



TSE Code : 4585

Supplementary Documents of Business Results for First Six Months of Fiscal Year 2019

July 31, 2019



Addressing Unmet Medical Needs

UMN Pharma Inc.

-
- Business Results for First Six Months of FY2019

 - On the Progress status of the Business Policy in FY2019
 - Capital and Business Alliance with Shionogi & Co., Ltd.
 - Development of In-House Next-Generation Bio-Pharmaceuticals
 - Other Policy Related

 - Major Actions from the third quarter of FY2019
 - Research and Development
 - Consultations on Transition to Phase 2
 - Business Forecasts in FY2019
 - Convertible Bond Conversion

■ Business Results for First Six Months of FY2019

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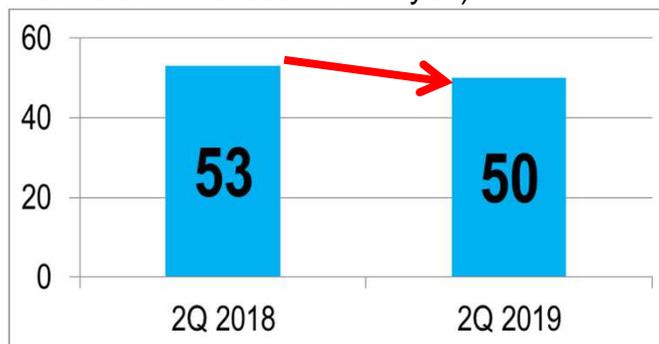
Summary of Financial Results for First Six Months of FY2019 (Non-consolidated)



- 2Q Net sales: Progressed as planned; 2Q Net loss: Progressed within the plan
- Net assets: 43 mil. yen, Cash balance: 692 mil. Yen: Both at the end of 2Q, and within the plan

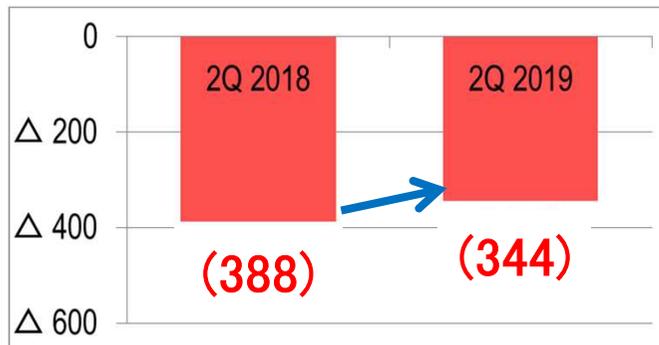
(Unit: Round down to less than M yen)

2Q YTD
Net Sales



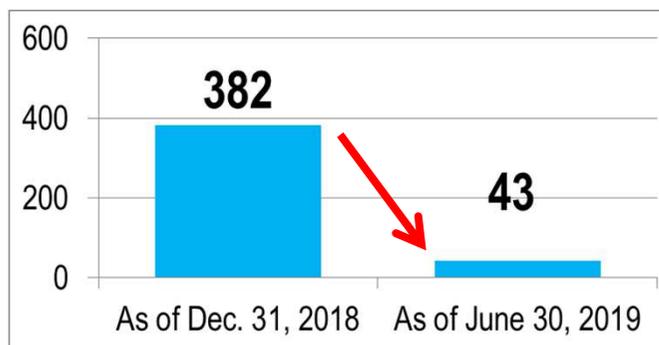
- Net sales in 2Q achieved as planned
- Net sales related to alliance with Shionogi & Co., Ltd. : Achieved the 3rd milestones
- Decreased slightly revenues from contract manufacturing business as a result of concentration on alliance work with Shionogi & Co., Ltd.

2Q YTD
Net Loss



- Cumulative net loss in 2Q progressed as planned (Budget value: (519) mil. yen)
- There was a land impairment loss of Akita plant, which recorded an extraordinary loss in 2Q of FY2018

Net Assets
at the end
of 2Q



- Net assets at the end of 2Q maintained positive, since cumulative net loss improved significantly from initial performance plan
- CB conversion timing related to the capital and business alliance with Shionogi & Co., Ltd. is expected in 4Q as initially planned (see P22 for details)

Non-consolidated Financial Results for 2Q in FY2019 vs Financial Forecasts in 2019

- Net sales: Progressed as planned, expected to achieve as planned in full year
- Operating income to Net income : Progressed within the plan



