Financial Summary
Consolidated Financial Results for the Six Months ended September 30, 2021(FY2021)
(Japanese standard)

October 28, 2021

Listed company name: JCR Pharmaceuticals Co., Ltd.
Listed stock exchange: Tokyo Stock Exchange
Code number: 4552 URL: https://www.jcrpharm.co.jp
Representative: (Title) Representative Director, Chairman and President
(Name) Shin Ashida
Person in charge of inquires: (Title) Corporate Officer, Executive Director, Administration Division
(Name) Yutaka Honda TEL: 0797(32)1995
Scheduled date to file the Securities Report: November 12, 2021
Scheduled date to commence dividend payments: December 10, 2021
Explanatory material for business results: Available
IR Conference: To be held (for institutional investors and analysts)

(Fractions smaller than one million yen omitted)

1. Consolidated Financial Results for 2Q FY2021 (April 1, 2021 to Sep. 30, 2021)

(1) Consolidated Operating Results (Cumulative) (Percentage shows year-on-year changes.)

	Net sales		Operating income		Ordinary income		Profit attributable to owners of parent	
Six Months Ended	million yen	%	million yen	%	million yen	%	million yen	%
Sep. 30, 2021	28,383	159.2	13,640	943.3	13,731	916.4	9,234	652.6
Sep. 30, 2020	10,951	(2.5)	1,307	31.0	1,351	37.7	1,227	33.0

(Reference) Comprehensive income: Six months ended Sep. 30, 2021: 9,192 million yen (628.2%),
Six months ended Sep. 30, 2020: 1,262 million yen (68.8%),

	Earnings per Share (basic)	Earnings per Share (diluted)
Six Months Ended	yen	yen
Sep. 30, 2021	74.66	74.36
Sep. 30, 2020	9.94	9.89

(Note) We conducted a 4-for-1 stock split on October 1, 2020. Calculations of "Earnings per share (basic)" and "Earnings per share (diluted)" are based on the assumption that the stock split was implemented at the beginning of the previous fiscal year.

(2) Consolidated Financial Position

	Total assets	Net assets	Equity ratio
Six Months Ended	million yen	million yen	%
Sep. 30, 2021	86,619	47,008	53.4
Sep. 30, 2020	73,784	38,557	51.3

(Reference) Shareholders' equity: As of Sep. 30, 2021: 46,249 million yen
As of Mar. 31, 2021: 37,864 million yen

2. Dividends

	Dividend per Share				
	1st quarter	2nd quarter	3rd quarter	Year-end	Annual
	Yen	Yen	Yen	Yen	Yen
FY2020		18.00	-	7.50	-
FY2021		10.00			
FY2021 (Forecast)			-	10.00	20.00

(Note) 1. Revisions were made to the most recently announced dividend forecast.
2. We conducted a 4-for-1 stock split on October 1, 2020. The year-end dividend per share shown for the fiscal year ended March 31, 2021 reflects the impact of this stock split, and the annual dividend is presented as "–". If the stock split is assumed to have been implemented at the beginning of the previous fiscal year, the 2nd quarter-end dividend per share for the fiscal year ended March 31, 2021 would be 4.50 yen and the annual dividend per share would be 12.00 yen.
3. Breakdown of the year-end dividend for the fiscal year ended March 31, 2021:
Ordinary dividend: 7.00 yen Commemorative dividend: 0.50 yen "

3. Consolidated Forecasts for the Fiscal Year Ending Mar. 31, 2022 (Apr. 1, 2021 – Mar. 31, 2022)

(Percentage figures for the fiscal year represent the changes from the previous year.)

	Net sales		Operating income		Ordinary income		Profit attributable to owners of the parent		Earnings per share
	million yen	%	million yen	%	million yen	%	million yen	%	yen
Year ending Mar. 31, 2022	52,000	72.8	21,700	162.4	21,700	155.6	15,400	123.4	124.70

(Note) No revisions were made to the most recently announced financial results forecast.

*Note

(1) Changes in significant subsidiaries during the period
(changes in specified subsidiaries resulting in the change in consolidation scope): None

(2) Application of specific accounting practices for preparing quarterly consolidated financial statements: None

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

1. Changes in accounting policy due to the revision of accounting standards, etc.: Yes
2. Changes in accounting principles other than 1. :None
3. Changes in accounting estimates : None
4. Restatements : None

(Note) For details, please refer to "2. Quarterly consolidated financial statements and important notes, (4) Notes to quarterly consolidated financial statements, (Changes in accounting policy)" on page 9 of the attached material.

