



Non-consolidated Financial Results for the First Three Months of Fiscal Year Ending Dec. 31, 2017 (Japanese GAAP)

April 28, 2017

Company name	UMN Pharma Inc.	Stock listings	Mothers of TSE
Securities code	4585	URL	http://www.umnpharma.com/en/
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Scheduled date of filing securities report	May 15, 2017	Scheduled date of Dividend payments	—
Supplementary materials for financial results:	None		
Briefing session of financial results:	None		

(Rounded down to nearest million yen)

1. Financial Results for the First Three Months of FY2017 (From Jan. 1, 2017 to Mar. 31, 2017)

(1) Operating results (Percentage indications show changes from corresponding figures for the previous period)

	Net sales		Operating income		Ordinary income		Net income	
	Million yen	%	Million yen	%	Million yen	%	Million yen	%
First three months of FY2017	2	—	(141)	—	206	—	206	—
First three months of FY2016	—	—	—	—	—	—	—	—

	Net income per share - basic	Net income per share - diluted
	Yen	Yen
First three months of FY2017	16.94	—
First three months of FY2016	—	—

(Note) The Company changed to disclose non-consolidated financial results from the first three months of fiscal year ending Dec. 31, 2017, and thus the figures for the first three months of FY2016 and year-on-year changes are not stated herein.

(2) Financial position

	Total assets	Net assets	Net assets as percentage of total assets
	Million yen	Million yen	%
As of Mar. 31, 2017	660	544	82.4
As of Dec. 31, 2016	694	208	29.2

(Reference) Shareholders' equity As of March 31, 2017 544 Million yen As of December 31, 2016 202 Million yen

2. Dividends

	Annual dividends per share				
	End of Q1	End of Q2	End of Q3	Year end	Total dividends
	Yen	Yen	Yen	Yen	Yen
FY2016	—	0 00	—	0 00	0 00
FY2017	—	—	—	—	—
FY2017(Forecast)	—	0 00	—	0 00	0 00

(Note) Revisions to the latest dividend forecast: None

3. Forecasts for the Fiscal Year Ending Dec. 31, 2017(from Jan. 1, 2017 to Dec. 31, 2017)

(Percentage indications show changes from corresponding figures for the previous period)

	Net sales		Operating income		Ordinary income		Net income		Profit per share
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Yen
FY2017	153	192.9	(512)	—	(167)	—	(170)	—	(13.96)

(Note) Revisions to the latest performance forecasts: None

*(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 March 31,2017	12,196,500	As of December 31,2016	12,046,500
As of March 31,2017	50	As of December 31,2016	50
For the first three months of FY2017	12,188,116	For the first three months of FY2016	9,591,504

2) Number of treasury shares

3) Average number of shares outstanding

* Disclosure concerning the implementation status of review procedures

This quarterly financial report is exempt from the quarterly review procedures as stipulated under the Financial Instruments and Exchange Act of Japan. At the date of disclosure, quarterly financial statement review procedures have not been completed under the Financial Instruments and Exchange Act of Japan.

** 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.

The Company changed to disclose non-consolidated financial results from the first three months of fiscal year ending Dec. 31, 2017. Because, the Company, as a non-consolidated single entity after relinquishing UNIGEN, is transforming its business model including pushing through the overall restructuring.

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1. Analysis of Operating Results and Financial Position

