Consolidated Financial Results for the Fiscal Year Ended December 31, 2021 [Japanese GAAP]

February 14, 2022

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Stock exchange listing: Tokyo Stock Exchange
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Scheduled date of Ordinary General Meeting of Shareholders: March 29, 2022
Scheduled date of filing securities report: March 29, 2022
Scheduled date of commencing dividend payments: -
Availability of supplementary briefing material on financial results: Available
Schedule of financial results briefing session: Scheduled (for securities analysts and institutional investors)

(Amounts of less than one million yen are rounded down.)

1. Consolidated Financial Results for the Fiscal Year Ended December 31, 2021 (January 1, 2021 to December 31, 2021)

(1) Consolidated Operating Results (% indicates changes from the previous corresponding period.)

	Operating revenue		Operating income		Ordinary income		Profit attributable to owners of parent	
Fiscal Year ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
December 31, 2021	1	(99.7)	(1,239)	−	(1,231)	−	(738)	−
December 31, 2020	342	(46.9)	(398)	−	(439)	−	(448)	−

(Note) Comprehensive income: Fiscal Year ended December 31, 2021: ¥ (731) million [-%]
Fiscal Year ended December 31, 2020: ¥ (450) million [-%]

	Net income per share	Diluted earnings per share	Return of equity	Ordinary income to total assets	Operating income to operating revenue
Fiscal Year ended	Yen	Yen	%	%	%
December 31, 2021	(25.70)	−	(12.6)	(19.9)	−
December 31, 2020	(17.02)	−	(8.9)	(8.6)	−

(Notes)
For diluted earnings per share, the figure is not presented as the Company recorded basic loss per share, although it had dilutive shares, although the Company had dilutive shares.

(2) Consolidated Financial Position

	Total assets	Net assets	Equity ratio	Net assets per share
	Million yen	Million yen	%	Yen
As of December 31, 2021	6,069	5,549	91.4	191.57
As of December 31, 2020	6,277	6,206	98.9	217.67

(Reference) Equity: As of December 31, 2021: ¥5,549 million
As of December 31, 2020: ¥6,206 million

(3) Cash flow

	Cash flows from operating activities	Cash flows from investing activities	Cash flows from financing activities	Cash and cash equivalents at the end of period
	Million yen	Million yen	Million yen	Million yen
As of December 31, 2021	(747)	171	72	4,936
As of December 31, 2020	(376)	(830)	2,777	5,421

2. Dividends

	Annual dividends				
	1st quarter-end	2nd quarter-end	3rd quarter-end	Year-end	Total
	Yen	Yen	Yen	Yen	Yen
Fiscal year ended December 31, 2020	-	0.00	-	0.00	0.00
Fiscal year ended December 31, 2021	-	0.00	-	0.00	0.00
Fiscal year ending December 31, 2022 (Forecast)	-	0.00	-	0.00	0.00

3. Consolidated Financial Results Forecast for the Fiscal Year Ending December 31, 2022 (January 1, 2022 to December 31, 2022)

The earnings forecasts for fiscal year 2022 are not presented due to the difficulty of formulating reasonably accurate estimates at this time. For further details, please refer to page 4 "Explanation of Consolidated Financial Results Forecast and Other Forward-looking Information"

*** Notes:**

(1) Significant changes to subsidiaries during the Fiscal Year ended December 31, 2021 (changes in specified subsidiaries resulting in changes in scope of consolidation): No
Notes on changes in significant subsidiaries during the Fiscal Year ended December 31, 2021

(2) Changes in accounting policies, changes in accounting estimates, and retrospective restatement
1) Changes in accounting policies due to the revision of accounting standards: No
2) Changes in accounting policies other than 1) above: No
3) Changes in accounting estimates: No
4) Retrospective restatement: No
Notes on changes in accounting policies

(3) Total number of issued shares (common shares)
1) Total number of issued shares at the end of the period (including treasury shares):
December 31, 2021: 28,967,500 shares
December 31, 2020: 28,515,600 shares

2) Total number of treasury shares at the end of the period:
December 31, 2021: 63 shares
December 31, 2020: - shares

3) Average number of shares during the period:
Fiscal Year ended December 31, 2021: 28,752,685 shares
Fiscal Year ended December 31, 2020: 26,349,967 shares

* These financial results are outside the scope of audit by certified public accountants or audit firms.

