



\*(Notes)

(1) Application of special accounting treatment in preparation of quarterly non-consolidated financial statements : None

(2) Changes in accounting policies, changes in accounting estimates, and restatements

1) Changes due to revised accounting standards : None

2) Changes due to revised accounting policies other than 1) : None

3) Changes in accounting estimates : None

4) Restatements : None

(3) Number of common shares issued

1) Number of shares issued  
(including treasury shares)

As of September 30,2019	15,296,500	As of December 31,2018	15,296,500
As of September 30,2019	50	As of December 31,2018	50
For the first nine months of FY2019	15,296,450	For the first nine months of FY2018	12,796,450

2) Number of treasury shares

3) Average number of shares outstanding

\* This quarterly summary of consolidated financial results is excluded from quarterly review by certified public accountants or auditing corporations.

\*\* Explanation concerning the appropriate use of forecasts and other special instructions

(Notice regarding forward-looking statements)

This press release includes forward-looking statements based on a number of assumptions and beliefs in light of the information currently available to management and subject to significant risks and uncertainties. Consequently, any statements herein do not constitute assurances regarding the actual results. 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 launches, the pricing and product initiative of competitors, the inability of the company to market existing and new product effectively, interruptions in production, infringement of the company's intellectual property rights and the adverse outcome material litigation.

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## 1. Analysis of Operating Results and Financial Position

### (1) Analysis of Operating Results

The Japanese economy in the third quarter of the current fiscal year appears to begin to level off in corporate earnings and the employment environment, as the effects of the government's economic and fiscal policies appeared to have come round to be finished. In addition to the weakness of consumer spending in Japan, concerns about the global economic situation, such as recession fears due to the consumption tax increase, destabilization of the surrounding regional situation, and an increase of vigilance against the trend of US trade policy, have not been dispelled yet and still uncertain.

In the Japanese pharmaceutical industry, the growth of the medical pharmaceutical market has slowed due to measures to curb medical expenses, and expansion in world markets by the development of global pharmaceutical products is becoming more important.

In such a business environment, the Company has been developing "the next-generation biopharmaceutical in-house development business" aiming to create higher value-added "next-generation logical vaccine" that is capable of higher efficacy and efficient production.

In "Next-generation biopharmaceutical in-house development project", based on the agreement of the capital and business alliance signed with Shionogi & Co., Ltd. (hereinafter referred to as "Shionogi") on October 31, 2017, which includes fundamental core technology related to drug discovery regarding vaccine for preventing infection in humans, a part of the in-house development pipeline that the Company has been developing in next-generation biopharmaceutical development project, and new development candidates targets other than in-house developed pipeline as initial basic development candidates, the Company has been actively promoting R&D activities related to fundamental core technology and basic research on development candidates in order to achieve the third milestones based on the agreement. The Company received milestone fees in the second quarter on May 22, 2019 after being confirmed that the third milestones were achieved based on the achievement status per semiannual. The Company has confirmed that the fourth milestones condition has been achieved set in the capital and business alliance on October 1, 2019. The Company has almost achieved its initial objectives in the development of fundamental core technology. In addition, the Company is going to record the fourth milestones fees as sales in the fourth quarter of the current fiscal year.

The specific progress of R&D in the third quarter is as follows; The Company conducted multiple trial productions using the 600L full-scale culture tank that started in the first quarter after several small-scale trial productions at Akita Plant. The Company confirmed the adaption of the target protein expression of new development candidates of development of fundamental core technology. In addition, the Company has also discussed with the authorities regarding the application of regulatory guidelines that are important in establishing basic technology, and has confirmed that contents of the current research and development are generally in line with regulatory guidelines. Furthermore, the Company has established fundamental core technology adapted evaluation based on GMP, as a result of promoting research and development related to the final stage of development of fundamental core technology. The fundamental core technology that the Company has recently established is a technology platform that can be operated internationally, using genetic recombination technology that produces protein that is the drug substance for biopharmaceuticals, including next-generation logical vaccine that the Company has been aiming to create. In addition, regarding the fundamental research of development candidates that the Company has been progressing in parallel, the Company has been studying on selection of \*\*adjuvant and application of drug delivery technology. In a plurality of development candidates, the Company is about to acquire important knowledge concerning the creation of next-generation logical vaccine. With regard to development candidates that are under priority consideration, the Company generally decided on pharmaceutical packages and is drawing up the details of the development plan. In addition, the test results in line with the target product profile were obtained with regard to the priority development candidates products, in the pharmacological test using animals, and the selection of development candidates is progressing smoothly. Based on the above progress, the Company has already started consultations with Shionogi for the second phase of the alliance and activities for full-scale development has been steadily progressing.

