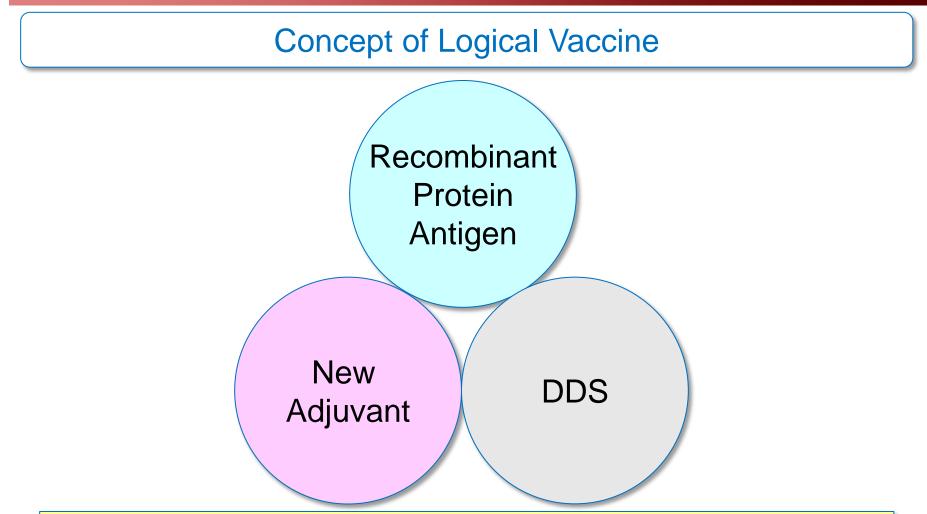
Disclosed on February 14, 2018; Upcoming Research and Development Direction

- Development of core technologies: Construction of new worldwide basic technologies
- Fundamental research on development candidates: Create optimal logical next generation vaccine for each infectious disease