* Explanation of the proper use of financial results forecast and other notes

The earnings forecast and other forward-looking statements herein are based on information available and certain assumptions judged to be reasonable as of the date of publication of this document. They do not represent a commitment from the Company that they will be achieved. Actual results may differ significantly from these forecast due to a wide range of factors. Please refer to page4 of the attachment for matters related to the earnings forecast.

Furthermore, the disclosure that was made on November 15, 2021 titled "Business Plans and Matters Related to High Growth Potential" was scheduled to be released again in February 2022. It is now scheduled for March 2022.

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1. Qualitative Information on the Financial Results for the Period Under Review

(1) Explanation of Business Results

The Japanese economy during the Fiscal Year ended December 31, 2021 saw possibilities for recovery in regard to economic activities and social life mid-year due to the distribution of vaccines for COVID-19, however, due to the spread of the Omicron variant late in the year it is now expected to take a long time for the economy to recover, and it is becoming increasingly difficult to foresee the future.

Under the corporate philosophy of "Every Life Deserves Attention," the Group has been conducting research and development with the goal of providing groundbreaking precision medicines for genetic diseases, most of which are rare diseases. Based on our proprietary CRISPR-GNDM® platform, which serves as the technological foundation, the Company has continued to lead cutting-edge research as a leading company from its establishment in 2016 to the current consolidated cumulative period, which is the sixth fiscal year since its establishment as the world's first company to develop gene modulation therapy using CRISPR. In order to bring these achievements to fruition, the current fiscal year has been a period of full-scale efforts toward clinical trials.

In the past, we have been developing pipelines using CRISPR-GNDM® technology both on our own and in collaboration with partners, but we have begun to broaden our capabilities with the aim of more efficient and speedy research and development and horizontal deployment of our development know-how. As a result, we believe that we are now able to provide higher added value not only by promoting the "in-house pipeline" in which we develop therapeutic drugs with our own funds, but also by providing the know-how we have established to the "collaborative pipeline" in which we develop therapeutic drugs in collaboration with partners.

During the current consolidated cumulative period, research and development for the collaborative pipeline and in-house pipeline, centering on MDL-101, progressed smoothly. The lead pipeline, MDL-101, continues to be developed, in parallel to partnering discussion with multiple pharma companies, in order to achieve the fastest possible entry into clinical trials. In particular, we are conducting process development and preparing for GLP studies. As this is a gene regulation treatment that has not yet been tested in clinic worldwide, it will be important to confirm the necessary hurdles for the start of trials with the relevant regulatory agencies. The Company is filing a request for an INTERACT meeting with the FDA within 1Q/2022 and preparing to file for a Pre-IND meeting by the end of the year.

During this period, the pipeline portfolio was reorganized. When Astellas decided to discontinue product development of MDL-206 for Angelman syndrome in August, Modalis went through the necessary steps to obtain licensing rights and rebuilt the system to enable research in-house to further develop the molecule. On the other hand, in accordance with Astellas' decision to discontinue the MDL-204 pipeline at the end of 2021, we made a decision not to take over the pipeline. In this way, we believe that it is important to set up stage gates and make appropriate go/no-go decisions at the point of transition from the research stage to the costly and time-consuming development stage in order to optimize the allocation of limited resources and increase the probability of success thereafter. At the same time, we are setting up new target areas and incubating new pipelines. When these pipelines achieve a certain level of criteria, we will promote them as pipelines and invest resources to develop them.

In April of this year, the Company sublicensed CRISPR/Cas9 foundational IP, which was originally licensed from Editas, to Astellas for the MDL-201 and 202 target genes. In addition to our own patents, we have introduced external patents that are necessary for manufacturing and sales in the future, thereby securing FTO (Freedom to Operate) for our pipeline and protecting our products with multilayered intellectual property.