The following in terms of the in-house development pipeline, in the basic research of development candidates in accordance with the partnership with Shionogi, has been promoting the research and development based on its own technology, and the selection of development candidates has been progressing. All progress as of this disclosure date is in basic research stage.

- **UMN-101 : Recombinant seasonal influenza HA vaccine**
- **UMN-102 : Recombinant H1N1 influenza HA vaccine**
- **UMN-103 : Recombinant Rotavirus vaccine**
- **UMN-104 : Recombinant Norovirus vaccine**

In addition, although the Company entered into the joint research agreement with National Institutes of Biomedical Innovation, Health and Nutrition (hereinafter referred to as “NIBIOHN”) as the period from June, 2017 to the end of June, 2019, in order to go ahead with research and development activities aimed at creating “Next-generation logical vaccine”, state-of-the-art biopharmaceuticals including new vaccine, by fusing new adjuvant seeds owned by NIBIOHN and manufacturing technology owned by the Company. The joint research period has been extended by the end of June 2020 to further study. In addition, The Company have started joint research on translational research and its clinical research with Professor Ken Ishii, M.D., Ph.D., Division of Vaccine Science, Department of Microbiology and Immunology, The Institute of Medical Science, The University of Tokyo since October 15, 2019, aiming to implement clinical development in the infectious disease prevention vaccine candidate group that the Company has been possessing.

On the other hand, in terms of “the contract manufacturing business for biopharmaceuticals”, in addition to having an obligation to advance the business related to the first phase with Shionogi, there were no orders for new projects since the Company are concentrating management resources on research and development activities in the first phases for the time being in order to prioritizing to make progress to the second phase.

Concerning the introduction of new development pipeline, the Company has been actively working on as one of the introduction routes of the newly developed pipeline through the achievement of the contracts with universities and public research institutions so far, not only for consignment of manufacturing at the research stage but also for candidates that are expected to be commercialization that has come out.

On the financial side, the Company has received an invoice for the exercise of stock acquisition rights related to the bonds with stock acquisition rights as of October 3, 2019, concerning unconverted balance, ¥715,200 thousand (2,400 thousand shares), of the first unsecured convertible bonds with stock acquisition rights that the Company assigned to Shionogi & Co., Ltd. on November 16, 2017, since the Company almost achieved the planned purpose regarding the development of fundamental core technology related business and capital alliance. The balance of the bonds with stock acquisition rights is zero as of this disclosure date as the result of the exercise. Shionogi owns 5,500 thousand shares, and the shareholding ratio of it is 31.08%, which is scheduled to hold in medium and long term. Shionogi has agreed not to transfer or sell them without prior consent of the Company and not to lend them without reasonable reason during the business and capital alliance. Net asset are expected to remain positive as of the end of December 2019 as assumed based on the full-year forecast for the fiscal year ending December 2019 disclosed on February 14, 2019, as a result of the increase in the Company’s capital and capital surplus of ¥357,600 thousand (total of ¥715,200 Thousand) respectively on October 3, 2019, although net assets at the end of the third quarter were negative.

As a result of the above, net sales amount of the third-quarter was ¥50,000 thousand (a decrease of 6.7% from the same period last year). On the other hand, by recorded research and development expenses related to the alliance with Shionogi, the operating loss amounted to ¥533,010 thousand (Operating loss of ¥469,630 thousand in the same period of the previous year), the ordinary loss amounted to ¥534,060 thousand (Ordinary loss of ¥470,056 thousand in the same period of the previous year), and the net loss amounted to ¥ 535,606 thousand (Net loss of ¥587,412 thousand in the same period of the previous year).

In addition, since the Company has a single segment of R&D of medical drugs and related business, the description of business results by segment is omitted.

\*Next-generation logical vaccine:

The next-generation logical vaccine that the Company has been aiming for is a development concept of vaccine, integrated recombinant protein antigen production technology, adjuvant technology and formulation/drug delivery technology, utilizing various knowledge, know-how and technology of biopharmaceutical technology platform, which has been developed for over 10 years by the Company.