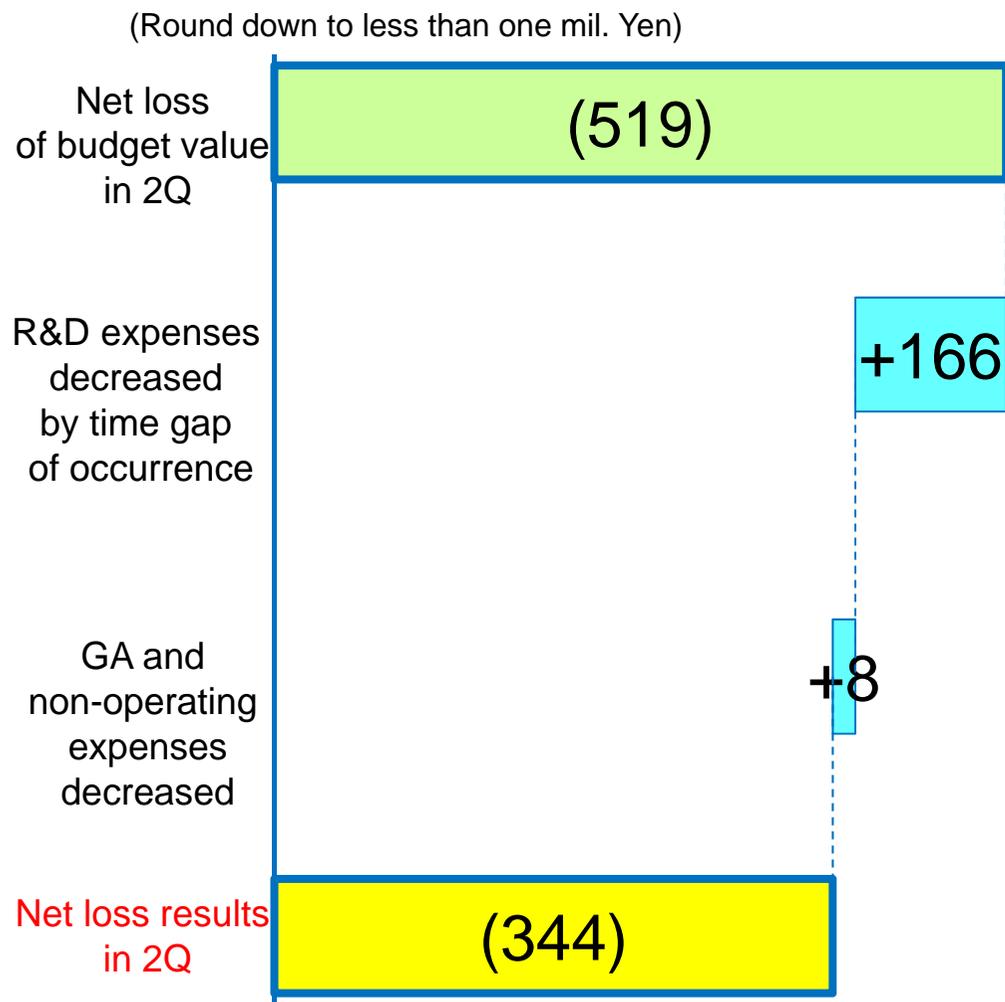
(Round down to less than M yen)	FY2019 FCST	2Q YTD Results for FY2019	Progress Rate against Full-year FCST	Remarks
Net sales	100	50	50.0%	<ul style="list-style-type: none"> • Achieved as planned in 2Q • Aim at achievement of the 4th milestones, and transition to Phase 2
Cost of sales	-	-	-	
R&D expenses	737	271	36.8%	<ul style="list-style-type: none"> • Progressed within the plan against 437 M yen of 2Q budget • Assume landing within the plan at the end of FY2019, although some expenses move to from 2Q to after 3Q
SG&A expenses	250	121	48.7%	<ul style="list-style-type: none"> • Progressed within the plan against 127 M yen of 2Q budget • Assume landing within the plan at the end of FY2019
Operating income	(887)	(342)	38.7%	Assume landing within the plan at the end of FY2019
Ordinary income	(891)	(343)	38.6%	Same the above
Quarterly net income	(893)	(344)	38.6%	<ul style="list-style-type: none"> • Absorbed impact of impairment loss by cost reduction • Assumed landing as planned at the end of FY2019, as disclosed on 14 Feb, 2019
Quarterly net income per share (yen)	(58.36) yen	(22.53) yen		

Analysis of increase/decrease of net loss in 2Q of FY2019

- R&D expenses: Reduced significantly compared to budget, due to decrease of personnel etc.
- Administrative expenses: Landed within the budget due to decreased recruitment fee



【Main contents of each increase/decrease】



R&D budget in 2Q: 437 M yen -> Result: 271 M yen

- Decreased 65 M yen by time gap of occurrence
- Decreased 23 M yen of personnel exp. etc.
- Decreased, 78 M yen of other exp. (may occur after 3Q)
- 22 M yen as raw materials for test production at Akita plant in BS is expected to change expenses in 3Q gradually .

Administrative exp. budget in 2Q: 127 M yen -> Result: 121 M yen

- Decreased 5 M yen of recruitment fee
- Decreased 3M yen of other administrative and non-operating exp.
- * Continue to cut expenses after 3Q

➢ **Net loss landed at a significant reduction compared to the budget due to the above cost reduction factors**

■ Business Results for First Six Months of FY2019

■ On the Progress status of the Business Policy in FY2019

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- Development of In-House Next-Generation Bio-Pharmaceuticals
- Other Policy Related

■ Major Actions from the third quarter of FY2019

- Research and Development
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Disclosed on Feb 14, 2019; Business Direction for FY2019

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



FY2019 = The first year to full-scale development

<Matters to be achieved>

- Achievement for the 3rd and 4th milestones
- Selection of development pipelines
- Agreement for transition to Phase 2

<Consultations key points of Phase 2 >

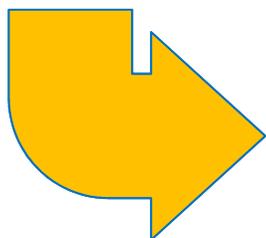
- Maximization of business value from collaboration
- Making mid-long term WIN-WIN relationship by utilizing each strength

<Source of potential growth >

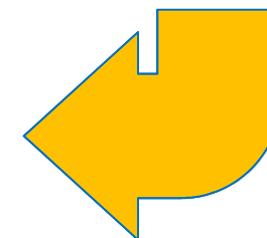
- Establishment of fundamental technology related to biopharmaceutical drug production
- Optimizing portfolio of development pipelines
- Aggressive expansion to application of fundamental technology

To realize the above;