In October, the Company's U.S. subsidiary, which is the Company's R&D base, relocated from Cambridge to Waltham, Massachusetts. We expect that this tripling of floor space will provide us with an opportunity to attract talented candidates from the Greater Boston area. Since the relocation, we have increased the number of researchers, and the U.S. team now has about 30 people. While the U.S. is close to full employment, and the competition for talent is becoming fierce, we have been able to secure and maintain a high level of retention of

talented personnel.

Furthermore, the Company plans to report on the establishment of CRISPR-GDM® technology and the results of each pipeline at the 25th Annual Meeting of the American Society for Gene and Cell Therapy (ASGCT) to be held in Washington D.C. in May 2022. As a leader in gene modulation therapy, we are determined to contribute to the further development of the industry by sharing the challenges of the technology, its solutions, and therapeutic applications.

We believe that the impact of COVID-19 on our business results for the current consolidated cumulative period will be limited.

In regard to the violation of the agreement (lock-up system) of Securities Listing Regulations and Enforcement Rules for Securities Listings Regulations by a shareholder of the Company, the Group has received an irregular income of ¥485,881 thousand as a countermeasure.

As a result, for the Fiscal Year ended December 31, 2021, operating revenue amounted to ¥1,100 thousand, operating loss to ¥1,239,444 thousand, ordinary loss to ¥1,231,299 thousand, and loss attributable to owners of parent to ¥738,956 thousand.

The Group consists of a single business segment of developing therapeutic agents for genetic disorders. Accordingly, the Company omits statements of segment information.

(2) Explanation of Financial Position

Status of Assets, Liabilities and Net Assets

(Current Assets)

Total current assets at the end of the fiscal year under review decreased by ¥381,502 thousand from the end of the previous fiscal year to ¥5,067,043 thousand. This is mainly attributable to a decreased in cash and deposits by ¥485,282 thousand.

(Non-Current Assets)

Total non-current assets at the end of the fiscal year under review increased by ¥173,622 thousand from the end of the previous fiscal year to ¥1,002,093 thousand. This is mainly attributable to an increased in buildings of ¥76,793 thousand and tools, furniture and fixtures of ¥96,072 thousand.

(Current Liabilities)

Total current liabilities at the end of the fiscal year under review increased by ¥122,451 thousand from the end of the previous fiscal year to ¥180,717 thousand. This is mainly attributable to an increased in accounts payable- other of ¥89,248 thousand and accrued expenses of ¥8,528 thousand.

(Non-Current Liabilities)

Total non-current liabilities at the end of the fiscal year under review increased by ¥327,313 thousand from the end of the previous fiscal year to ¥339,207 thousand. This is attributable to an increase in long-term advances received by ¥285,559 thousand.

(Net Assets)

Total net assets at the end of the fiscal year under review decreased by ¥657,644 thousand from the end of the previous fiscal year to ¥5,549,212 thousand. This is mainly attributable to a decrease in retained earnings by ¥738,956 thousand thanks to the posting of loss despite an increase in share capital and capital surplus by ¥37,127 thousand.

(3) Explanation of Cash Flows

Cash and cash equivalents (hereinafter referred to as "cash") at the end of the fiscal year under review amounted to ¥4,936,193 thousand, down by ¥485,282 thousand from ¥5,421,476 thousand at the previous fiscal year end. The status of respective cash flows and key factors are as follows.

(Cash Flows from Operating Activities)

Net cash used in operating activities during the Fiscal Year ended December 31, 2021 amounted to ¥747,466 thousand. This is mainly attributable to the posting of loss before income taxes of ¥745,417 thousand.

(Cash Flows from Investing Activities)

Net cash provided by investing activities during the Fiscal Year ended December 31, 2021 amounted to ¥171,563 thousand. This is mainly attributable to the posting of proceeds from contribution received for right to use patent of ¥329,670 thousand.

(Cash Flows from Financing Activities)

Net cash provided by financing activities during the Fiscal Year ended December 31, 2021 amounted to ¥72,633 thousand. This is mainly attributable to the posting of proceeds from issuance of common shares ¥72,731 thousand.