By next-generation logical vaccine, the Company has been aiming at the realization of optimal high effectiveness and high productivity for a target infectious disease. In other words, by utilizing formation/drug delivery technology, it is possible to realize high effectiveness by inducing optimal immunity for each targeted infectious disease. In addition, by utilizing adjuvant technology, not only it is possible to realize high effectiveness with less antigen amount, but also it is possible to secure a supply amount that can cover the market with the Company's current production system and also to contribute to cost reduction, by introducing efficiently producing recombinant protein antigens.

\*\*Adjuvant: Pharmaceutical additives for the purpose of immunopotentiating to increase effectiveness of vaccine.

## (2) Analysis of Financial Position

The financial position as of September 30, 2019 is as follows,

Total assets amounted to ¥660,678 thousand, which corresponds to a decrease of ¥516,695 thousand compared to the end of the previous fiscal year.

Current assets amounted to ¥561,316 thousand, which corresponds to a decrease of ¥516,008 thousand compared to the end of the previous fiscal year, mainly due to a decrease of ¥537,325 thousand in cash and cash deposits.

Non-current assets amounted to ¥99,361 thousand, which corresponds to a decrease of ¥686 thousand compared to the end of the previous fiscal year.

Liabilities amounted to ¥805,351 thousand, which corresponds to an increase of ¥10,113 thousand compared to the end of the previous fiscal year.

Net assets amounted to ¥(144,673) thousand, which corresponds to a decrease of ¥526,808 thousand compared to the end of the previous fiscal year, mainly due to net loss of ¥ 535,606 thousand incurred during the period.

## (3) Explanation of Non-consolidated Financial Results Forecasts and Other Forward-looking Information

There is no change from our financial results for the fiscal year ending December 31, 2019 released on February 14, 2019.

2. Quarterly Non-consolidated Financial Statements  
(1) Quarterly Non-consolidated Balance Sheets

(Thousands of yen)

	Previous fiscal year (as of Dec. 31, 2018)	Third quarter of FY2019 (as of Sep. 30, 2019)
<b>Assets</b>		
Current assets		
Cash and deposits	1,018,410	481,084
Raw materials	5,946	42,651
Other	52,968	37,580
Total current assets	1,077,324	561,316
Non-current assets		
Property, plant and equipment	80,605	80,605
Investments and other assets	19,442	18,755
Total non-current assets	100,048	99,361
Total assets	1,177,373	660,678
<b>Liabilities</b>		
Current liabilities		
	52,854	62,705
Non-current liabilities		
Convertible bond-type bonds with share acquisition rights	715,200	715,200
Asset retirement obligations	23,469	23,732
Other	3,714	3,714
Total non-current liabilities	742,384	742,646
Total liabilities	795,238	805,351
<b>Net assets</b>		
Shareholders' equity		
Capital stock	679,415	679,415
Capital surplus	679,415	679,415
Retained earnings	(984,931)	(1,520,538)
Treasury shares	(197)	(197)
Total shareholders' equity	373,701	(161,905)
Share acquisition rights	8,433	17,231
Total net assets	382,134	(144,673)
Total liabilities and net assets	1,177,373	660,678

## (2) Quarterly Non-consolidated Statements of Income

(Thousands of yen)

	Nine months ended Sep. 30, 2018 (From Jan. 1, 2018 to Sep. 30, 2018)	Nine months ended Sep. 30, 2019 (From Jan. 1, 2019 to Sep. 30, 2019)
Net sales	53,610	50,000
Cost of sales	1,677	—
Gross profit	51,933	50,000
Selling, general and administrative expenses	521,564	583,010
Operating loss	(469,630)	(533,010)
Non-operating income		
Interest income	5	11
Office work fee	2,592	—
Other	25	187
Total non-operating income	2,623	198
Non-operating expenses		
Interest on bonds	2,402	1,176
Issuance cost of subscription rights to shares	599	—
Foreign exchange losses	47	71
Total non-operating expenses	3,049	1,248
Ordinary loss	(470,056)	(534,060)
Extraordinary losses		
Impairment loss	80,605	—
Loss on liquidation of business	36,272	—
Total extraordinary losses	116,878	—
Loss before income taxes	(586,934)	(534,060)
Income taxes - current	477	1,546
Total income taxes	477	1,546
Net loss	(587,412)	(535,606)