(4) Number of shares outstanding (common stocks)

1. Number of shares outstanding at the end of the period (including treasury stock)
2. Number of shares treasury stock at the end of the period
3. Average number of shares outstanding during the period (quarterly cumulative amount)

As of Sep. 30, 2021	129,686,308 shares	As of March 31, 2021	129,686,308shares
As of Sep. 30, 2021	5,935,544 shares	As of March 31, 2021	6,071,644 shares
As of Sep. 30, 2021	123,686,414 shares	As of Sep. 30, 2020	123,427,591 shares

(Note) We conducted a 4-for-1 stock split on October 1, 2020. Calculations for "Average number of shares during the period" are based on the assumption that the stock split was implemented at the beginning of the previous fiscal year.

* The quarterly financial statements are outside of the scope of quarterly review by a certified public accountant or an audit firm.

* Explanation on the appropriate use of forecasts of financial results and other comments

(Note on forward-looking statements, etc.)

Forward-looking statements, such as forecasts of financial results, contained in this document are based on information currently available to the Company and certain assumption that are judged as rational. The Company does not assure the achievement of these forecasts. In addition, actual financial results may differ significantly from forecasts due to various reasons. For assumptions underlying forecasts of financial results and notes regarding the appropriate use of forecasts of financial results, please refer to "1. Qualitative information for quarterly financial statements, (3) Explanation on projections such as forecasts of consolidated financial results" on page 3 of the attached material.

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1. Qualitative information for quarterly financial statements

(1) Explanation on financial results

[1] Financial results for 2Q FY2021

Net sales amounted to 28,383 million yen (up 159.2% year on year).

Total net sales of our mainstay products increased year on year. The main reasons for this increase were the sales launch of IZCARGO® I.V. infusion 10mg, which was placed on the National Health Insurance (NHI) reimbursement price list in May 2021, and an increase in sales volume of our recombinant human growth hormone product GROWJECT®, despite an NHI price revision in April 2021.

In addition, total net sales increased substantially year on year. This increase was mainly because we launched sales of AstraZeneca K.K.'s COVID-19 vaccine solution in March 2021 and revenue from licensing rose year on year.

Profits increased significantly at every level, with operating income of 13,640 million yen (up 943.3%), ordinary income of 13,731 million yen (up 916.4%) and profit attributable to owners of parent of 9,234 million yen (up 652.6%).

As a result of proactive R&D activities and development activities in line with progress on clinical trials, R&D expenses totaled 3,520 million yen (up 1,113 million yen, or 46.2%, year on year).

In September 2021, JCR and Takeda Pharmaceutical Company Limited concluded an agreement to promote collaboration and commercialization of JR-141 in specific regions. JR-141 is a next-generation therapy for Hunter syndrome. With this agreement, the JCR Group has taken a further step toward becoming a global specialty pharma in the rare disease arena.

	Previous quarterly consolidated results (cumulative) (April 1, 2020 to September 30, 2020)	Current quarterly consolidated results (cumulative) (April 1, 2021 to September 30, 2021)	Rate of change
	Amount (million yen)	Amount (million yen)	%
Net sales	10,951	28,383	159.2
Operating income	1,307	13,640	943.3
Ordinary income	1,351	13,731	916.4
Profit attributable to owners of the parent	1,227	9,234	652.6

[2] Main components of sales

	Previous quarterly consolidated results (cumulative) (April 1, 2020 to September 30, 2020)	Current quarterly consolidated results (cumulative) (April 1, 2021 to September 30,2021)	Rate of change
	Amount (million yen)	Amount (million yen)	%
Human growth hormone product **GROWJECT®**	6,538	6,689	2.3
Treatment for mucopolysaccharidosis type II **IZCARGO® for I.V. Infusion**	-	985	-
Treatment for renal anemia	3,390	3,011	(11.2)
Epoetin Alfa BS Inj. [JCR]	1,696	1,512	(10.8)
Darbepoetin Alfa BS Inj. [JCR]	1,694	1,498	(11.6)
Regenerative medicine products **TEMCELL® HS Inj.**	784	1,717	118,9
Treatment for Fabry disease **Agalsidase Beta BS I.V. Infusion [JCR]**	220	323	47.0
Income from contractual payments	10	7,557	74,360.5
AZD1222 stock solution	-	8,046	-

[3] Status of R&D

[Treatments for lysosomal storage disorders]

