

Consolidated Financial Results for the First Nine Months of Fiscal Year Ending December 31, 2016 (Japanese GAAP)

October 31, 2016

Company name UMN Pharma Inc. Stock listings Mothers of TSE

Securities code 4585 URL http://www.umnpharma.com/en/

Representative Tatsuyoshi Hirano Chairman and CEO

Contact person Hiroyuki Hashimoto CFO (TEL)+81-45-595-9840

Scheduled date of filing securities report November 14, 2016 Scheduled date of Dividend payments —

Supplementary materials for financial results: None

Briefing session of financial results: None

(Rounded down to nearest million yen)

1. Consolidated Financial Results for the First Nine Months of FY2016 (From January 1, 2016 to September 30, 2016)

(1) Consolidated operating results (cumulative)

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

	Net sales		Operating income		Ordinary i	ncome	Profit attribu	
	Million yen	%	Million yen	%	Million yen	%	Million yen	%
First nine months of FY2016	64	(8.4)	(2,777)	_	(2,977)	_	(2,728)	_
First nine months of FY2015	70	(93.5)	(2,959)	_	(3,075)	_	(3,074)	_

(Note) Comprehensive First nine months income of FY2016

(2,978) Million yen (-%) First nine months of FY2015

(3,074)Million yen (—%)

	Earnings per share	Diluted earnings per share
	Yen	Yen
First nine months of FY2016	(273.01)	_
First nine months of FY2015	(321.28)	_

(2) Consolidated financial position

(2) Consolidated illianelar posit	Consonance immediate position						
	Total assets	Net assets	Net assets as percentage of total assets				
	Million yen	Million yen	%				
As of September 30, 2016	12,848	(148)	(1.2)				
As of December 31, 2015	11,808	333	2.8				

(Reference) Shareholders'

equity

As of September 30, 2016 (148) Million yen As of December 31, 2015 333 Million yen

2. Dividends

	Annual dividends per share							
	End of Q1	End of Q1 End of Q2 End of Q3 Year end Total di						
	Yen	Yen	Yen	Yen	Yen			
FY2015	_	0 00	_	0 00	0 00			
FY2016	_	0 00	_					
FY2016(Forecast)				0 00	0 00			

(Note) Revisions to the latest dividend forecast: None

3. Forecasts for the Fiscal Year Ending December 31, 2016(from January 1, 2016 to December 31, 2016)

(Percentages show changes from corresponding figures for the previous period)

	Net sale	es	Operating inco	me	Ordinary incon	ne	Net income attributable to ov of parent		Profit per share
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Yen
FY2016	84	(58.3)	(3,391)	_	(3,699)	_	(3,451)	_	(342.35)

(Note) Revisions to the latest performance forecasts: None

*(Notes)

(1) Changes in the number of significant subsidiaries in the period(changes in specified subsidiaries : None affecting the scope of consolidation)

(2) Application of special accounting treatment in preparation of consolidated quarterly financial statements : None

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

1) Changes due to revised accounting standards : Yes

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

3) Changes in accounting estimates : None

4) Restatements : None

(4) Number of common shares issued

1) Number of shares issued (including treasury shares)

2) Number of treasury shares

3) Average number of shares issued

As of September 30,2016	11,396,500	As of December 31,2015	9,581,500
As of September 30,2016	50	As of December 31,2015	50
For the first nine months of FY2016	9,994,945	For the first nine months of FY2015	9,570,703

^{*} 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.

Contents of Attached materials

1.	Analy	sis of Operating Results and Financial Position	2
	(1)	Analysis of Operating Results	2
	(2)	Analysis of Financial Position	3
	(3)	Explanation of Consolidated Financial Results Forecasts and Other Forward-looking Information	3
2.	Summ	nary Information (Notes)	4
	(1)	Changes in Significant Subsidiaries during the Period · · · · · · · · · · · · · · · · · · ·	4
	(2)	Application of Simplified Accounting Methods and/or Special Accounting Methods · · · · · · · · · · · · · · · · · · ·	4
	(3)	Changes in Accounting Policies, Changes in Accounting Estimates, Restatements	4
3.	Quarte	erly Consolidated Financial Statements	5
	(1)	Quarterly Consolidated Balance Sheets	5
	(2)	Quarterly Consolidated Statements of Income and Comprehensive Income	7
	(3)	Quarterly Consolidated Statements of Cash Flows	9

