JCR Pharmaceuticals Co., Ltd.

Q2 Financial Results Briefing for the Fiscal Year Ending March 2020

November 6, 2019

Event Summary

[Company Name]	JCR Pharmaceuticals Co., Ltd.	
[Event Type]	Earnings Announcement	
[Event Name]	Q2 Financial Results Briefing for the Fiscal Year Ending March 2020	
[Fiscal Period]	FY2019 Q2	
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[Venue]	5F, Station Conference Tokyo Sapia Tower 1-7-12 Marunouchi Chiyoda-ku, Tokyo 100-0005	
[Venue Size]	231 m^2	
[Participants]	100	
[Number of Speakers]	6	
	Shin Ashida	Chairman, President, CEO & COO
	Toru Ashida	Senior Executive Director of Corporate Strategy, Head of Quality Assurance Division, Corporate Planning Division, Administration Division, and Medical Affairs Department
	Akihiro Haguchi	Corporate Officer, Executive Director, Administration Division
	Kazunori Tanizawa	Executive Director, Development Division
	Hiroyuki Sonoda, Ph.D.	Corporate Officer, Executive Director, Research Planning Division
	Yoshihiro Ota	Director, Accounting Administration Division
[Analyst Names]*	Hidemaru Yamaguchi	Citi Group Global Markets Japan
	Fumiyoshi Sakai	Credit Suisse Securities
	Shohei Oda	Morgan Stanley MUFG Securities
	Kazuaki Hashiguchi	Daiwa Securities
	Hironoshin Nomura	Mizuho Securities

*Analysts that SCRIPTS Asia was able to identify from the audio who spoke during Q&A.

Presentation

Moderator: We will now hold a results briefing for JCR Pharmaceuticals Co., Ltd. for the second quarter of the fiscal year ending March 2020.

To begin with, I would like to introduce today's participants. The Chairman, President, CEO and COO, Shin Ashida.

Shin Ashida: Thanks.

Moderator: Executive Officer, General Manager of Research and Planning Division, Dr. Hiroyuki Sonoda.

Sonoda: Good morning. Thanks.

Moderator: Toru Ashida, Director in charge of Corporate Strategic Affairs.

Toru Ashida: Thanks.

Moderator: Kazunori Tanizawa, Head of R&D Division.

Tanizawa: Good morning. Thanks.

Moderator: Akihiro Haguchi, Corporate Officer and Executive Officer of Administration Headquarters.

Haguchi: Thanks.

Moderator: Lastly, Yoshihiro Ota, Director and General Manager of the Accounting Administration Division.

Ota: Thanks.