- In treatments for lysosomal storage disorders, a priority field for development, we are currently conducting development of new drugs that employ our unique blood-brain barrier (BBB) technology, J-Brain Cargo®.
- In May 2021, we launched sales of Pabinafsup Alpha (development number: JR-141), a treatment for hematological transit-type Hunter Syndrome, in Japan (product name: IZCARGO® intravenous infusion 10ml). In the Federal Republic of Brazil, we filed an application for marketing authorization with the Brazilian National Health Authority (ANVISA) in December 2020. In other regions, the Company was newly designated as a Fast Track (*1) by the U.S. Food and Drug Administration (FDA) in February 2021 and as a PRIME (*2) by the European Medicines Agency (EMA) in October 2021. Currently, we are preparing to commence trials for the global Phase 3 clinical trials to be conducted in the United States, Brazil, and Europe.
- We are currently conducting Phase 1/2 clinical trials in Japan, Brazil, and the U.S. for a treatment enzymes formulation for hematobral transit-type compolysaccharides I (development number: JR-171). The Company was designated as an orphan drug by the FDA in February 2021 and by the European Commission (EC) in March 2021. In addition, we received Fast Track designation (*1) from the FDA in October 2021, and we expect to expedite clinical development, prioritization reviews and early approval in the U.S.

- We have also been successively conducting R&D into other treatments for lysosomal storage disorders that employ J-Brain Cargo®, including a treatment for Pompe disease (development code: JR-162), a treatment for Sanfilippo syndrome type A (development code: JR-441), a treatment for Sly syndrome (development code: JR-443), and a treatment for Sanfilippo syndrome type B (JR-446). We will also develop each of these treatments globally.

[Regenerative medicine products]

- Currently, we are conducting a Phase I/II clinical trial of TEMCELL® HS Inj. for the additional indication of neonatal hypoxic ischemic encephalopathy (HIE) (development code: JR-031HIE).
- We are now conducting a Phase I/II clinical trial of an allogeneic regenerative medical product using dental pulp stem cells (DPCs) for the indication of acute cerebral infarction (development code: JTR-161/JR-161).

[Human growth hormone product]

- Currently, we are conducting a Phase III clinical trial for an additional indication for GROWJECT® in patients with short stature homeobox-containing gene (SHOX) deficiency.
- In March 2021, we initiated a Phase II clinical trial of a recombinant long-acting growth hormone (development code: JR-142).

*1 FDA Fast Track Designation

The FDA Fast Track is a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to enable early delivery of important new drugs to the patients. A drug that receives Fast Track designation may be allowed more frequent meetings with the FDA to discuss the drug's development plan, followed by priority review and an accelerated approval when relevant criteria are met.

2 EMA PRIME (PRiority MEdicines)

PRIME is a scheme launched by the European Medicines Agency (EMA) to enhance support for the development of medicines that target an unmet medical need. Through PRIME, EMA offers early and proactive support to medicine developers to enable accelerated assessment of medicines applications and may grant eligibility for accelerated assessment.

(2) Overview of Financial Conditions

[1] Status of assets, liabilities and net assets

As of September 30, 2021, total assets amounted to 86,619 million yen (an increase of 12,834 million yen increase from March 31, 2021), total liabilities were 39,610million yen (an increase of 4,383 million yen), and net assets were 4,708 million yen (an increase of 8,451 million yen).

Current assets increased by 9,876 million yen from March 31, 2021 to 58,422 million yen, mainly due to increases in notes and accounts receivable-trade and inventories, which were partly offset by a decrease in cash and deposits. Non-current assets increased by 2,958 million yen from March 31, 2021 to 28,197 million yen, mainly due to an increase in property, plant and equipment.

Current liabilities increased from March 31, 2021 by 6,558 million yen to 35,586 million yen, mainly due to increases in special suspense account for tax purpose reduction entry and short-term loans payable. Non-current liabilities totaled 4,024 million yen, a decrease of 2,174 million yen from March 31, 2021.

Net assets increased by 8,451 million yen from March 31, 2021 to 47,008 million yen, mainly due to the recording of profit attributable to owners of parent, despite the payment of dividends.

As a result, the equity ratio was 53.4% as of September 30, 2021, an improvement of 2.1 percentage points from March 31, 2021.

At this point in time, the JCR Group has not felt the impact of the COVID-19 pandemic. However, the global outlook remains uncertain. In order to achieve sustainable global growth, we need to secure a flexible and stable source of funds. Accordingly, we have concluded commitment line agreements with our financial institutions for a total of 15.5 billion yen for the purpose of securing operating funds as a backup plan.