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

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

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

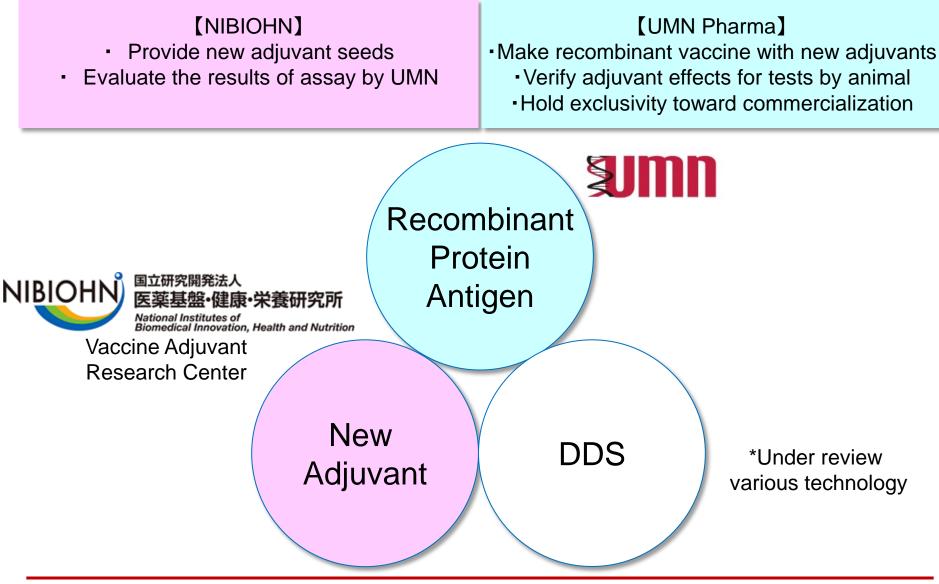


## New vaccine with high efficacy and high productivity created due to integration of above technologies

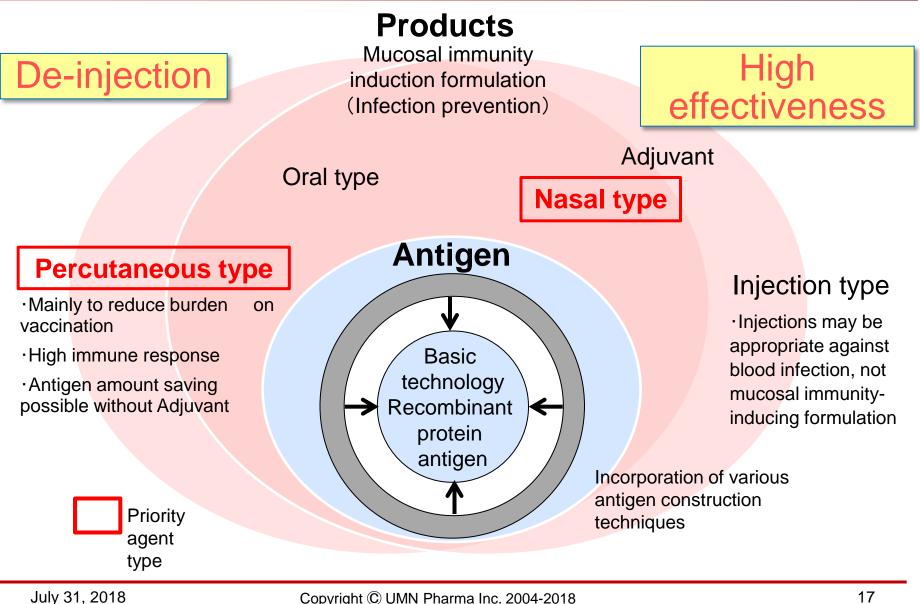
#### Disclosed on July 31, 2017; Start Joint Research with NIBIOHN

 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





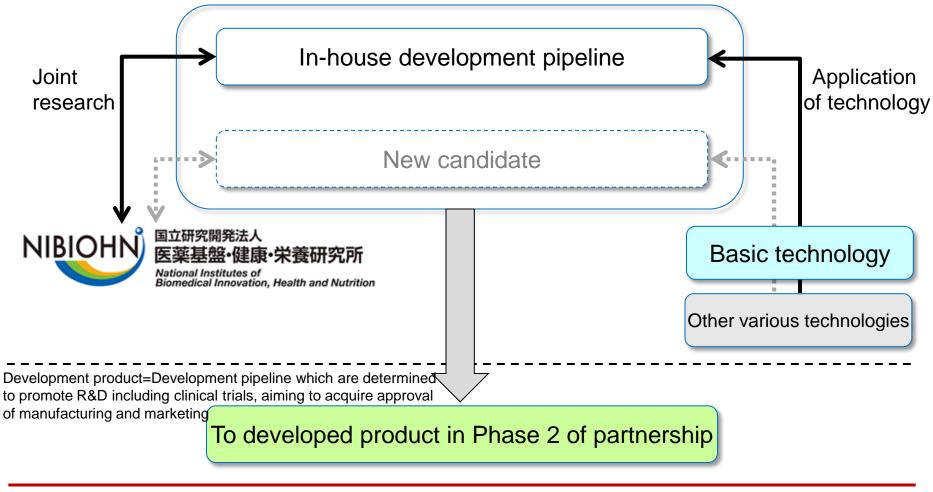
## **Target of Next Generation Logical Vaccine**



Basic research on development candidates for creation of next generation logical vaccine

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

#### Fundamental research on development candidates



Progress status of basic research on development candidates for creation of next generation logical vaccine

- Certain results with multiple development pipelines - > Transition to development candidate products
- Expansion of joint research with NIBIOHN, and discussion with Shionogi for development and commercialization

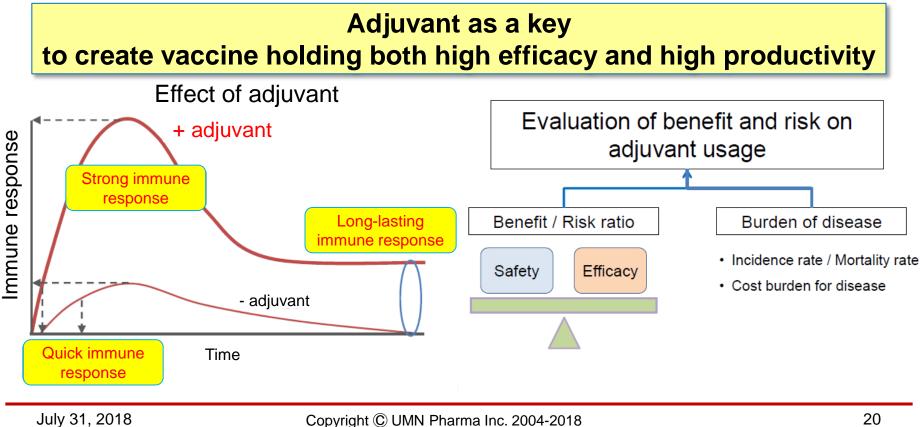
Fundamental research on development candidates	<ul> <li>Certain results in creating of next generation logical vaccine by multiple in-house development pipelines         <ul> <li>Adjuvants and formations/ Realized high effectiveness and productivity with combination of drug delivery technology</li> <li>Implementing application of fundamental core technology to in-house developed pipelines sequentially</li> <li>Planning to develop multiple new candidates products</li> <li>Response in progress to intellectual property related assuming commercialization</li> </ul> </li> </ul>
Joint research with NIBIOHN	<ul> <li>Expanding of objects (antigen) of joint research dated 1 Dec., 2017, and extending of period dated June 22, 2018</li> <li>Applied new adjuvant of NIBIOHN to in-house developed pipeline, and acquired data on immune response</li> <li>Future plans         <ul> <li>Expand scope of joint research when developing new candidates as development candidates</li> <li>Examine jointly various efficacy and safety evaluation methods for development and commercialization of new vaccine</li> </ul> </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  $\geq$ immune response
- $\geq$ 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  $\succ$