(1) Analysis of Operating Results

During the three months ended March 31, 2017, UMN Pharma Inc. (“The Company”) has energetically engaged in biopharmaceutical contract manufacturing business and continuously allocated the operational resources and advanced R&D activities of UMN-2002 (recombinant norovirus VLP single vaccine, hereinafter referred to as “UMN-2002”) for the prevention from norovirus; and UMN-2001 (recombinant rotavirus VP6 single vaccine, hereinafter referred to as “UMN-2001”); and UMN-2003 (recombinant norovirus VLP + recombinant VP6 combination vaccine, hereinafter referred to as “UMN-2003”) for the prevention of norovirus and rotavirus that are principal causative virus of viral gastroenteritis ; and Zikavirus vaccine (hereinafter referred as “ Zikavirus vaccine): and UMN-0502 (recombinant influenza HA vaccine for the prevention of seasonal influenza, hereinafter referred to as “UMN-0502”); and UMN-0501 (recombinant influenza HA vaccine (H5N1) for the prevention of pandemic influenza, hereinafter referred to as “UMN-0501”); and UMN-0901 (recombinant influenza HA vaccine (H9N2), hereinafter referred to as “UMN-0901”) for which the possibility of pandemic has been indicated by WHO besides H5N1.

In terms of the carrying out development for UMN-0502 and UMN-0501 for Japan in collaboration with Astellas Pharma Inc. (“Astellas”), after submission of an application for marketing approval of recombinant influenza HA vaccine ASP7374 by Astellas for the prevention of seasonal influenza to the Ministry of Health, Labour and Welfare in May, 2014, the Company, in collaboration with Astellas, responded to the related inquiries from Pharmaceutical and Medical Agency (“PMDA”) for the approval during the period.

However, as shown in the release, on January 10, 2017, “Notice Received from Astellas for its Exercise of Termination Right of the Agreement to Co-develop ASP7374 (UMN-0502) and ASP7373 (UMN-0501)”, the Company has received notice from Astellas to exercise termination right on the agreement as Astellas reached a conclusion that it would be difficult to obtain the approval of APS7374 from PMDA and thus the application should be turned down by Astellas. According to Astellas, the conclusion was drawn after the meeting held between Astellas and PMDA, where the regulator’s point of view was presented from PMDA to Astellas that after considering the benefits and the risks of ASP7374, PMDA had no intension to continue the review process any further as little clinical significance was recognized for ASP7374. As of today, Astellas has already commenced the procedure to withdraw the application for marketing approval of ASP7374 with PMDA and the Company and Astellas have settled the termination of the agreement.

In response to the request to exercise the cancellation right from Astellas, the Company posted consolidated extraordinary loss and non-consolidated extraordinary loss both for provision for loss on liquidation of business. Thus making significant downward revision of both consolidated and non-consolidated financial results forecasts for the fiscal year ending December 31, 2016, and under such an abrupt change in the business circumstances, the Company has reached the conclusion that it is impossible for the Company to financially support UNIGEN and to go further as a group anymore. As a result, the Company, with IHI Corporation (“IHI”) as the business partner or 50% shareholder of UNIGEN concurrently acting as disclosed on January 31, 2017, decided to transfer all the shares of UNIGEN owned by the Company and IHI to API Co., Ltd. (“API”), which wishes to become a sponsor of UNIGEN.

Upon the execution of this share transfer, the Company has been transforming its business model along with the fundamental change in the business circumstances, including pushing through the overall restructuring. The “Basic Agreement on Business Collaboration”, where the Company and IHI concluded to jointly operate the influenza vaccine drug substance manufacturing business reached on January 25, 2010, has been terminated.

Following the reorganization of the Group structure as a result of the significant change in the business environment of the Company, the Company has formulated new business policies, as a single company, which is specialized in CMC development and industrialization for examination stages. The Company has redefined the business domain as “next-generation biopharmaceuticals in-house development project” and “contract manufacturing business for biopharmaceuticals”, specializing in CMC development and examination for industrialization. Please see “Supplementary Documents of Business Results for Fiscal Year 2016 Ended Dec. 31, 2016”.

In terms of UMN-0501, Astellas filed an application for cancellation of the designation of orphan drugs to the authorities,

which was approved in March, 2017. According to the procedure above, the Company has transferred ¥336 million, which received as research subsidies targeting UMN-0501 before, to non-operating income as subsidy income from long-term deposits in the first quarter of the current fiscal year.