[2] Status of cash flows

Cash and cash equivalents stood at 20,412 million yen as of September 30, 2021, a decrease of 5,848 million yen from March 31, 2021. The status of each type of cash flow and the major reasons for changes are stated below.

(Cash flows from operating activities)

Net cash used in operating activities amounted to 4,747 million yen, an increase of 8,979 million yen compared with the corresponding period of the previous fiscal year.

This was mainly due to an increase in notes and accounts receivable-trade of 13,934 million yen, income taxes paid of 2,435 million yen, and an increase in inventories of 1,491 million yen, while there were quarterly income before income taxes of 12,729 million yen and recorded depreciation and amortization of 922 million yen.

(Cash flows from investing activities)

Net cash used in investing activities was 236 million yen (a decrease of 4,247 million yen in net cash used from the same period of the previous fiscal year).

The main use of cash was 4,514 million yen for the purchase of property, plant and equipment, which was partly offset by subsidies received of 4,345 million yen.

(Cash flows from financing activities)

Net cash used in financing activities was 930 million yen (a change of 9,798 million yen from net cash provided by financing activities in the same period of the previous fiscal year). This was mainly attributable to cash dividends paid of 928 million yen.

(3) Explanation on projections such as forecasts of consolidated financial results

Looking at consolidated financial results for the six months ended September 30, 2021, sales and profits both increased significantly year on year.

There have been no changes to the forecasts for the fiscal year ending March 31, 2022 announced on September 30, 2021.

2. Quarterly consolidated financial statements and important notes

(1) Quarterly consolidated balance sheets

(millions of yen)

	As of March 31, 2021	As of September 30, 2021
Assets		
Current assets		
Cash and deposit	26,260	20,412
Notes and accounts receivable-trade	8,183	22,117
Merchandise and finished goods	1,367	1,353
Work in process	3,538	5,342
Raw materials and supplies	8,649	8,351
Other	546	844
Total current assets	48,545	58,422
Non-current assets		
Property, plant and equipment		
Buildings and structures, net	6,295	6,208
Land	7,663	7,663
Construction in progress	841	4,420
Other, net	2,371	2,222
Total property, plant and equipment	17,172	20,515
Intangible assets		
Patent right	2,988	2,850
Other	244	246
Total intangible assets	3,232	3,096
Investments and other assets		
Investment securities	2,572	2,422
Other	2,266	2,167
Allowance for doubtful accounts	(4)	(4)
Total investments and other assets	4,833	4,584
Total non-current assets	25,238	28,197
Total assets	73,784	86,619

(millions of yen)

	As of March 31, 2021	As of September 30, 2021
Liabilities		
Current liabilities		
Notes and accounts payable-trade	2,932	1,465
Short-term loans payable	12,850	15,050
Income taxes payable	2,646	3,563
Special suspense account for tax purpose reduction entry	3,828	8,174
Provision for bonuses	850	1,064
Provision for directors' bonuses	63	51
Other	5,855	6,216
Total current liabilities	29,028	35,586
Non-current liabilities		
Bonds payable	500	500
Long-term loans payable	4,750	2,550
Retirement benefit liability	798	825
Other	151	148
Total non-current liabilities	6,199	4,024
Total liabilities	35,227	39,610
Net assets		
Shareholders' equity		
Capital stock	9,061	9,061
Capital surplus	10,941	10,994
Retained earnings	20,904	29,213
Treasury stock	(3,685)	(3,603)
Total shareholders' equity	37,222	45,666
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	691	581
Deferred gains or losses on hedges	0	0
Foreign currency translation adjustments	(18)	27
Remeasurements of defined benefit plans	(31)	(26)
Total accumulated other comprehensive income	641	583
Share acquisition rights	517	567
Non-controlling interests	174	191
Total net assets	38,557	47,008
Total liabilities and net assets	73,784	86,619

(2) Quarterly consolidated statements of income and quarterly consolidated statements of comprehensive income

(Quarterly consolidated statements of income)