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



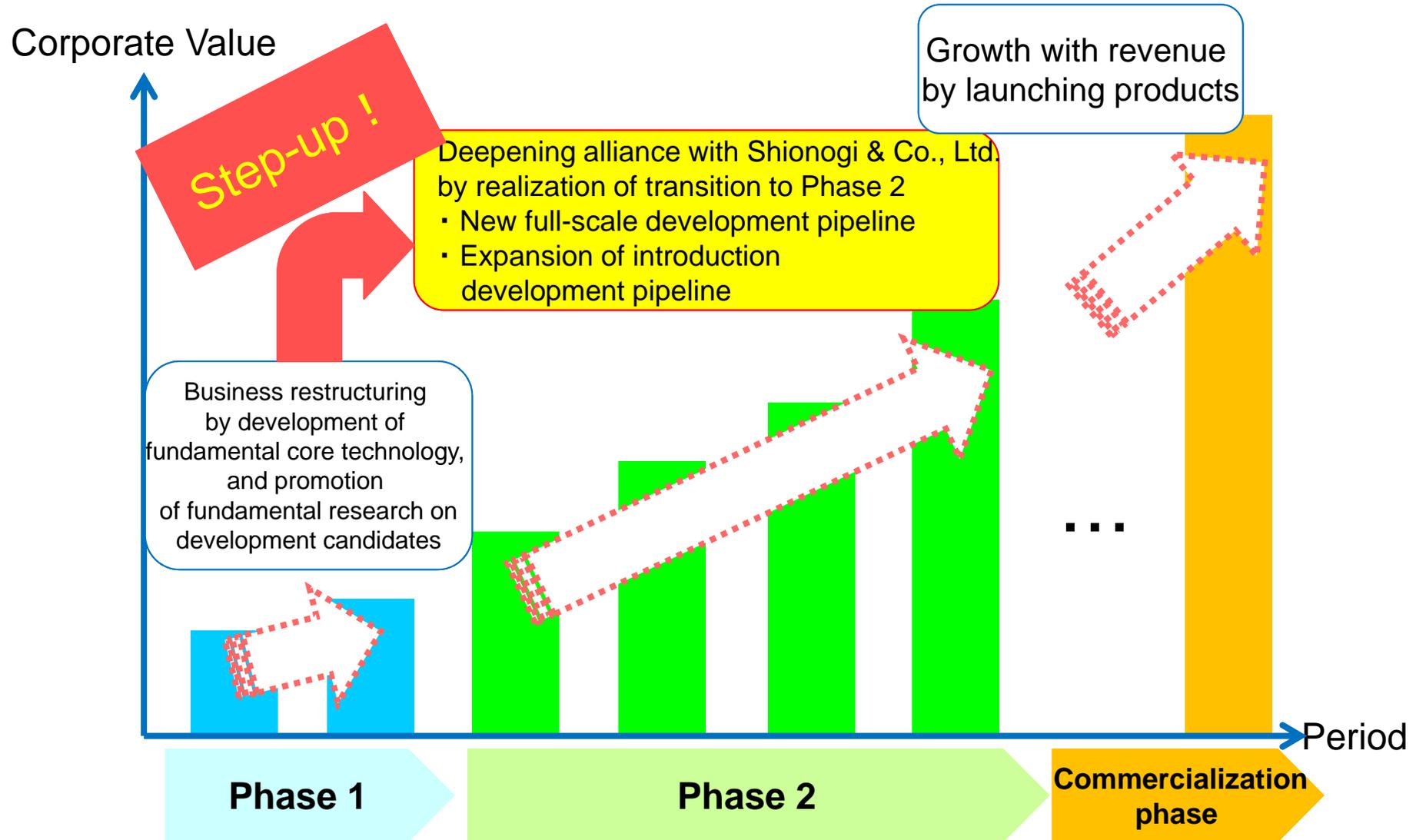
**Realization of sustainable growth
of enterprise value**



Plan to disclose figures in mid-term management plan after transition to Phase 2

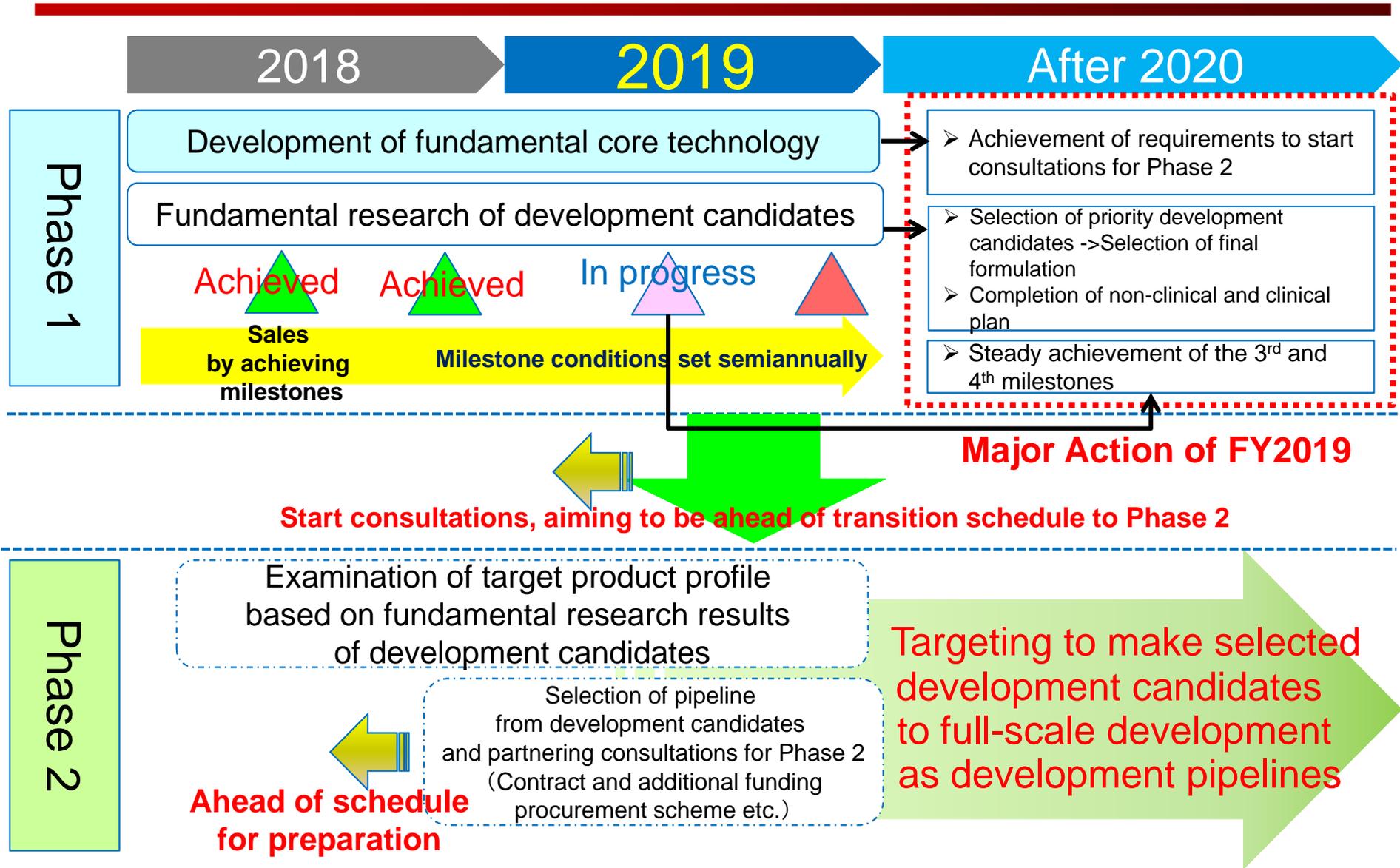
Disclosed on Feb 14, 2019; Medium- to Long-term Growth Scenario