1. Analysis of Operating Results and Financial Position

(1) Analysis of Operating Results

During the first nine months of FY2016 ended September 30, 2016, the operational resources of UMN Pharma Inc. ("the Company") continued to be strategically allocated to R&D activities of 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; and UMN-2002 (recombinant norovirus VLP single vaccine, hereinafter referred to as "UMN-2002") for the prevention for norovirus 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). The Company has been carrying out development of UMN-0502 and UMN-0501 for Japan in collaboration with Astellas Pharma Inc. ("Astellas"), and of UMN-0502, UMN-0501 and UMN-0901 for South Korea in collaboration with Ildong Pharmaceutical Co., Ltd.

As for UMN-0502, 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 concerned authorities have been continuously reviewing the application for the approval based upon the guidelines such as ICH (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use), and the Company, in collaboration with Astellas, has continuously been responding to the related inquiries from Pharmaceutical and Medical Agency ("PMDA") for the approval during the period.

But on October 18, 2016, the Company has concluded that, judging from the current review progress of UMN-0502 by the concerned authorities, obtaining the approval would take further more time than anticipated on May 25, 2016, when the Company disclosed the consolidated financial results forecasts for the fiscal year 2016, and thus announced the downward revision of the forecasts.

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.

Regarding UMN-2003, taking UMN-2002 project with Daiichi Sankyo being in progress into consideration, the Company has decided to concentrate its resources more on UMN-2002, rather than UMN-2003 (recombinant norovirus VLP + recombinant rotavirus VP6 combination vaccine), and has transformed the licensing agreement with Dr. Timo Vesikari and Dr. Vesna Blazevic of University of Tampere Vaccine Research Center, Finland, dated January 23, 2012, for the exclusive license for Rotavirus and Norovirus combination vaccine, into the non-exclusive license for Norovirus single vaccine.

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 it secures a right to participate in 'International Zika Vaccine Consortium' that PSC has taken an initiative and is now preparing for the final partnership agreement among prospective participants, mainly global corporations and entities in Latin America such as Sinergium Biotech & Mundo Sano of Argentina. In the Consortium, PSC and the participants would cooperatively develop Zika virus vaccine for the prevention of Zika virus infectious disease, which has been currently spreading in Latin American and other areas. The Company is regarding this opportunity as a chance to enrich the portfolio of in-house pipeline.

Regarding biopharmaceutical contract manufacturing business, the Company completed a part of the ongoing contracts and additionally received order to produce candidate antigen for a novel vaccine.

Under the 'Basic Agreement for supply of Flublok® Drug Substance from UNIGEN Inc. ('UNIGEN', consolidated subsidiary of the Company) with PSC on February 12, 2016, UNIGEN has been driving the project forward as a main counterparty and an outsourcee. On April 7, 2016 (the US local time), Type C meeting (a preparatory Q&A meeting between Food and Drug Administration ("FDA") and an applicant before submitting application) between PSC and FDA was held, where the necessary steps to obtain the licensure from FDA for UNIGEN Gifu plant ("Gifu plant") as a manufacturing facility of Flublok® drug substance were discussed and confirmed. UNIGEN has now become more confident that the process for the licensure could be moved forward as planned and prepared in close collaboration with PSC. On July 15, 2016, UNIGEN started trial manufacturing of Flublok® drug substance in full scale (21,000L) at Gifu plant in order for PSC to collect data for its sBLA (Supplemental Biologics License Application) submission to FDA. The trial manufacturing was already completed in early October 2016 and at the trial manufacturing, UNIGEN has achieved much higher yield than those in the previous cases

of Performance Qualification (PQ) and Process Validation (PV) in producing the proteins, which have been attained by means of using novel strains which PSC had already used in its manufacturing and succeeded in realizing very high yields. That could lead to higher efficiency in the future commercial production at Gifu plant. The Flublok® drug substances manufactured have already been sent to PSC as planned and PSC will acquire relevant data necessary for submission of BLA to FDA as early as possible. Furthermore, 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.