(4) Explanation of Consolidated Financial Results Forecast and Other Forward-Looking Information

Progress is being made on three collaboration pipelines and four in-house pipelines. The Company aims to secure upfront payments and milestone income for licensing of the MDL-101, MDL-104, MDL-205 and MDL-206, in addition to achieving a development milestone income for licensing of the MDL-201 collaboration pipeline. The lead pipeline, MDL-101, continues to be developed, in parallel to partnering discussion with multiple pharma companies, in order to achieve the fastest possible entry into clinical trials. MDL-101 has progressed to the stage where key safety concerns have been eliminated based on animal testing results from preclinical studies in non-human primates, and the Company will continue to conduct negotiations for licensing under more favorable terms. Furthermore, the Company will continue conducting R&D with the aim of adding new pipelines and capturing milestone income from licensing and joint R&D pipelines.

In addition to the items mentioned above, the Company is setting up new target areas and incubating new pipeline. When these pipelines achieve a certain level of criteria, the Company will promote them as pipelines and invest resources to develop them and the Company aims to secure upfront payments and milestone income. However, at present, there are many uncertain factors affecting our business performance, including the progress of negotiations with our partners, significant fluctuations in performance due to upfront payments for licensing, the possibility of concluding agreements with new partners, and the acquisition of new pipelines.

Regarding R & D expenses, which are the main expense items of the Group, it is determined whether the expenses will be borne by the Group or the other party depending on the contents of the license out and the joint R&D agreement. Similar to the forecast of the business profit, there are many uncertainties.

In regard to the future outlook, the Company believes it is difficult to disclose an appropriate and rational figure due to many uncertainties, so the Company has decided not to disclose the full-year earnings forecast. When it becomes possible to make a forecast, the Company will promptly make an announcement.

2. Consolidated Financial Statements and Primary Notes

(1) Consolidated Balance Sheets

(Thousand yen)

	As of December 31, 2020	As of December 31, 2021
Assets		
Current assets		
Cash and deposits	5,421,476	4,936,193
Other	27,070	130,850
Total current assets	5,448,546	5,067,043
Non-current assets		
Property, plant and equipment		
Buildings	92	76,885
Machinery and equipment	48,448	42,773
Tools, furniture and fixtures	1,233	97,306
Construction in progress	–	6,818
Total Property, plant and equipment	49,774	223,784
Intangible assets		
Right to use patent	767,445	704,729
Software	374	273
Total intangible assets	767,819	705,003
Investments and other assets	10,876	73,305
Total non-current assets	828,470	1,002,093
Total assets	6,277,017	6,069,137
Liabilities		
Current liabilities		
Accounts payable- other	18,159	107,407
Accrued expenses	17,156	25,684
Income taxes payable	21,619	19,282
Other	1,331	28,342
Total current liabilities	58,266	180,717
Non-current liabilities		
Long-term advances received	–	285,559
Provision for share-based compensation for director	–	988
Provision for share-based compensation for employee	–	4,775
Deferred tax liabilities	11,893	5,052
Other	–	42,832
Total non-current liabilities	11,893	339,207
Total liabilities	70,160	519,925
Net assets		
Shareholders' equity		
Share capital	2,707,320	2,744,447
Capital surplus	4,029,055	4,066,182
Retained earnings	(527,519)	(1,266,476)
Treasury stock	–	(97)
Total shareholders' equity	6,208,855	5,544,055
Accumulated other comprehensive income		
Foreign currency translation adjustment	(1,998)	5,156
Total accumulated other comprehensive income	(1,998)	5,156
Total net assets	6,206,857	5,549,212
Total liabilities and net assets	6,277,017	6,069,137

(2) Consolidated Statements of Income and Comprehensive Income

Consolidated Statements of Income

(Thousand yen)