- Focus on alliance business with Shionogi & Co., Ltd. in FY2019, and aim for transition to Phase 2
- Aim to improve corporate value through full-scale development of new pipeline from FY2020



Disclosed on Feb 14, 2019; Major Action of FY2019: Research development and transition to Phase 2

- Phase 1: Steady achievement of the 3rd and 4th milestone conditions, which is progressing as planned
- Phase 2 : Advance preparatory work ahead of schedule by promoting fundamental research on development candidates





- Selection of formulation for development as a next-generation logical vaccine and decision of development plan
- Positive consultations to make intellectual property from development candidates about creation of next-generation logical vaccine

R&D

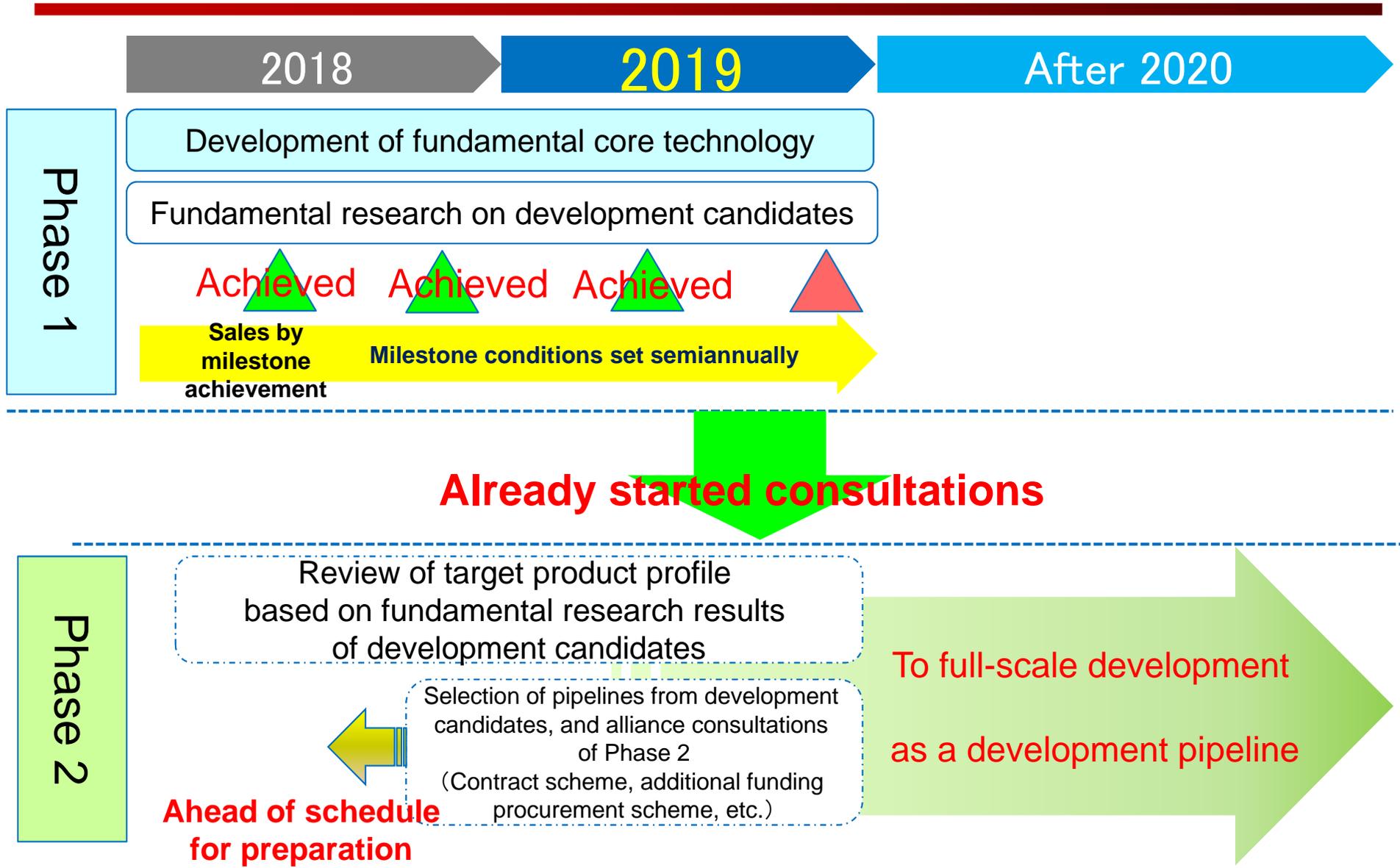
- Selection of final formulation as a next-generation logical vaccine of preferred development candidates
 - Application of fundamental technology
 - Selection of combination of antigen/ adjuvant formulation/ drug delivery technology, and of formulation for development
 - Evaluation of effectiveness and productivity
- Drawing up of non-clinical and clinical development plans of development candidates

