



March 30, 2023
JCR Pharmaceuticals Co., Ltd.

Translation

Revision of Consolidated Financial Forecasts for Fiscal Year Ended March 31, 2023

Mar. 30, 2023-- JCR Pharmaceuticals Co., Ltd. (TSE 4552; Chairman and President: Shin Ashida; “JCR”) announced that the Company made the following revisions to the consolidated earnings forecasts for the fiscal year ended March 31, 2023 disclosed on May 12, 2022 (at the time of the financial results announcement) based on the current business performance.

1. Revision of consolidated financial forecasts for the fiscal year ended March 31, 2023

(Unit: Millions of yen)

	Net Sales	Operating Income	Ordinary Income	Profit attributable to owners of parent	Earnings per share (yen)
Previously announced forecasts (A)	45,000	14,500	14,500	10,300	83.25
Revised forecasts (B)	34,200	5,000	5,200	3,800	30.59
Change (B-A)	(10,800)	(9,500)	(9,300)	(6,500)	—
Change (%)	(24.0) %	(65.5) %	(64.1) %	(63.1) %	—
Actual Results of the previous fiscal year	51,082	19,933	20,512	14,507	117.26

2. Reason for the revision

The main reasons for the downward revision of the forecast for the fiscal year ending March 31, 2023 are that license revenue and product sales have not reached the forecast.

The revised forecast for license revenue is 6,500 million yen falling short of the previously announced forecast of 15,400 million yen. This is due to the fact that the licensing agreements for lysosomal storage disease (“LSD”) programs, such as JR-171, JR-441 and JR-446, are still under negotiation, also taking into consideration that JCR intends to partner programs at their best value inflection point.

In addition, although sales of some products are expected to exceed the results of the previous fiscal year, total pharmaceutical products sales is expected to fall short of the initial forecast. The revised break-down of sales forecast is <Appendix 1> below.

In terms of expenses, the revised forecast for R&D expenses is 8,900 million yen (9,000 million yen in the initial forecast). This is because that our recent R&D activities, mainly in the area of LSD programs for global, have been progressing on schedule. The revised forecast for sales, general, and administrative expenses is 11,500 million yen (12,500 million yen in the initial forecast) because of effort to reduce expenses, etc.

As a result, we have revised our full-year forecasts downward for net sales, operating income, ordinary income and profit attributable to owners of parent from those announced on May 12, 2022. There is no change in the year-end dividend forecast from the 10.00 yen per share announced on May 12, 2022.

<Appendix 1>

The revised forecast breaks down of product sales.

(Unit: Millions of yen)

	Previously announced forecasts (A)	Revised forecasts (B)	Change (B-A)	Change (%)	(Reference) Actual results of the previous fiscal year
GROWJECT®	13,100	12,000	(1,100)	(8.4) %	12,945
IZCARGO®	5,210	4,500	(710)	(13.6) %	3,003
TEMCELL® HS Inj.	3,530	3,400	(130)	(3.7) %	3,497
Treatments for renal anemia	4,930	4,750	(180)	(3.7) %	5,875
Epoetin Alfa BS Inj. [JCR]	2,630	2,650	20	0.8 %	2,876
Darbepoetin Alfa BS Inj. [JCR]	2,300	2,100	(200)	(8.7) %	2,998
Agalsidase Beta BS I.V. Infusion [JCR]	760	1,000	240	31.6 %	711
Total pharmaceutical products	27,530	25,650	(1,880)	(6.8) %	26,032
License Revenue	15,400	6,500	(8,900)	(57.8) %	10,571
Other	140	120	(20)	(14.3) %	102
AZD1222 bulk	1,930	1,930	—	—	14,375
Total Net Sales	45,000	34,200	(10,800)	(24.0) %	51,082

Note: The forecasts of financial results shown above are projections prepared based on information available to management as of the date of the announcement of this news release. Actual financial results may differ from these forecasts due to various reasons.

3. Progress in R&D

JCR's progress on R&D of our project portfolio in LSDs, growth hormone, cell therapy and regenerative medicine is in line with internal expectations. Based on the data obtained from preclinical and clinical studies JCR is aiming to further expand LSD programs globally. Partnerships will remain an important strategy to accelerate the portfolio. In addition to the progress in partnering negotiations (see below), we are proceeding with basic research, including process development and non-clinical studies, and clinical trials. Our pipeline is <Appendix 2> below.

As a result of the general applicability of the J-Brain Cargo® technology to central nervous system ("CNS") diseases outside of LSDs, JCR today announced the signing of a Research Collaboration, Option and License Agreement with Alexion, AstraZeneca Rare Disease ("Alexion") to develop an undisclosed therapeutic molecule that applies JCR's proprietary J-Brain Cargo®, blood-brain barrier penetration technology, for the treatment of a neurodegenerative disease. The agreement with Alexion is the first international partnership

to apply the J-Brain Cargo® technology for the treatment of a neurodegenerative disease. JCR will continue to form partnerships to apply the J-Brain Cargo® technology, which has the potential to treat multiple CNS indications, for a wide range of the CNS disease areas outside of our core business, LSD.