Progress status in strengthening functions at R&D sites

- Yokohama Lab.: Mainly focusing on basic research on development candidates for Phase 2

- Akita Plant: Completed re-launch to achieve consecutive milestones, and continue maintenance of GMP system



Yokohama Lob.: Completed maintenance to promote multiple projects  $\triangleright$ Maintenance at Yokohama Lab. of experimental environment Completed re-launch of equipment at Akita Plant  $\geq$ Akita Plant: Re-launch Reinforcement of R&D sites Yokohama Lob. and Akita Lab.: • Promoting basic R&D of development candidates Akita Plant:  $\succ$ Enhancement Promoting R&D related to fundamental core technology at each site •Establishing structure for GMP operation \*Strengthening effective GMP system through supported by Shionogi At 2Q= Achieved reinforcement of R&D and production related • Total of 26 members, with an increase of 10 Number of Strengthen Jan 2018 R&D personnel **R&D** organization by positive adoption Yokohama Lab. 3 of human resources Akita Lab. 4 of R&D/Manufacturing Akita Plant 9

·Secure manufacturing-related core personnel at Akita Plant

16

Aug 2018

(Plan)

6

4

16

26

TOTAL

Difference

3

0

7

10



#### Business Results for First Six Months of FY 2018

### On the Progress of the Business Policy in FY2018

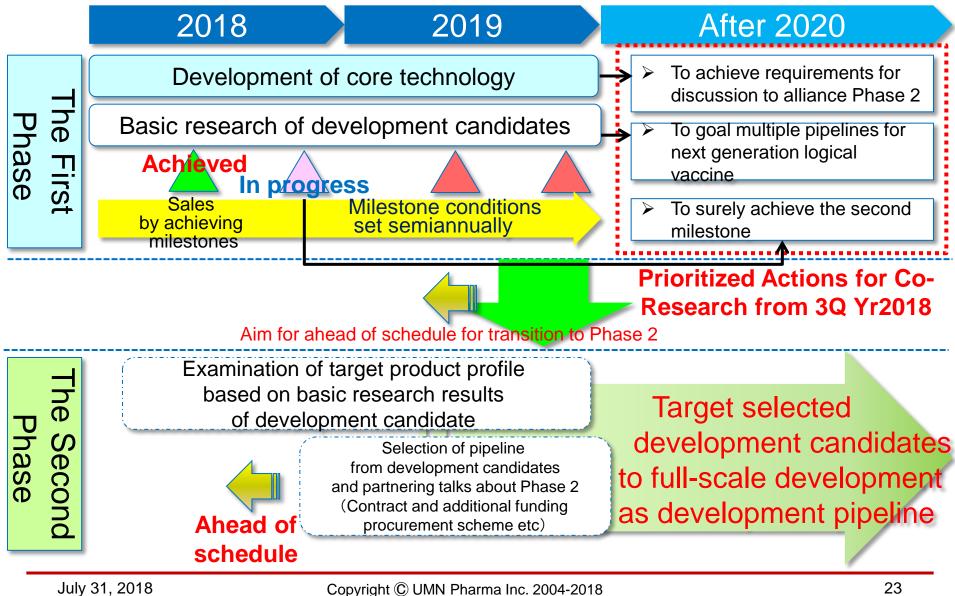
- Capital and Business Alliance with Shionogi & Co., Ltd.
- Development of In-House Next-Generation Bio-Pharmaceuticals
- Other Policy Related