Strategy of intellectual property

- Consultations on utilization of external intellectual property related to creation of next-generation logical vaccine
- Positive consultations to make intellectual property related to commercialization of development candidates

Progress status of capital and business alliance with Shionogi & Co., Ltd. in the first half of FY2019

- Achieved the 3rd milestones in Phase 1
- Already started consultations for transition to Phase 2



Progress status of development of fundamental core technology

- Completed maintenance of the one step before the final stage; currently in the final stage
- Conducted consultations with regulatory authorities regarding application of guidelines, etc., and confirmed compliance



Outline of the development of fundamental core technology

- Maintenance of complete set of technology necessary to develop and supply biopharmaceuticals worldwide, including vaccines
 - Possible to obtain approval corresponding regulation and pharmaceutical affairs to each countries
 - Be competitive in productivity and cost
- Maintenance of our own fundamental core technology reflecting the latest knowledge and technology
- The established fundamental technology will be sequentially applied to development candidates products.



Progress status

- Completed maintenance of the one step before the final stage
 - Already addressed the issues in promoting drug development using this technology
 - Determined final technical content (package), and under transition to final maintenance
- Confirmed the application for development candidate products and protein expression at 600 L scale
 - Applied the development technology to the selected development candidate products, and confirmed protein expression assessment
 - Conducted a preliminary productivity assessment
- Consulted with the regulators regarding applicability of regulatory guidelines to fundamental core technology
 - Confirmed that the direction of fundamental core technology is in line with regulatory guidelines

Progress status of the selection of development candidate products

- Candidate 1: Roughly determined the formulation package, and non-clinical and CMC research for development
- Candidate 2: Acquiring data to finalize the formulation package, and considering next candidates



Candidate 1

- Almost confirmed to formulate pharmaceutical package (logical vaccine)
 - Almost established logical vaccine with target formulation characteristics
 - Already selected antigens, adjuvants, and drug delivery technologies that are components of logical vaccine
 - Under consideration for non-clinical and CMC studies to determine final formulations
- Development & launch plan
 - Made plans for non-clinical & clinical with calculation of development costs
 - Under consideration of launch plan for commercialization

Candidate 2 and Next Candidates

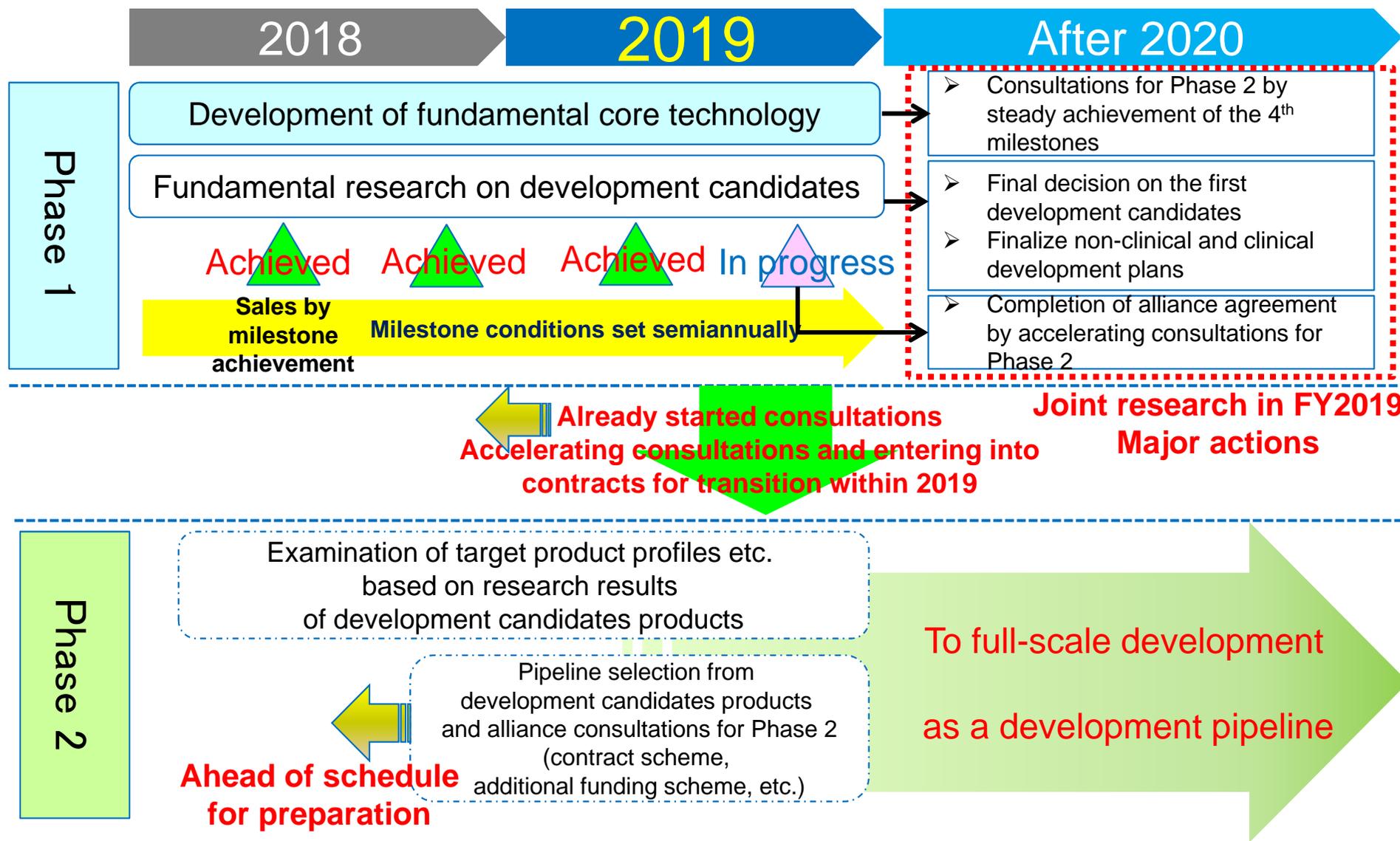
- Regarding candidate 2, under determination for the formulation package
 - Already acquired data to help determine the formulation package with additional studies for finalization to be conducted
- There are several other candidates under consideration
 - Under consideration for multiple candidates as next candidates following candidate product 1 and 2
 - Prioritize candidates based on the target product profiles and planed to consider application of fundamental core technology and formulation package sequentially