In terms of next-generation biopharmaceuticals in-house development project, the company energetically conducted R&D activities between UMN-2002 and UMN-2001 newly established and alliance activities as in-house existing pipelines as well. As for South Korean market, although Ildong Pharmaceutical Co., Ltd. has prepared upcoming clinical trial of UMN-0502, after the results of the review process by PMDA in Japan, Ildong Pharmaceutical Co., Ltd. has been reexamining their development policies with the Company and PSC. As for other East Asia, the Company has been also getting inquiries from other East Asian countries since PSC has announced on October 11, 2016, that the FDA has approved its quadrivalent formulation of Flublok[®] influenza vaccine for adults 18 years of age and older.

Regarding the development of establishing a new pipeline of UMN-2001, the Company has been conducting immunogenicity tests using model mice, and is getting the findings of increase of target immunogenic chemicals. In addition, the Company has been going ahead to make alliances as early as possible globally and domestically. As for UMN-2002, under the joint research agreement with Daiichi Sankyo Company, Limited (“Daiichi Sankyo”) in February 2014, the Company made further optimization of the manufacturing process, while Daiichi Sankyo continuously conducted basic research using the VLP antigen produced on the refined process and provided by the Company. Currently, however, the project has been run considerably behind schedule.

In addition to other existing pipelines, the Company has been performing percussions of joint developments to companies, in terms of new R&D candidates that aimed not only for conducting entrusted tests along with achievements so far, but also for assuming productivity.

In order to make sure long-term sustainable growth, the Company is seeking for new vaccine candidates by further leveraging BEVS platform, and on June 28, 2016, the Company signed a partnership agreement with Protein Sciences Corporation (“PSC”), in which secures a right to participate in ‘International Zikavirus Vaccine Consortium’ that PSC has taken an initiative. Currently, preclinical studies using its lead protein based Zikavirus vaccine candidate, created using PSC’s proprietary BEVS technology, have been conducted by PSC, which were sponsored by National Institute of Allergy and Infectious Disease, National Institutes of Health through its pre-clinical support program. In addition, in January 2017, the Institute of Technology in Immunobiologicals of the Oswaldo Cruz Foundation (Bio-Manguinhos/ Fiocruz) of Brazil has joined the multinational consortium, thus making the consortium composed of entities from five countries, the United States, Mexico, Brazil, Argentina and Japan. Currently, the Company have been preparing for various exams with clinical trials in mind, discussing a draft agreement with the consortium for formal agreement.

In terms of the contract biopharmaceuticals manufacturing business, the Company has been preparing to accept continuous orders of new vaccine candidate antigens from various domestic research institutions that the Company has been continuously accepting so far. In addition, the Company has started consultation concerning manufacturing contract by BEVS to new domestic research organizations. The Company has already received several inquiries from potential customers, and some of which are concerned with antigens for other than vaccines, or those for other than human use. So, the Company has been establishing flexible system so as to meet various needs for variety of customers to build long-term relationships. In addition, in terms of human drugs, the company has been discussing to respond to requests of contract manufacturing using Akita plant’s 600L culture tank, reviewing estimation for cost and schedule to make the best effort to cover the costs by maximizing utilization of the capabilities of Akita plant.

On the other hand, as a result of reviewing the business strategy in terms of the joint business contract of antibody biosimilar between the Company, Yakult Honsha Co., Ltd (“Yakult Honsha”) and API, the Company, Yakult Honsha and API have agreed to terminate the contract dated March 31, 2017.

In terms of financial aspects, the Company issued 1.5 million shares as the 20th stock acquisition right (with amendment of the exercise price) on November 4, 2016 to allocate to Evolution Biotech Fund, in order to increase the production capacity of Gifu plant to realize Flublok[®] drug substance export business for the US, to promote in-house development pipeline, to seek for new seeds and to reinforce financial position, especially operational capital and repayments of loans at Gifu plant.

As a result of exercising 150 thousand shares in January, 2017, although cumulative total of 800 thousand shares was exercised so far, since the stock price changed to less than 563 yen, which is lower limit exercise price, the Company has decided to purchase and cancel 700 thousand of outstanding shares at the Board of Directors meeting dated on March 21, 2017. As a result of the exercising, the actual cumulative amount of the procurement after the issue expenses are deducted has become ¥717 million.