#### Major Action from the third quarter of FY2018

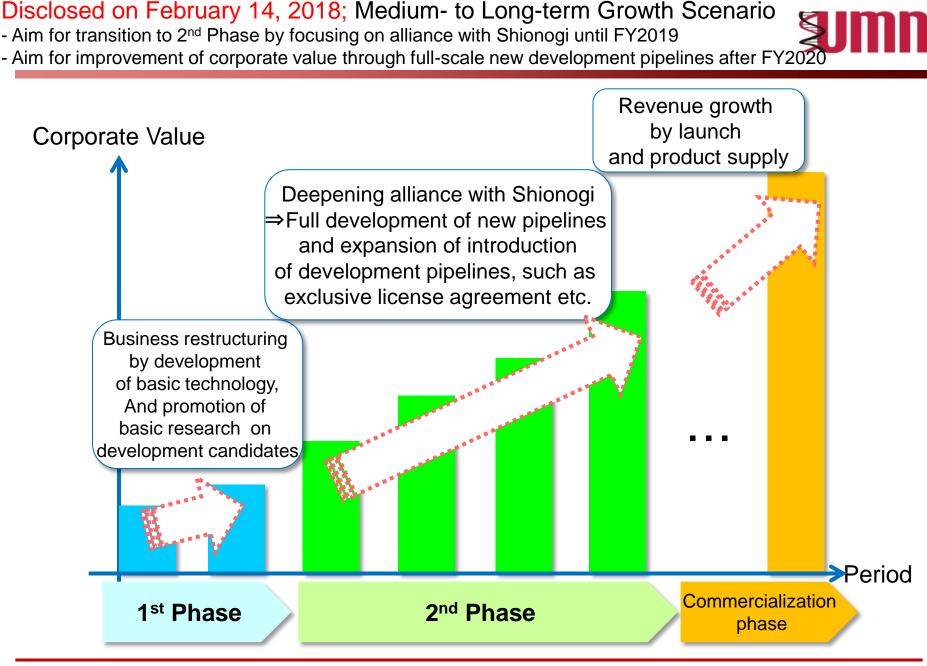
- Research and Development
- Convertible Bond Conversion

Prospects of Phase 1 and transition to Phase 2

- Progressed as planned for the 2<sup>nd</sup> milestone achievement in the 1<sup>st</sup> phase
- Aim for ahead of schedule for transition to 2<sup>nd</sup> Phase with basic research on development candidates



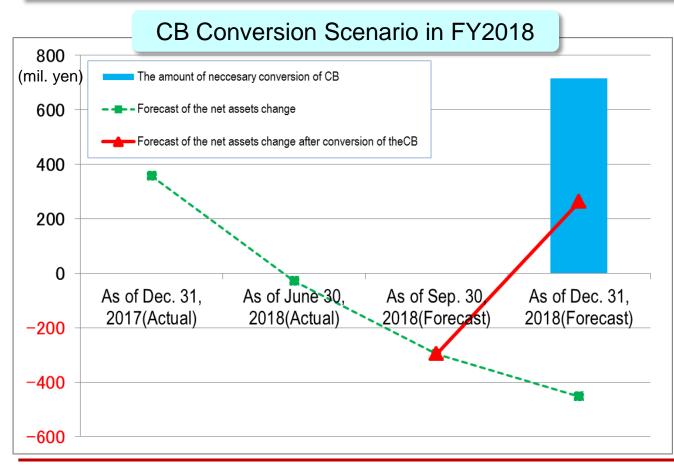
All Rights Reserved.



Major Actions for 3Q and beyond in FY2018; conversion of CB

- The 2<sup>nd</sup> milestone related R&D progress and stock price, 298 yen as conversion price are critica

- Assume 4Q as a timing of CB conversion
  - Not assume CB conversion until the end of 3Q, since the timing of the confirming 2<sup>nd</sup> milestone achievement will be within 4Q
  - Assume that negative net assets will continue even at the end of 3Q
  - Expect that Shionogi will decide and implement conversion policy within 4Q



[Concerning assumed conversion scale] There is no change, since it made progress within the range announced of February 14, 2018. (ref. to P5 of this document).

\*\*As long as alliance with Shionogi & Co., Ltd. has been maintained, without prior consent of the Company, in accordance with the clause, Shionogi cannot transfer the acquired shares. Disclosed on February 14, 2018; Capital Alliance with Shionogi & Co., Ltd.