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Major Actions after 3Q in FY2019: Research and development and achievement of transition to Phase 2
 –Phase 1: Achieve the 4th milestones and complete development of fundamental core technology
 –Phase 2: Determine development items by fundamental research on development candidates, and achieve Transition to Phase 2 within FY2019



Major Actions after 3Q in FY2019: Development of fundamental core technology

- Implement final development maintenance to establish fundamental core technology
- Link development candidate products with fundamental core technology to promote them



Establishment of fundamental core technology

- Implement final development maintenance to establish fundamental core technology
 - Implement final maintenance based on the findings acquired so far to establish fundamental core technology
- Sequentially obtain data required in order to receive regulatory approval in country by country

Promotion of Research and Development

- Implement and promote antigen production for development candidate 1
 - Produce antigens for using in non-clinical and CMC for candidate 1 by applying on the final development of the fundamental core technology
- Apply fundamental core technology to development candidate 2 and link it with research for establishment of the formulation package

Major Actions after 3Q in FY2019: Selection of development candidate products

- Candidate 1: Promote to confirm development formulation
- Continue to study development candidate 2 as well as next candidates



Candidate 1

- Promote to confirm development formulation
 - Realize the development products by finalizing development formulation
 - Move to a process to the start of non-clinical GLP studies
- Development and launch plans
 - Conduct business evaluation on plans by drawing up both plans for development and launch

Candidate 2 and next other candidates

- Promote various studies to determine formulation package (logical vaccine) of the candidate 2
 - Consider combinations of antigens, adjuvants and drug delivery that can achieve target drug profiles
 - Complete plans to non-clinical and clinical development
- Development of other candidates
 - Formulate target product characteristics for each candidates product and prioritize it together with the possibility of creating logical vaccine
 - Sequentially study the application of fundamental core technology and the formulation package based on the prioritization

Disclosed on Feb 14, 2019; FY2019 Financial Forecasts (Non-Consolidated)

- Reflect only the 1st phase R&D activities
- Plan to disclose promptly a revision plan after Phase 2 agreement, if necessary



(Unit: M yen)	FY2018 Results (Non-consolidated)	FY2019 Forecasts (Non-consolidated)	Forecasts Prerequisites
Net Sales	103	100	Sales of milestone achievement related to the 1 st 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 related to CB conversion
Operating Income (Loss)	(606)	(887)	Loss expansion compared to FY2018 due to strengthening of R&D activities with Shionogi & Co., Ltd. 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 assets value positive at the end of Dec, 2019.
Net Income (Loss) per share	(55.12)	(58.36)	

- 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 Feb 14, 2019; Financial Forecasts for FY2019 : Cost of sales, R&D expensed, Other SG&A expenses
 - R&D expenses: Record expenses only related to the 1st phase of alliance with Shionogi & Co., Ltd.
 - 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	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 expenses, within the above	*1,578	25	-*	-*	-*

*including 107 of lease fee

* Fixed asset acquisition expenses are expensed by lump-sum depreciation.

	Points	Details
R&D Expenses	Full-scale test manufacturing of Akita plant, and development of candidates	<ul style="list-style-type: none"> ➤ Full-scale CMC development using 600L of Akita plant ➤ Continue recruitment of R&D and manufacturing personnel ➤ Add facility investment to support Data Integrity ➤ Incorporate elements of expenses shifted out of FY2018
Other SG&A Expenses	Increase in expenses of intellectual property and recruitment	<ul style="list-style-type: none"> ➤ Continue cost restraint ➤ Plan to introduce expenses to intellectual property and recruitment ➤ Reflect the impact of increase in corporate tax by CB conversion