	Six months ended September 30, 2020	Six months ended September 30, 2021
Net sales	10 ,951	28,383
Cost of sales	3,513	4,485
Gross profit	7,438	23,898
Selling, general and administrative expenses	6,130	10,258
Operating profit	1,307	13,640
Non-operating income		
Interest income	3	3
Dividend income	11	16
Foreign exchange gains	54	84
Other	21	28
Total non-operating income	91	132
Non-operating expenses		
Interest expenses	18	22
Commission expenses	4	6
Other	23	12
Total non-operating expenses	47	41
Ordinary income	1,351	13,731
Extraordinary income		
Reversal of provision for loss on guarantees	12	―
Reversal of allowance for doubtful accounts	19	―
Other	―	0
Total extraordinary income	31	0
Extraordinary losses		
Loss on disposal of non-current assets	1	0
Loss on cancellation of contracts	―	*1,000
Other	―	1
Total extraordinary losses	1	1,002
Profit before income taxes	1,381	12,729
Income taxes – current	809	3,311
Income taxes – deferred	(659)	179
Total income taxes	150	3,490
Profit	1,231	9,238
Profit attributable to non-controlling interests	4	4
Profit attributable to owners of parent	1,227	9,234

(Quarterly consolidated statements of comprehensive income)

(millions of yen)

	Six months ended September 30, 2020	Six months ended September 30, 2021
Profit	1,231	9,238
Other comprehensive income		
Valuation difference on available-for-sale securities	41	(109)
Deferred gains or losses on hedges	(0)	(0)
Foreign currency translation adjustment	(21)	58
Remeasurements of defined benefit plans, net of tax	11	5
Total other comprehensive income	31	(45)
Comprehensive income	1,262	9,192
(Comprehensive income attributable to)		
Comprehensive income attributable to owners of parent	1,261	9,176
Comprehensive income attributable to non-controlling interests	0	16

(3) Quarterly consolidated Statements of Cash Flows

(millions of yen)

	Six months ended September 30, 2020	Six months ended September 30, 2021
Cash flows from operating activities		
Profit before income taxes	1,381	12,729
Depreciation and amortization	872	922
Increase (decrease) in provision for loss on guarantees	(12)	–
Increase (decrease) in net defined benefit liability	25	32
Decrease (increase) in net defined benefit asset	10	4
Increase (decrease) in provision for bonuses	143	214
Share-based compensation expenses	149	177
Interest and dividends income	(15)	(19)
Interest expenses	18	22
Foreign exchange losses (gains)	(43)	(9)
Decrease (increase) in notes and accounts receivable-trade	1,462	(13,934)
Decrease (increase) in accounts receivable-other	(63)	(39)
Decrease (increase) in inventories	(1,562)	(1,491)
Increase (decrease) in prepaid expenses	(28)	(157)
Increase (decrease) in accounts payable-trade	423	(1,466)
Increase (decrease) in accounts payable-other	(85)	2,040
Increase (decrease) in accrued consumption taxes	(90)	(174)
Increase (decrease) in advanced received	1,931	(1,105)
Other, net	100	(51)
Subtotal	4,616	(2,309)
Interest and dividends income received	19	19
Interest expenses paid	(23)	(22)
Income taxes (paid) refund	(380)	(2,435)
Net cash provided by (used in) operating activities	4,232	(4,747)
Cash flows from investing activities		
Payments into time deposits	(300)	(300)
Proceeds from withdrawal of time deposits	–	300
Purchase of property, plant and equipment	(1,437)	(4,514)
Subsidies received	–	4,345
Purchase of patent	(2,747)	–
Other, net	0	(68)
Net cash provided by (used in) investing activities	(4,484)	(236)
Cash flows from financing activities		
Increase (decrease) in short-term borrowings	9,070	–
Proceeds from long-term borrowings	300	550
Repayment of long-term borrowings	(450)	(550)
Proceeds from issuance of bonds	500	–
Repayments of lease obligations	(37)	(9)
Net decrease (increase) in treasury shares	8	7
Dividends paid	(525)	(928)
Other, net	1	–
Net cash provided by (used in) financing activities	8,867	(930)
Effect of exchange rate change on cash and cash equivalents	21	66
Net increase (decrease) in cash and cash equivalents	8,637	(5,848)
Cash and cash equivalents at beginning of period	10,928	26,260
Cash and cash equivalents at end of period	19,565	20,412

(4) Notes to quarterly consolidated financial statements

(Notes on premises as a going concern)

No corresponding item existed.

(Notes on any significant changes in the amount of shareholders' equity)

No corresponding item existed.

(Changes in accounting policy)

(Application of Accounting Standard for Revenue Recognition, etc.)

The Company has applied the "Accounting Standard for Revenue Recognition" (ASBJ Statement No. 29, March 31, 2020; hereinafter "Revenue Recognition Accounting Standards"), etc. from the beginning of 1Q FY2021 (April 1, 2021 to June 30, 2021), and recognizes revenue as the amount expected to be received in exchange for promised goods or services when control of the goods or services is transferred to the customer.