	For the Fiscal Year ended December 31, 2020	For the Fiscal Year ended December 31, 2021
Operating revenue	342,000	1,100
Operating expenses		
Research and development expenses	531,896	1,009,523
Selling, general and administrative expenses	208,454	231,020
Total operating expenses	740,351	1,240,544
Operating loss	(398,351)	(1,239,444)
Non-operating income		
Interest income	52	57
Subsidy income	79	205
Foreign exchange income	–	12,238
Other	285	355
Total non-operating income	417	12,856
Non-operating expenses		
Listing expenses	20,104	–
Interest expense	–	1,090
Foreign exchange loss	4,967	–
Stock issuance cost	16,374	1,523
Loss on retirement of non-current assets	–	2,097
Other	169	–
Total non-operating expenses	41,614	4,711
Ordinary loss	(439,549)	(1,231,299)
Extraordinary income		
Income of compensation	–	485,881
Total extraordinary income	–	485,881
Loss before income taxes	(439,549)	(745,417)
Income taxes - current	1,210	1,333
Income taxes - deferred	7,648	(7,794)
Total income taxes	8,858	(6,460)
Loss	(448,407)	(738,956)
Loss attributable to owners of parent	(448,407)	(738,956)

Consolidated Statements of Comprehensive Income

(Thousand yen)

	For the Fiscal Year ended December 31, 2020	For the Fiscal Year ended December 31, 2021
Loss	(448,407)	(738,956)
Other comprehensive income		
Foreign currency translation adjustment	(1,918)	7,154
Total other comprehensive income	(1,918)	7,154
Comprehensive income	(450,325)	(731,801)
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	(450,325)	(731,801)

(3) Consolidated Statements of Changes in Equity

Fiscal Year Ended December 31,2020

(Thousand yen)

	Shareholders' equity			
	Share capital	Capital surplus	Retained earnings	Treasury stock
Balance at beginning of current period	1,300,000	2,621,735	(79,112)	－
Changes of items during period				
Issuance of new shares	1,407,320	1,407,320		
Purchase of treasury stock				
Profit attributable to owners of parent			(448,407)	
Net changes of items other than shareholders' equity				
Total changes of items during period	1,407,320	1,407,320	(448,407)	－
Balance at end of current period	2,707,320	4,029,055	(527,519)	－

	Shareholders' equity	Accumulated other comprehensive income		Total net assets
	Total shareholders' equity	Foreign currency translation adjustment	Total accumulated other comprehensive income	
Balance at beginning of current period	3,842,623	(80)	(80)	3,842,542
Changes of items during period				
Issuance of new shares	2,814,640			2,814,640
Purchase of treasury stock	－			－
Profit attributable to owners of parent	(448,407)			(448,407)
Net changes of items other than shareholders' equity		(1,918)	(1,918)	(1,918)
Total changes of items during period	2,366,232	(1,918)	(1,918)	2,364,314
Balance at end of current period	6,208,855	(1,998)	(1,998)	6,206,857

Fiscal Year Ended December 31,2021

(Thousand yen)

	Shareholders' equity			
	Share capital	Capital surplus	Retained earnings	Treasury stock
Balance at beginning of current period	2,707,320	4,029,055	(527,519)	－
Changes of items during period				
Issuance of new shares	37,127	37,127		
Purchase of treasury stock				(97)
Loss attributable to owners of parent			(738,956)	
Net changes of items other than shareholders' equity				
Total changes of items during period	37,127	37,127	(738,956)	(97)
Balance at end of current period	2,744,447	4,066,182	(1,266,476)	(97)

	Shareholders' equity	Accumulated other comprehensive income		Total net assets
	Total shareholders' equity	Foreign currency translation adjustment	Total accumulated other comprehensive income	
Balance at beginning of current period	6,208,855	(1,998)	(1,998)	6,206,857
Changes of items during period				
Issuance of new shares	74,255			74,255
Purchase of treasury stock	(97)			(97)
Profit attributable to owners of parent	(738,956)			(738,956)
Net changes of items other than shareholders' equity		7,154	7,154	7,154
Total changes of items during period	(664,799)	7,154	7,154	(657,644)
Balance at end of current period	5,544,055	5,156	5,156	5,549,212