- Raised1.639 billion yen by new shares and CB (Total 5,500K shares, Dilution ratio 31.08%)

- Appropriation for R&D, capital investment and operating capital until the end of 2019

New shares	Common stock : 600K shares Issue price : 298 yen Volume of issuance : 179 million yen
1st Unsecured Convertible Bond with Stock Acquisition Rights (CB)	Volume of issuance : 1.46 billion yen (Stock acquisition right part 4,900K shares) Conversion price : 298 yen Interest rate on corporate bonds : 0.22% Maturity redemption date : November 15, 2021 (No advance redemption clause excluding grounds for delisting)

[Other major matters]

- > Shionogi cannot transfer acquired shares without prior consent by alliance agreement.
- UMN cannot raise capital financing without prior consent of Shionogi.
- UMN will issue and allocate new CB to Shionogi under the most recent stock price condition when converting CB cannot be executed due to stock price on assumed timing.

#### Points on future CB conversion :

- Shionogi decides conversion policy based on the state of development progress in 1<sup>st</sup> Phase and the expected our net asset status at the end of the FY.
- Important points in order to prevent the debt-excess situation again in FY:

1) Achievements from steady progress in development, 2) Stock price status

(The necessary CB conversion amount for FY2018 and FY2019 are described later)

## Finally - We are re-challenging -

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 technologies, know-how, and past failures.

Re-challenge for commercialization of biopharmaceuticals with centering on partnership with Shionogi & Co., Ltd.

Management resource policy

People: Already secured necessary personnel according to plan, focusing on improving the quality through education and training Goods: Progressed on R&D as planned, making further efforts to bring it to the 2<sup>nd</sup> phase earlier than planned Money: While using necessary funds, continues cost reduction to unnecessary



# Appendix

### Financial Results for First Six Months of FY2018

Relevant materials related to performance forecast of FY2018, disclosed on 14 February, 2018

#### Summary of Financial Results for First Six Months (2Q) of FY2018 vs 2Q of FY2017

- Revenue: Significantly increased by the first milestone revenue

- Each profit and loss stage: Operating loss improved; below ordinary PL has influence of special factor in FY2017

(Millions of Yen)	2Q of FY2017 - Actual -	2Q of FY2018 - Actual -	Year-to-year comparison (rounding off mil. Yen)		Main factors of the year-to-year difference
Net Sales	2	53	+50	+1721.4%	Substantial increase by the first milestone from Shionogi & Co., Ltd.
Cost of Sales	1	1	(0)	-	
R&D expenses	193	234	+40	+21.1%	Increase by co-operation-related R&D expense with Shionogi & Co., Ltd., Experiment environment maintenance at Yokohama Lab., re-setup expense at Akita Plant, and hiring recruitment etc.
Other SG&A expenses	122	122	+0	+0%	Restrained to the same level as 2Q of FY2017 due to cost reduction
O p e r a t i n g Income(Loss)	(315)	(305)	+9	-	Loss reduction at the stage of operating profit and loss
Ordinary Income(Loss)	34	(307)	(341)	_	Remained almost flat, excluding a transfer to non-operating income of UMN-0501 Orphan Grant 336 mil. of FY2017
Q u a r t e r l y Net Income(Loss)	34	(388)	(422)	—	Recognized impairment loss, (80.6) mil.yen, at 2Q
Quarterly net income(Loss) per share (yen)	2.79	(30.34)			

Balance Sheets as of June 30, 2018 vs. Dec 31, 2017

- Assets: 1,312 mil of cash and deposits as planed -
- Net Assets: Within the plan, although recorded negative net asset at 2Q -



(Round down to mil. yen)	Year ended As of Dec. 31, 2017	Six months ended As of June 30, 2018	Difference	Remarks
Cash and deposits	1,734	1,312	(421)	Cash flow balance within plan
Other current assets	102	83	(19)	
Total current assets	1,836	1,396	(440)	
Tangible fixed assets	-	80	+80	Acquired land at Akita Plant
Other fixed assets	54	24	(29)	Reduced due to refund of land guarantee at Akita Plant
Total fixed assets	54	105	+50	
Total assets	1,891	1,501	(390)	
Current liabilities	46	42	(4)	
Non-current liabilities	1,487	1,487	+0	Allocated 1,460 mil. yen of CB to Shionogi & Co., Ltd.
Total liabilities	1,533	1,529	(4)	
Capital stock & capital surplus	613	613	-	
Retained earnings	(256)	(644)	(388)	
Others	(0)	2	+2	21st stock acquisition right related to SO
Total net assets	357	(28)	(385)	Negative net assets at the end of 2Q,(as planned)
Total liabilities & net assets	1,891	1,501	(390)	
July 31, 2018 Copyright © UMN Pharma I			004-2018	30

All Rights Reserved.