As for financial aspects, the Board of Directors of the Company approved a resolution, on May 25, 2016, to enter into #19 warrants (with provision for revising exercise price) purchase agreement with the Evolution Biotech Fund with dilutive share issuable of 1,800,000 shares when fully exercised. The projected funds to be raised at the issuance was 3,092 million yen, which was initially planned to be used for the additional capital investment at UNIGEN Gifu plant to enhance manufacturing capacity in order to meet the projected future demands including those of Flublok® for the US market, conducting R&D for existing in-house pipeline and prospective new pipelines, as well as repayment of loans for reinforced financial position. On September 1, 2016, the exercise of 1,800,000 shares on #19 warrants was completed and the funds raised resulted in as much as 2,219 million yen, which was short of 873 million yen compared to the initial projection. So, the Board of Directors of the Company, on October 18, 2016, approved a resolution of the change in use of the funds raised from the one announce on May 25, 2016.

As a result, consolidated net sales for the first nine months of FY2016 totaled ¥64,773 thousand (net sales decreased by 8.4% compared to the same period of the previous fiscal year). Reflecting the costs incurred for answering the inquiries from PMDA for the approval of UMN-0502 and R&D activities for other projects, as well as reflecting the facility related fixed costs of Gifu plant, which had booked as work in process on the balance sheet, recognized as R&D expenses during 3nd quarter after the decision made not to start commercial production during 2016, operating loss reached to ¥2,777,624 thousand (compared to operating loss of ¥2,959,845 thousand in the same period of the previous fiscal year), with ordinary loss of ¥2,977,973 thousand (compared to ordinary loss of ¥3,075,559 thousand in the same period of the previous year) and loss attributable to owners of parent of ¥2,728,707 thousand (compared to loss attributable to owners of parent of ¥3,074,842 thousand in the same period of the same fiscal year).

(2) Analysis of Financial Position

The consolidated financial position as of September 30, 2016 is as follows,

Total assets amounted to \(\pm\)12,848,734 thousand, which corresponds to an increase of \(\pm\)1,040,427 thousand compared to the end of the previous fiscal year.

Noncurrent assets amounted to \$9,417,721 thousand, which corresponds to an increase of \$913,174 thousand compared to the end of the previous fiscal year, mainly due to an increase of \$1,837,316 thousand in construction in progress and depreciation on property, plant and equipment of \$928,448 thousand.

Liabilities amounted to \$12,997,485 thousand, which corresponds to an increase of \$1,522,959 thousand compared to the end of the previous fiscal year, mainly due to an increase of \$2,362,500 thousand in short-term loans payable and a decrease of \$808,000 thousand in long-term loans payable.

Net assets resulted in (\$148,751) thousand, which corresponds to a decrease of \$482,532 thousand compared to the end of the previous fiscal year, mainly due to net loss attributable to owners of parent of \$2,728,707 thousand incurred during the period and an increase in capital of \$2,216,500 thousand raised from the exercise of \$19 warrants.

Cash and cash equivalents position

The balance of cash and cash equivalents stood at ¥1,322,145 thousand as of September 30, 2016, which corresponds to an increase of ¥480,023 thousand compared to the end of the previous fiscal year.

(Cash flows from operating activities)

Net cash used in operating activities for the first nine months of FY2016 totaled \(\pm\)1,633,095 thousand, mainly due to loss before income taxes of \(\pm\)2,977,973 thousand, depreciation of \(\pm\)928,448 thousand, and a decrease in inventories of \(\pm\)294,840 thousand.

(Cash flows from investment activities)

Net cash used in investment activities for the first nine months of FY2016 totaled ¥1,841,523 thousand, mainly due to ¥1,843,413 thousand used in purchase of property, plant and equipment.

(Cash flows from financing activities)

Net cash provided by financing activities for the first nine months of FY2016 totaled \$3,954,642 thousand, mainly due to an increase in short-term loans payable of \$2,400,000 thousand, repayment of long-term loans payable of \$845,500 thousand, repayments of lease obligations of \$79,007 thousand, proceeds from issuance of common stock of \$2,216,500 thousand and proceeds from share issuance to non-controlling shareholders of \$248,250 thousand.