In addition, at the Board of Directors' Meeting held on January 31 and March 21, 2017, the Company has made resolutions on changes in the use of the procured funds due to the changes in situation such as the reorganization of the group structure and the divergence of the procurement amount between the estimate and actual.

In consideration of the financial situation, the Company have made resolutions at the ordinary general meeting of shareholders held on March 30, 2017, the reduction of the amount of capital from ¥10,117 million as of December 31, 2016, to ¥150 million, and of legal capital surplus from ¥9,786 million as of December 31, 2016, to ¥150 million, transferring both to other capital surplus; and the reduction of the other capital surplus from ¥19,603 million as of December 31, 2016, to 0 yen, transferring to retained earnings in order to reduce carry forward deficit on May 2, 2017, as effective date.

In addition, the Company has been in the grace period for delisting under the regulation of the listing policy of securities since, since consolidated net assets as of December 31, 2016, exceeded liabilities of ¥10,920 million on the securities report of the fiscal year ended December 31, 2016, which is submitted on March 31, 2017.

The grace period is until December 31, 2017. However, as mentioned above, as a result of transferring the business of UNIGEN, which was a consolidated subsidiary of the Company, the Company has decided to manage the business on a stand-alone basis since the fiscal year ended December, 2017. The excess of liabilities of ¥10,920 million in net assets as of the end of December, 2016 has already been eliminated by the non-consolidation of UNIGEN, and the non-consolidated net assets of the Company as of March 31, 2017 is ¥544 million yen.

In order to avoid excessive debt and to stabilize the medium- and long-term management foundation to earn revenues, the Company has been rebuilding the existing in-house development pipeline as "Next Generation Biopharmaceutical In-house Development Project", and pursuing researches and introductions of new seeds by partnership with pharmaceutical companies,

In "Contract Manufacturing Business for Biopharmaceuticals", the Company specialize in "CMC development and industrialization study of biopharmaceuticals", and seek for secure profitability and expand business by industrialization consignment etc. such as contract manufacturing of biopharmaceutical drugs in the initial development stage, development of drug substance manufacturing process, commissioned work of standardization of analytical test concerning various quality control such as process standard test, and industry consultation business aimed at scale-up business, using Yokohama Lab, Akita Lab and Akita Plant owned by the Company, widely from domestic to overseas companies and research institutions.

As a result of the above, net sales for the first quarter of the current fiscal year were ¥2,943 thousand. On the other hand, operating loss is ¥141,129 thousand due to account expenses related to research and development of each pipeline.

As mentioned above, ordinary profits were ¥206,650 thousand due to recording subsidy income of ¥336,618 thousand as research grant for rare diseases of UMN-0501, and net profits for the quarter were ¥206,491 thousand.

Since the Company is a single segment of research and development of medical drugs and related businesses, the description of business results by segment is omitted.

*CMC : Chemistry, Manufacturing and Control

(2) Analysis of Financial Position

The financial position as of Mar. 31, 2017 is as follows,

Total assets amounted to ¥660,215 thousand, which corresponds to a decrease of ¥34,140 thousand compared to the end of the previous fiscal year.

Current assets amounted to ¥616,054 thousand, which corresponds to a decrease of ¥34,099 thousand compared to the end of the previous fiscal year, mainly due to a decrease of ¥18,097 thousand in cash and cash deposits.

Noncurrent assets amounted to ¥44,160 thousand, which corresponds to a decrease of ¥40 thousand compared to the end of the previous fiscal year.

Liabilities amounted to ¥116,027 thousand, which corresponds to a decrease of ¥369,541 thousand compared to the end of the previous fiscal year.

Net assets amounted to ¥544,188 thousand, which corresponds to an increase of ¥335,401 thousand compared to the end of the previous fiscal year, mainly due to net income of ¥ 206,491 thousand incurred during the period.