#### Cash Flows for the First Six Months of FY2018

- Decreased 287 mil. yen from cash flows from operating activities

- Cash & cash equivalents decreased 421 mil. yen, comparing to the end of FY2017 (within the plan)



(Round down to mil. yen)	Six months ended As of June 31, 2018 (Actual)	Remarks
Cash flows operating activities		
Quarterly profit (loss) before income taxes	(387)	
Adjustment of non-cash items, etc.	85	Impairment loss etc.
Others	17	
Subtotal	(285)	
Income taxes paid	(1)	
Net cash provided by (used in) operating activities	(287)	
Net cash provided by (used in) investing activities	(133)	Expenditure on land acquisition at Akita Plant, etc.
Net cash provided by (used in) financing activities	(0)	
Net increase (decrease) in cash and cash equivalents	(421)	
Cash & cash equivalents at beginning of period of 2Q	1,734	
Cash & cash equivalents at end of period of 2Q	1,312	No change in the status that necessary business funds are secured by the end of 2019

Disclosed on February 14, 2018; Non-consolidated Financial Forecasts for FY2018 ending Dec 31, 2018 - Sales plan: Conservatively recorded mainly on milestone revenues related to business alliance with Shionogi & Co., Ltd.

- Operating loss: Increase against YOY because of R&D expenses related development of core technologies and assessment of cand

(Millions of yen)	FY2017 Actual (Non-consolidated)	Forecasts for FY2018 (Non-consolidated)	Assumptions & conditions for Financial Forecasts of FY2018
Net sales	104	102	Sales due to achievement of milestone related to 1 <sup>st</sup> Phase and contracted business from academia
Cost of sales	3	-	Record cost of sales related to contracted business as R&D expenses
R&D expenses	380	657	Estimate expenses for R&D for core technologies and basic research of development candidates, for test manufacturing at Akita plant from the second half of FY, and for personnel
Other SG&A expenses	219	249	Estimate increase mainly for IP and recruitment expenses
Operating Income(Loss)	(498)	(803)	Estimate loss expansion due to strengthening of R&D activities with Shionogi
Ordinary Income(Loss)	(158)	(809)	Record bond interest and CB conversion related expenses on non-operating expenses %FY2017=Recorded 336 Mil. yen of UMN-0501 Orphan Grant on Non- operating income
Net Income(Loss)	(159)	(810)	CB conversion policy becomes an important point in order to maintain the net asset value positive at the end of Dec, 2018. (CB conversion scenario is described later)
Net Income(Loss) per share	(12.96)	(63.31)	

• 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.

• There is a possibility that forecasts may differ due to various uncertain factors.

Disclosed on February 14, 2018; Forecasts for FY2018 : Cost of sales, R&D expenses, Other SG&A expenses

- R&D expenses: Assume increase related to collaboration with Shionogi
- Other SG&A expenses : Assume increase related mainly to human resource recruitment



Account items (Millions of yen)	FY 2015 Actual (consolidated)	FY 2016 Actual (consolidated)	FY 2016 Actual (non-consolidated)	FY 2017 Actual (non-consolidated)	FY 201 Forecasts (non-consolidated)
Cost of sales	52	39	51	3	-
R&D expenses	2,933	3,151	279	380	657
Other SG&A expense	es 424	444	273	219	249
SG&A expenses	3,357	3,596	553	599	906
Depreciation expenses, within the above, *including 107 of lease fee *including 107 of lease fee *including 107 of lease fee *including 107 of lease fee *including 107 of lease fee					
R&D expenses	Point       Details         R&D expenses       Re-launch of Akita plant Related to R&D, manufacturing Active recruitment       > Estimate increase including improvement of experimental environment at Yokohama lab. and maintenance and depreciation, utility exp. related to re-launch at Akita plant         > Active adoption for R&D and manufacturing related personnel to strengthen R&D organization         > Estimate to increase expenses related to cooperation with Shionogi				
Other SG&A expenses	Increase expenses of IP related and recruitment <ul> <li>Implemented all necessary cost reduction by the end of Dec 2017</li> <li>Plan to introduce expenses of intellectual property and recruitment</li> </ul>				
July 31, 2018	Copyright © UMN Pharma Inc. 2004-2018 33				



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.