As a result, a portion of commission expenses previously recorded in selling, general and administrative expenses has been deducted from net sales. In addition, a portion of sales promotion expenses previously recorded in the net amount has been included in net sales and cost of sales.

In applying the Revenue Recognition Accounting Standards, etc., the Company follows the transitional treatment set forth in the proviso of Paragraph 84 of the Revenue Recognition Accounting Standards. The cumulative effect of retroactively applying the new accounting policy to periods prior to the beginning of 1Q FY2021 has been added to or subtracted from retained earnings at the beginning of 1Q FY2021, and the new accounting policy has been applied from the beginning balance of that period. However, the Company has applied the method stipulated in Paragraph 86 of the Revenue Recognition Accounting Standards, and accordingly the new accounting policy has not been applied to contracts for which nearly the entire amount of revenue had been recognized prior to 1Q FY2021.

The resulting effects on the consolidated financial results for 2Q FY2021 are as follows: a 29 million yen increase in net sales, a 152 million yen increase in cost of sales, a 123 million yen decrease in selling, general and administrative expenses, and no impact on operating income, ordinary income, or profit before income taxes. In addition, there was no impact on the balance of retained earnings at the beginning of 1Q FY2021.

(Application of Accounting Standard for Fair Value Measurement, etc.)

The Company has applied the "Accounting Standard for Fair Value Measurement" (ASBJ Statement No. 30, July 4, 2019; hereinafter "Fair Value Measurement Accounting Standards") from the beginning of 1Q FY2021 (April 1, 2021 to June 30, 2021). In accordance with the transitional treatment prescribed in Paragraph 19 of the Fair Value Measurement Accounting Standards and Paragraph 44-2 of the "Accounting Standard for Financial Instruments" (ASBJ Statement No. 10, July 4, 2019), the Company will apply the new accounting policies set forth in the Fair Value Measurement Accounting Standards, etc. at a future date. This has no impact on the quarterly consolidated financial statements.

(Concerning quarterly consolidated statements of income)

* Loss on cancellation of contracts

In May 2021, we terminated an agreement concluded for first right of refusal pertaining to certain products currently in the preclinical stage of development upon mutual agreement of the parties.

This resulted in a loss on cancellation of contract.

3. Other

R&D Pipeline

Recombinant drug products

Code Nonproprietary Name	**Status**	**Indication** **Remarks**
JR-141 BBB-Penetrating Iduronate -2-sulfatase (rDNA origin)	Brazil: Marketing approval obtained	Mucopolysaccharidosis II (Hunter syndrome)
	Global: Phase III	ERT J-Brain Cargo®
JR-171 BBB-Penetrating α-L-Iduronidase (rDNA origin)	Global: Phase I/II	Mucopolysaccharidosis I (Hurler syndrome, etc)
		ERT J-Brain Cargo® J-MIG System®
JR-162 J-Brain Cargo® - applied acid α-glucosidase (rDNA origin)	Preclinical	Pompe disease
		ERT J-Brain Cargo®
JR-441 BBB-Penetrating heparan N-sulfatase (rDNA origin)	Preclinical	Mucopolysaccharidosis III-A (Sanfilippo syndrome type A)
		ERT J-Brain Cargo®
JR-443 BBB-penetrating β-glucuronidase (rDNA origin)	Preclinical	Mucopolysaccharidosis VII (Sly's syndrome)
		ERT J-Brain Cargo®
JR-446 BBB-penetrating α-N-acetylglucosaminidase (rDNA origin)	Preclinical	Mucopolysaccharidosis III-B (Sanfilippo syndrome type B)
		ERT J-Brain Cargo®
JR-401X Somatropin (rDNA origin)	Phase III (Japan)	SHOX deficiency
		Expanded Indication of GROWJECT®
JR-142 Long-acting Growth hormone (rDNA origin)	Phase II (Japan)	Pediatric Growth Hormone deficiency
		J-MIG System®

(Note) ERT= Enzyme Replacement Therapy

Allogeneic regenerative medical product

Code Nonproprietary Name	**Status** (Japan)	**Indication** **Remarks**
JR-031HIE Human mesenchymal stem cells	Phase I/II	Neonatal hypoxic ischemic encephalopathy
		Expanded Indication of TEMCELL® HS
JTR-161／JR-161 Dental pulp stem cells (DPCs)	Phase I/II	Acute cerebral infarction
		Co-development with Teijin Limited