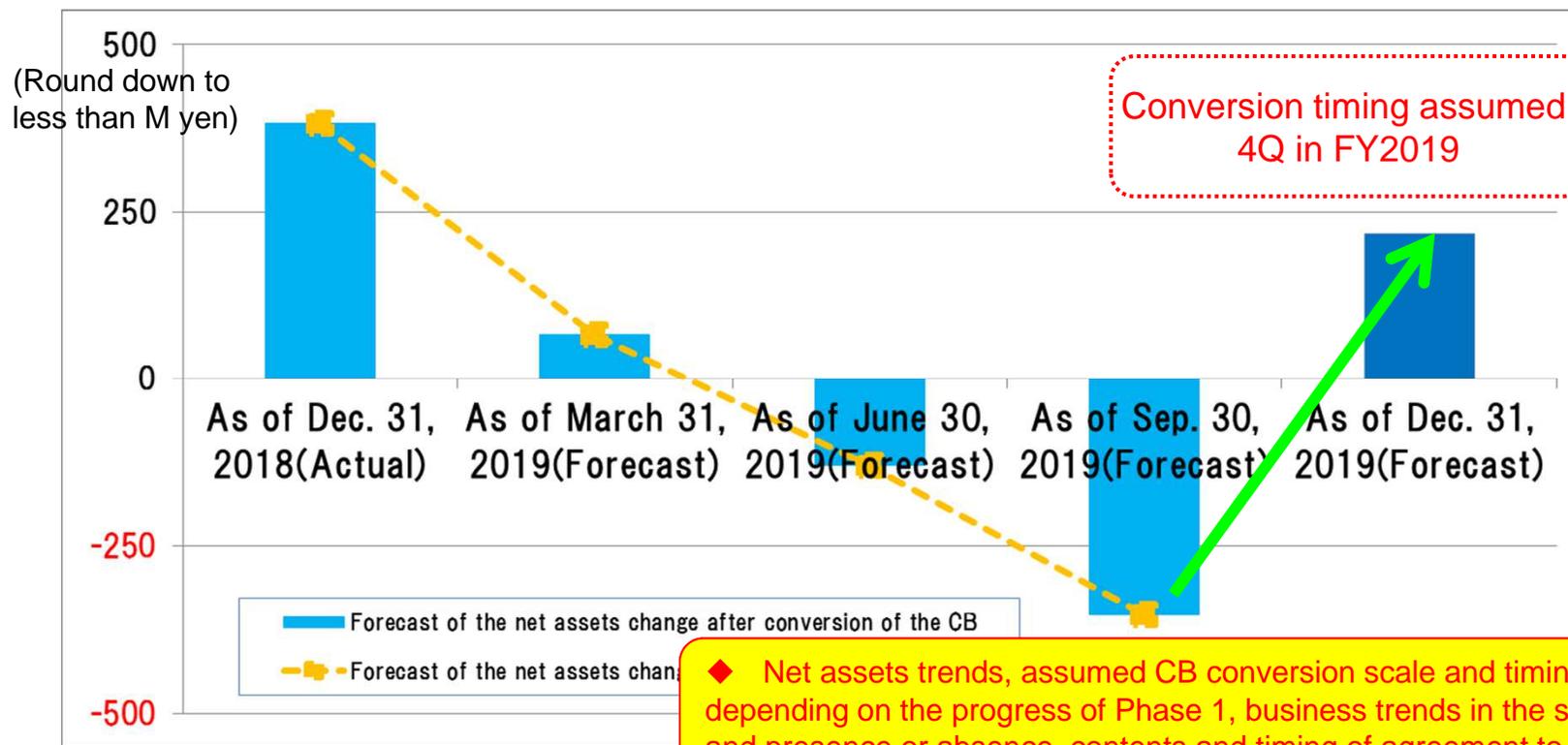
Disclosed on Feb 14, 2019; Conversion Scenario of the 1st Convertible Bond-Type Bonds with Subscription Rights to Shares (CB) in FY2019



- 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 1st phase, promote conversion to Phase 2 through consultations 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



◆ Net assets trends, assumed CB conversion scale and timing may differ, depending on the progress of Phase 1, business trends in the same industry, and presence or absence, contents and timing of agreement to shift to Phase 2.

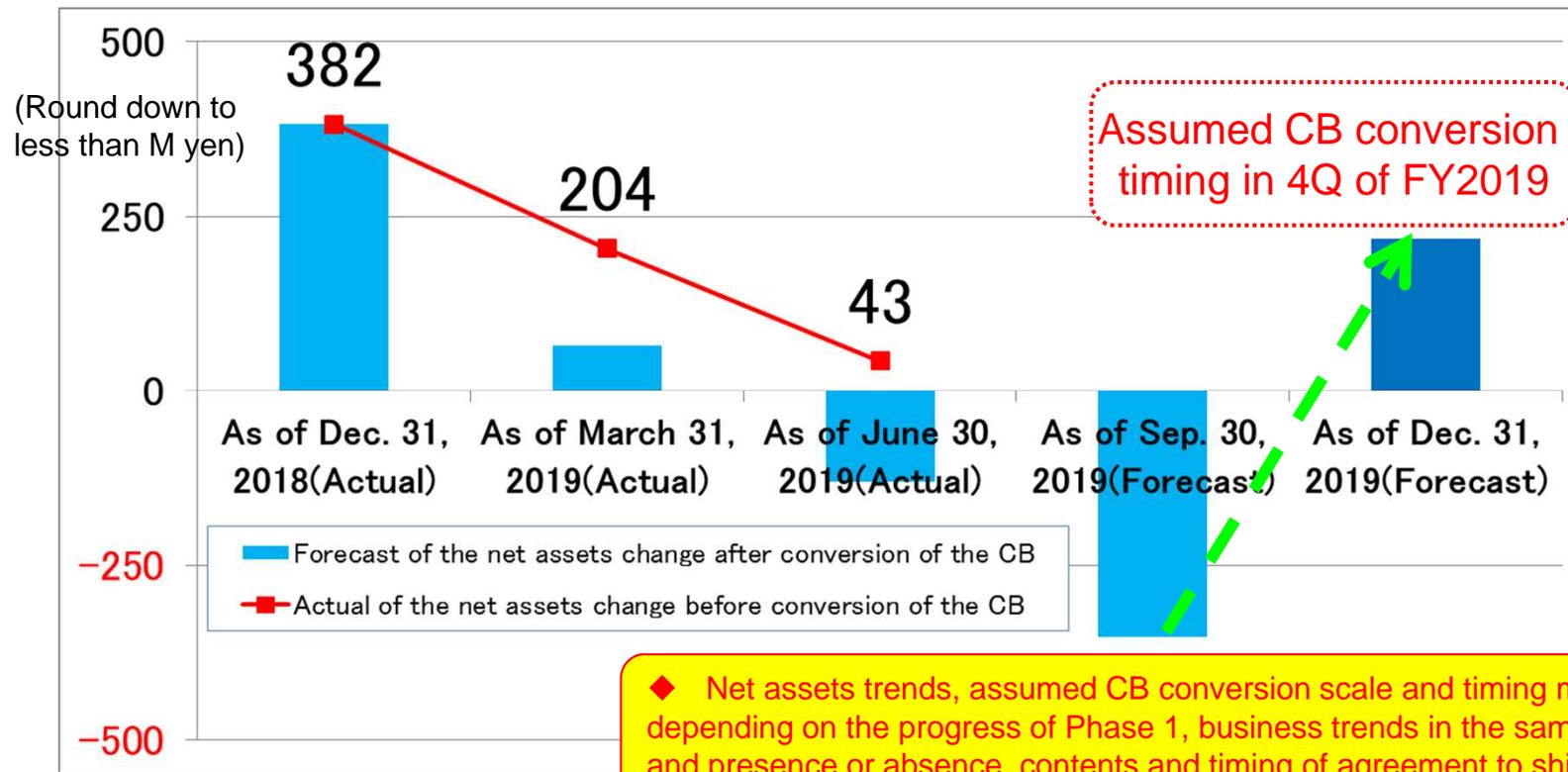
Trends in net assets amount until 2Q of FY2019