<Appendix 2>

R&D pipeline

Code (INN)	Status	Indication	Remarks
JR-141 (pabinafusp alfa)	Global: Phase III	MPS type II (Hunter Syndrome)	<ul style="list-style-type: none"> J-Brain Cargo® FY2025-2027 Approval in US, EU, Brazil
JR-171 (lepunafusp alfa)	Global: Phase I/II	MPS type I (Hurler Syndrome etc.)	<ul style="list-style-type: none"> J-Brain Cargo® FY2023 pivotal trial
JR-162	Preclinical	Pompe disease	<ul style="list-style-type: none"> J-Brain Cargo®
JR-441	Preclinical	MPS type IIIA (Sanfilippo A Syndrome)	<ul style="list-style-type: none"> J-Brain Cargo® FY2023 Ph I/II
JR-443	Preclinical	MPS type VII (Sly Syndrome)	<ul style="list-style-type: none"> J-Brain Cargo®
JR-446	Preclinical	MPS type IIIB (Sanfilippo B Syndrome)	<ul style="list-style-type: none"> J-Brain Cargo® FY2023 Ph I/II
JR-479	Preclinical	GM2 Gangliosidosis (Sandhoff, Tay-Sachs disease)	<ul style="list-style-type: none"> J-Brain Cargo® ~FY2025 Ph I
JR-471	Process Development	Fucosidosis	<ul style="list-style-type: none"> J-Brain Cargo®
JR-401X	Filed	SHOX deficiency	<ul style="list-style-type: none"> Expanded indication of GROWJECT®
JR-142	Japan: Phase II (Completed patient recruitment)	Pediatric growth hormone deficiency	<ul style="list-style-type: none"> Recombinant long-acting growth hormone FY2023 Ph III
JR-031HIE	Japan: Phase I/II	Hypoxic ischemic encephalopathy in neonates	<ul style="list-style-type: none"> Expanded indication of TEMCELL®HS Inj.

MPS: Mucopolysaccharidosis

About JCR Pharmaceuticals Co., Ltd.

JCR Pharmaceuticals Co., Ltd. (TSE 4552) is a global specialty pharmaceuticals company that is redefining expectations and expanding possibilities for people with rare and genetic diseases worldwide. We continue to build upon our 48-year legacy in Japan while expanding our global footprint into the US, Europe, and Latin America. We improve patients' lives by applying our scientific expertise and unique technologies to research, develop, and deliver next-generation therapies. Our approved products in Japan include therapies for the treatment of growth disorder, Fabry disease, acute graft-versus host disease, and renal anemia. Our investigational products in development worldwide are aimed at treating rare diseases including MPS I (Hurler, Hurler-Scheie and Scheie syndrome), MPS II (Hunter syndrome), MPS III A and B (Sanfilippo type A and B), and more. JCR strives to expand the possibilities for patients while accelerating medical advancement at a global level. Our core values – reliability, confidence, and persistence – benefit all our stakeholders, including employees, partners, and patients. Together we soar. For more information, please visit <https://www.jcrpharm.co.jp/en/site/en/>.

Cautionary Statement Regarding Forward-Looking Statements

This document contains forward-looking statements that are subject to known and unknown risks and uncertainties, many of which are outside our control. Forward-looking statements often contain words such as “believe,” “estimate,” “anticipate,” “intend,” “plan,” “will,” “would,” “target” and similar references to future periods. All forward-looking statements regarding our plans, outlook, strategy and future business, financial performance and financial condition are based on judgments derived from the information available to us at this time. Factors or events that could cause our actual results to be materially different from those expressed in our forward-looking statements include, but are not limited to, a deterioration of economic conditions, a change in the legal or governmental system, a delay in launching a new product, impact on competitors’ pricing and product strategies, a decline in marketing capabilities relating to our products, manufacturing difficulties or delays, an infringement of our intellectual property rights, an adverse court decision in a significant lawsuit and regulatory actions.

This document involves information on pharmaceutical products (including those under development). However, it is not intended for advertising or providing medical advice. Furthermore, it is intended to provide information on our company and businesses and not to solicit investment in securities we issue.

Except as required by law, we assume no obligation to update these forward-looking statements publicly or to update the factors that could cause actual results to differ materially, even if new information becomes available in the future.

Contact:

Investors & Media:

JCR Pharmaceuticals Co., Ltd.

Corporate Communications

ir-info@jcrpharm.co.jp

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