- (3) Explanation of Consolidated Financial Results Forecasts and Other Forward-looking Information We have revised our consolidated financial results forecasts for the fiscal year ending December 31, 2016 on October 18, 2016 from those announced on May 25, 2016. Please refer to the release on October 18, 2016 for details.
- 2. Summary Information (Notes)
- (1) Changes in Significant Subsidiaries during the Period No applicable items.
- (2) Application of Simplified Accounting Methods and/or Special Accounting Methods No applicable items.
- (3) Changes in Accounting Policies, Changes in Accounting Estimates, Restatements (Application of the Accounting Standard for Business Combination, etc.)

"The Accounting Standard for Business Combination" (Corporate Accounting Standards No.21;September 13,2013), "the Accounting Standard for Consolidated Financial Statements" (Corporate Accounting Standards No.22;September 13,2013), "the Accounting Standard for Business Divestitures" (Corporate Accounting Standards No.7;September 13,2013), etc. were adopted in the first quarter of this consolidated fiscal period. The indications of quarterly net income, etc. were changed, and nomenclature of minority interests was changed to non-controlling interests. In order to reflect the change of the indications, the quarterly consolidated financial statements of the prior cumulative consolidated second quarter and the consolidated financial statements of the prior consolidated fiscal year are reclassified.

These changes in accounting standards have no impact on profits.

(Adoption of practical solution on a change in depreciation method due to Tax Reform 2016)

UMN Pharma Inc. adopted the "Practical Solution on a Change in Depreciation Method due to Tax Reform 2016" (ASBJ Practical Issue Task Force (PITF) No.32, issued on June 17,2016) from the second quarter ended June 30,2016, and changed the method for the depreciation of facilities attached buildings and structures acquired on or after April 1,2016 from the declining-balance method to the straight-line method.

There is no effect of this change on the quarterly consolidated financial statements for the nine months ended June 30,2016.

3. Quarterly Consolidated Financial Statements

(1) Quarterly Consolidated Balance Sheets

		(Thousands of yen)
	Previous fiscal year (as of December 31, 2015)	Third quarter of FY2016 (as of September 30, 2016)
Assets		
Current assets		
Cash and deposits	842,121	1,322,145
Accounts receivable-trade	17,897	17,897
Work in process	417,590	61,698
Raw materials and supplies	1,685,139	1,746,191
Advance payments-trade	25,390	65,850
Other	315,620	217,230
Total current assets	3,303,759	3,431,012
Noncurrent assets		
Property, plant and equipment		
Buildings and structures, net	4,680,456	4,386,225
Machinery and equipment, net	2,555,545	2,076,029
Tools, furniture and fixtures, net	72,904	57,647
Lease assets, net	426,233	345,891
Construction in progress	401,254	2,238,571
Total property, plant and equipment	8,136,395	9,104,365
Intangible assets	171,795	118,900
Investments and other assets	196,356	194,455
Total noncurrent assets	8,504,547	9,417,721
Total assets	11,808,306	12,848,734
Liabilities		, ,
Current liabilities		
Accounts payable-trade	342,886	320,209
Short-term loans payable	3,600,000	6,000,000
Current portion of long-term loans payable	1,119,000	1,081,500
Accounts payable-other	82,842	139,863
Income taxes payable	21,819	27,877
Other	163,479	181,061
Total current liabilities	5,330,029	7,750,512
Noncurrent liabilities		.,,,.
Long-term loans payable	5,210,000	4,402,000
Long-term deposits received	340,332	340,332
Assets retirement obligations	175,482	177,920
Other	418,682	326,719
Total noncurrent liabilities	6,144,496	5,246,972
Total liabilities	11,474,525	12,997,485
Net assets	11,171,525	12,777,100
Shareholders' equity		
Capital stock	8,697,869	9,820,956
Capital surplus	8,366,869	9,820,936
Retained earnings	(16,730,760)	(19,459,467)
Treasury stock	(10,730,760)	(19,439,467)
•	333,781	(148,751)
Total shareholders' equity	333,/81	(148,/51)

		(Thousands of yen)
	Previous fiscal year (as of December 31, 2015)	Third quarter of FY2016 (as of September 30, 2016)
Total net assets	333,781	(148,751)
Total liabilities and net assets	11,808,306	12,848,734

(2) Quarterly Consolidated Statements of Income and Comprehensive Income Quarterly Consolidated Statements of Income