- CB conversion timing assume in 4Q as planned
- Unconverted balance: 715 M yen (2400 K shares, 298yen/share)



- Net assets amount exceeded the plan and maintain positive until 2Q of FY2019
- No change in policy to maintain net assets positive at the end of FY2019 by CB conversion of unconverted share balance 715 M yen in FY2019
- The transition timing is expected to be 4Q as initial planned

Net assets amount of actual until 2Q and forecasts of 3Q and 4Q



Finally: Re-challenge goes to full-scale development stage



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 Phase 2
= We will take the first step to biotechnology business by full-scale development

Management Resource Policy

People: Secure necessary personnel->Focus on improving quality by training

Goods: Achieve milestones of Phase 1->Go to full-scale development through Phase 2

Money: Strengthen mid- to long-term financial base->Secure R&D funds, and continue cost reduction

Appendix

Final Results for First Six Months of FY2019

Financial Results for First Six Months(2Q) of FY2019 vs 2Q of FY2018 (Non-consolidated)

- Revenue: Almost flat with receiving of the 3rd milestones

- Each profit and loss stage: Operating and ordinary losses increased due to increase in R&D expenses, 2Q net loss improved



(Round down to less than M yen)	2Q of FY2018 Actual	2Q of FY2019 Actual	Year-to-year comparison (Rounding off M yen)		Main Factors for Change
Net Sales	53	50	(3)	(6.7)%	Almost flat with receiving of the 3 rd milestones from Shionogi & Co., Ltd.
Cost of sales	1	—	—	—	
R&D expenses	234	271	+37	+15.8%	R&D exp. Related to co-operation with Shionogi & Co., Ltd. increased, due to the increase of R&D personnel
Other SG&A expenses	122	121	(1)	(1.1)%	Reduced compared with FY2018, due to cost reduction
Operating Income	(305)	(342)	(37)	-	
Ordinary Income	(307)	(343)	(36)	-	
Net Profits	(388)	(344)	+43	-	80 M of Impairment loss of land of Akita plant recorded in 2Q of FY2018, as a special factor
Net Income per share	(30.34)yen	(22.53)yen			

Balance Sheets as of June 30, 2019 vs. as of Dec 31, 2018 (Non-consolidated)

- Total assets: 692 M yen of cash and cash equivalents stayed within the plan of FY2019
- Net assets: Remained positive in 2Q of FY2019



(Round down to less than M yen)	Year ended as of Dec. 31, 2018	Six months ended as of June 30, 2019	Change	Remarks
Cash and deposits	1,018	692	(325)	Cash flows stayed within the plan
Other current assets	58	47	(10)	
Total current assets	1,077	740	(336)	
Non-current assets	80	80	-	
Other non-current assets	19	19	(0)	
Total non-current assets	100	99	(0)	
Total assets	1,177	839	(337)	
Current liabilities	52	53	+0	
Non-current liabilities	742	742	+0	715 M yen of CB unconverted balance
Total liabilities	795	796	+1	
Capital stock & capital surplus	1,358	1,358	-	
Retained earnings	(984)	(1,329)	(344)	
Others	8	14	+6	New share acquisition rights related to the 21 st SO
Total net assets	382	43	(338)	Remained positive in 2Q of FY2019
Total liabilities & net assets	1,177	839	(337)	

Cash Flows for the First Six Months of FY2019 (Non-consolidated)

- Operating cash flow: Decrease of 326 M yen
- Cash and cash equivalents: Decrease of 325 M yen from the end of FY2018, stayed within the plan



(Round down to less than M yen)	Six months ended as of June 30, 2019 (Actual)	Remarks
Cash flows from operating activities		
Loss before income taxes (-)	(343)	
Share-based compensation expenses	6	
Other, net	12	
Sub total	(324)	
Income taxes paid etc.	(2)	
Cash flows from operating activities	(326)	
Cash flows from investing activities	0	
Cash flows from financing activities	-	
Net increase (decrease) in cash and cash equivalents (-)	(325)	
Cash and cash equivalents at beginning of period	1,018	
Cash and cash equivalents at end of 2Q	692	No change in the status of securing necessary funds by 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 uncertainties 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.