Cash and cash equivalents position

The balance of cash and cash equivalents stood at ¥548,000 thousand, which corresponds to a decrease of ¥18,097 thousand compared to the end of the previous fiscal year.

(Cash flows from operating activities)

Net cash used in operating activities for the first three months of FY2017 totaled ¥121,014 thousand, mainly due to income before income taxes of ¥206,650 thousand, and ¥336,618 thousand in deduction of subsidy income.

(Cash flows from investment activities)

No investment activities for the first three months of FY2017.

(Cash flows from financing activities)

Net cash provided by financing activities for the first three months of FY2017 totaled ¥102,916 thousand, mainly due to ¥25,000 in repayment of long-term loans payable, and ¥132,956 thousand in proceeds from issuance of common stock.

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

We have revised our financial results forecasts for the fiscal year ending December 31, 2017 on March 24, 2017 from those announced on February 14, 2017. Please refer to the release on March 24, 2017 for details.

2. Quarterly Financial Statements

(1) Quarterly Balance Sheets

(Thousands of yen)

	Previous fiscal year (as of Dec. 31, 2016)	First quarter of FY2017 (as of Mar. 31, 2017)
Assets		
Current assets		
Cash and deposits	566,098	548,000
Accounts receivable-trade	6,130	1,364
Other	77,925	66,689
Total current assets	650,154	616,054
Noncurrent assets		
Investments and other assets	44,201	44,160
Total noncurrent assets	44,201	44,160
Total assets	694,355	660,215
Liabilities		
Current liabilities		
Noncurrent liabilities		
Assets retirement obligations	22,787	22,871
Other	340,332	3,714
Total noncurrent liabilities	363,119	26,586
Total liabilities	485,568	116,027
Net assets		
Shareholders' equity		
Capital stock	10,117,021	10,184,536
Capital surplus	9,786,021	9,853,536
Retained earnings	(19,700,179)	(19,493,688)
Treasury stock	(197)	(197)
Total shareholders' equity	202,666	544,188
Subscription rights to shares	6,120	—
Total net assets	208,786	544,188
Total liabilities and net assets	694,355	660,215

(2) Quarterly Statements of Income

Quarterly Statements of Income

	(Thousands of yen)
	Three months ended Mar. 31, 2017 (From Jan. 1, 2017 to Mar. 31, 2017)
Net sales	2,943
Cost of sales	1,896
Gross profit	1,046
Selling, general and administrative expenses	142,176
Operating loss (-)	(141,129)
Non-operating income	
Interest income	4
Subsidy income	336,618
Other	12,166
Total non-operating income	348,788
Non-operating expenses	
Interest expenses	15
Stock issuance cost	993
Total non-operating expense	1,008
Ordinary income	206,650
Income before income taxes	206,650
Income taxes-current	159
Total income taxes	159
Net income	206,491

(3) Quarterly Statements of Cash Flows

	(Thousands of yen)
	Three months ended Mar. 31, 2017 (From Jan. 1, 2017 to Mar. 31, 2017)
Net cash provided by (used in) operating activities	
Income before income taxes	206,650
Interest income	(4)
Interest expenses	15
Stock issuance cost	993
Subsidy income	(336,618)
Decrease(increase) in notes and accounts receivable-trade	4,765
Other	5,797
Subtotal	(118,399)
Interest income received	3
Interest expenses paid	(15)
Income taxes paid	(2,602)
Net cash provided by (used in) operating activities	(121,014)
Net cash provided by (used in) investment activities	
Net cash provided by (used in) investment activities	—
Net cash provided by (used in) financing activities	
Repayment of long-term loans payable	(25,000)
Proceeds from issuance of common stock	132,956
Other	(5,040)
Net cash provided by (used in) financing activities	102,916
Net increase(decrease) in cash and cash equivalents	(18,097)
Cash and cash equivalents at beginning of the period	566,098
Cash and cash equivalents at end of the period	548,000