(4) Consolidated Statements of Cash Flows

(Thousand yen)

	For the Fiscal Year ended December 31, 2020	For the Fiscal Year ended December 31, 2021
Cash flows from operating activities		
Loss before income taxes	(439,549)	(745,417)
Depreciation	57,588	77,870
Increase (decrease) in provision for share-based compensation for director	–	988
Increase (decrease) in provision for share-based compensation for employee	–	4,775
Interest and dividend income	(52)	(57)
Subsidy income	(79)	(205)
Stock issuance cost	16,374	1,523
Listing expenses	20,104	–
Interest expense	–	1,090
Foreign exchange loss (income)	3,393	(11,729)
Loss on retirement of non-current assets	–	2,097
Compensation received	–	(485,881)
Decrease (increase) in trade receivables	6,600	–
Increase (decrease) in accounts payable - other	8,439	45,219
Increase (decrease) in accrued expenses	3,942	6,631
Decrease (increase) in consumption taxes refund receivable	(9,036)	(17,127)
Increase (decrease) in accrued consumption taxes	(43,960)	–
Other, net	477	(112,179)
Subtotal	(375,756)	(1,232,400)
Interest and dividends received	52	57
Subsidies received	79	205
Income taxes paid	(950)	(1,210)
Compensation received	–	485,881
Net cash provided by (used in) operating activities	(376,575)	(747,466)
Cash flows from investing activities		
Purchase of property, plant and equipment	(15,148)	(107,111)
Purchase of intangible assets	(814,866)	–
Proceeds from contribution received for right to use patent	–	329,670
Payment of lease deposits	(722)	(51,327)
Other, net	427	332
Net cash provided by (used in) investing activities	(830,310)	171,563
Cash flows from financing activities		
Proceeds from issuance of common shares	2,749,145	–
Proceeds from issuance of stock acquisition rights	49,120	72,731
Purchase of treasury stock	–	(97)
Payments of listing expenses	(20,104)	–
Other, net	(169)	–
Net cash provided by (used in) financing activities	2,777,992	72,633
Effect of exchange rate change on cash and cash equivalents	(6,865)	17,987
Net increase (decrease) in cash and cash equivalents	1,564,240	(485,282)
Cash and cash equivalents at the beginning of period	3,857,235	5,421,476
Cash and cash equivalents at the end of period	5,421,476	4,936,193

(4) Notes to Consolidated Financial Statements

(Notes on going concern assumption)

There is no relevant information.

(Segment information)

The Group consists of a single business segment of developing therapeutic agents for genetic disorders. Accordingly, the Company omits statements of segment information.

(Per share information)

	Fiscal Year ended December 31, 2020	Fiscal Year ended December 31, 2021
Net assets per share (Yen)	217.67	191.57
Net income per share (Yen)	(17.02)	(25.70)

NOTE 1. For the fiscal year ended December 31, 2020,and December 31, 2021,the figure is not presented as the Company recorded basic loss per share, although it had dilutive shares.

2. Net assets per share are calculated based on the following basis:

	Fiscal Year ended December 31, 2020	Fiscal Year ended December 31, 2021
Total net assets (thousands of yen)	6,206,857	5,549,212
Amounts deducted from total net assets (thousands of yen)	—	—
Average number of common shares during the period (shares)	6,206,857	5,549,212
Number of common shares at the end of the period used for the calculation of net assets per share (shares)	28,515,600	28,967,500

3. Net loss per share are calculated based on the following basis:

	Fiscal Year ended December 31, 2020	Fiscal Year ended December 31, 2021
Net loss per share (thousands of yen)		
Loss attributable to owners of parent (thousands of yen)	(448,407)	(738,956)
Net loss related to common shares (thousands of yen)	—	—
Loss attributable to owners of parent to common shares (thousands of yen)	(448,407)	(738,956)
Average number of common shares during the period (shares)	26,349,967	28,752,685
Dilutive shares that do not have a diluting effect and thus were not included in the calculation of diluted net income per share	—	—

(Significant subsequent events)

There is no relevant information.