		(Thousands of yen)
	Nine months ended September 30, 2015 (From January 1, 2015 to September 30, 2015)	Nine months ended September 30, 2016 (From January 1, 2016 to September 30, 2016)
Net sales	70,742	64,773
Cost of sales	34,913	24,796
Gross profit	35,828	39,976
Selling, general and administrative expenses	2,995,673	2,817,601
Operating loss (-)	(2,959,845)	(2,777,624)
Non-operating income		
Interest income	350	55
Foreign exchange gains	2,206	329
Subsidy income	76,263	66,362
Other	3,868	577
Total non-operating income	82,689	67,324
Non-operating expenses		
Interest expenses	109,423	145,350
Stock issuance cost	72	17,024
Commission fee	88,907	105,298
Total non-operating expense	198,403	267,674
Ordinary loss (-)	(3,075,559)	(2,977,973)
Loss before income taxes and minority interests (-)	(3,075,559)	(2,977,973)
Income taxes-current	4,741	4,516
Income taxes-deferred	(5,458)	(3,782)
Total income taxes	(717)	733
Net loss (-)	(3,074,842)	(2,978,707)
Loss attributable to non-controlling interests(-)	_	(250,000)
Loss attributable to owners of parent(-)	(3,074,842)	(2,728,707)

		(Thousands of yen)
	Nine months ended	Nine months ended
	September 30, 2015	September 30, 2016
	(From January 1, 2015 to	(From January 1, 2016 to
	September 30, 2015)	September 30, 2016)
Net loss before minority interest (-)	(3,074,842)	(2,978,707)
Comprehensive income (losses)	(3,074,842)	(2,978,707)
(Breakdown)		
Comprehensive income(losses) attributable to owners of parent	(3,074,842)	(2,728,707)
Comprehensive income(losses) attributable to non-controlling interests	_	(250,000)

(3) Quarterly Consolidated Statements of Cash Flows

	Nine months ended September 30, 2015 (From January 1, 2015 to September 30, 2015)	(Thousands of yen) Nine months ended September 30, 2016 (From January 1, 2016 to September 30, 2016)
Net cash provided by (used in) operating activities	,,	
Loss before income taxes and minority interests (-)	(3,075,559)	(2,977,973)
Depreciation	1,146,060	928,448
Interest income	(350)	(55)
Interest expenses	109,423	145,350
Commission fee	88,907	105,298
Stock issuance cost	72	17,024
Subsidy income	(76,263)	(66,362)
Decrease(increase) in notes and accounts receivable-trade	(7,734)	-
Decrease(increase) in inventories	(969,271)	294,840
Increase(decrease) in notes and accounts payable-trade	494,342	(22,677)
Increase(decrease) in deposits received	(14,081)	(4,508)
Other	(472,944)	103,531
Subtotal	(2,777,400)	(1,477,083)
Interest income received	350	56
Interest expenses paid	(108,403)	(145,741)
Proceeds from subsidy	76,263	66,362
Income taxes paid	(6,385)	(6,263)
Other	(69,325)	(70,427)
Net cash provided by (used in) operating activities	(2,884,899)	(1,633,095)
Net cash provided by (used in) investment activities		
Purchase of property, plant and equipment	(254,752)	(1,843,413)
Purchase of intangible assets	(2,600)	(110)
Payments for lease deposits	(8,045)	_
Collection of lease deposits	145	2,000
Proceeds from collection of guarantee deposits	600	_
Net cash provided by (used in) investment activities	(264,653)	(1,841,523)
Net cash provided by (used in) financing activities		
Increase in short-term loans payable	2,172,222	2,400,000
Repayment of long-term loans payable	(62,500)	(845,500)
Repayments of lease obligations	(75,006)	(79,007)
Proceeds from issuance of common stock	13,328	2,216,500
Proceeds from share issuance to non-controlling shareholders	_	248,250
Other	_	14,400
Net cash provided by (used in) financing activities	2,048,043	3,954,642
Net increase(decrease) in cash and cash equivalents	(1,101,509)	480,023
Cash and cash equivalents at beginning of the period	2,080,221	842,121
Cash and cash equivalents at end of the period	978,711	1,322,145