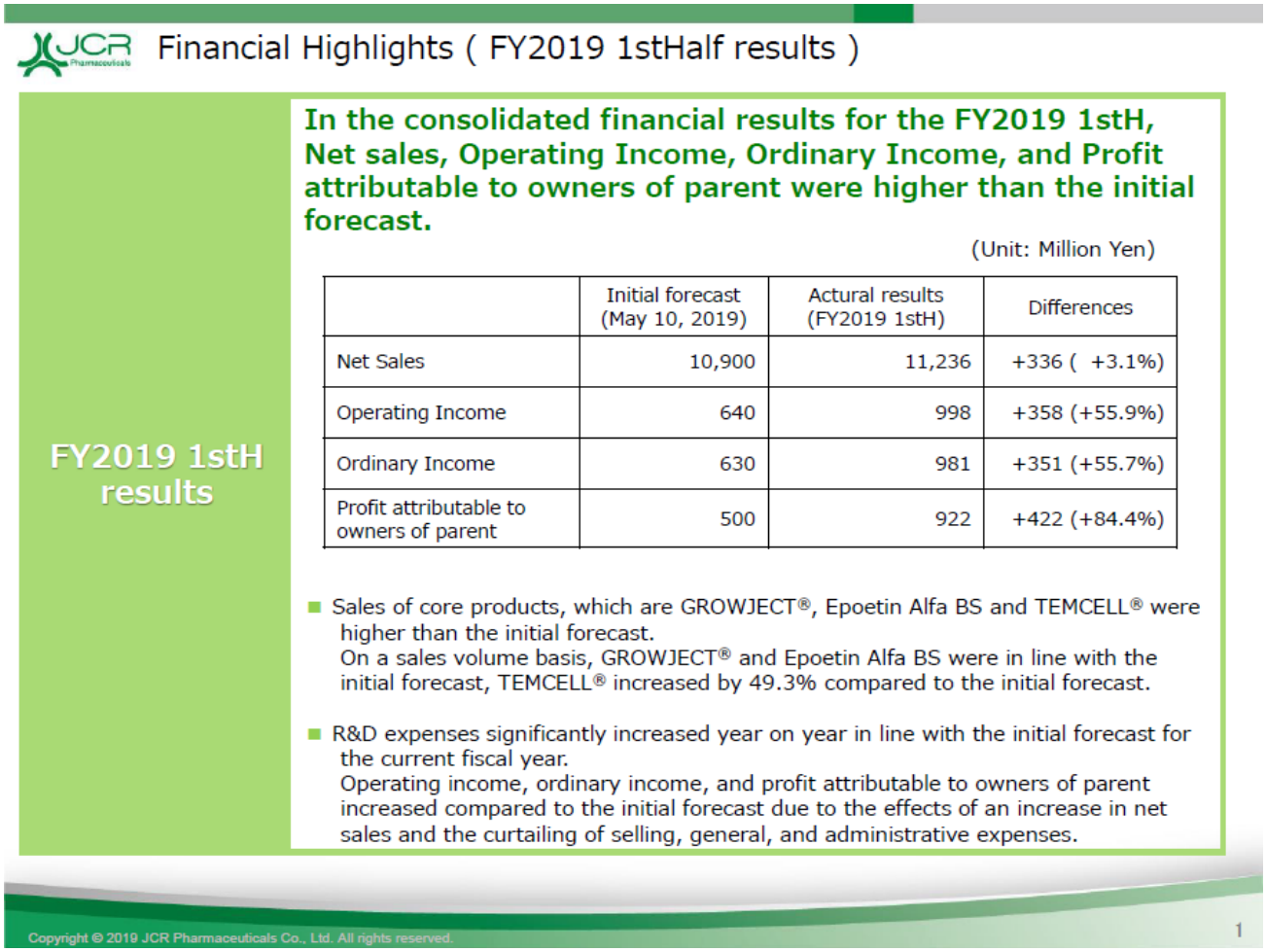
Moderator: We are pleased to confirm the materials we have on hand. Two copies of the materials and a questionnaire form are distributed for a total of three items. Today's materials are already available on our website.

Next, I will explain the flow of today's briefing session. First, Mr. Haguchi will present the financial results. Then Mr. Tanizawa will discuss research and development. In closing, Mr. Ashida will discuss his thoughts. Finally, we will take your questions.

Today's presentation will be video recorded. Please take note of this in advance.

Now, please turn your attention to the front screen for a presentation of our financial results.

Haguchi: Good morning. I am Haguchi of the Administration Division. To begin with, I will present an outline of the results for the second quarter of the fiscal year ending March 2020.



The figures for net sales and income are compared with the initially announced forecasts. Net sales increased 3.1% from the initial forecast to 11.23 billion yen. Looking at the breakdown, sales of GROWJECT, Epoetin Alfa BS, and TEMCELL increased compared with the initial forecast. However, sales of TEMCELL were 1.5 billion yen, compared with the initial forecast of 1.0 billion yen. As a result of this increase in TEMCELL sales, net sales increased by 330 million yen compared to the forecast.

Moving on to profits, R&D expenses increased substantially compared with the previous fiscal year, but this was in line with initial expectations. The increase in operating income was largely attributable to the positive effects of increased sales and the curtailment of increases in selling, general and administrative expenses. As a result, both operating income and ordinary income increased 55%, and net income increased 84% compared with the initial forecasts, both of which were favorable.

Consolidated Results

(Unit: Million yen)

Consolidated	Six Months Ended Sep.30, 2018	Six Months Ended Sep. 30, 2019 A	Year-on-Year	FY2019 (Apr. 1, 2019- Mar. 31, 2020) Initial Forecast B	Expected progress rate A/B
Net Sales	10,275	**11,236**	9.3%	26,400	42.6%
Cost of Sales	2,995	**3,173**	5.9%	7,300	43.5%
Gross Profit	7,280	**8,063**	10.8%	19,100	42.2%
SG&A	3,510	**3,809**	8.5%	7,630	49.9%
R&D Expenses	1,824	**3,255**	78.4%	6,330	51.4%
Operating Income	1,945	**998**	(48.7%)	5,140	19.4%
Ordinary Income	2,006	**981**	(51.1%)	5,150	19.0%
Profit*	1,377	**922**	(33.0%)	4,080	22.6%

*Profit attributable to owners of parent

(Reference)

R&D Expenses**	2,407	**3,539**	47.0%	6,921	51.1%

**R&D expenses before deducting contribution amount by collaborative R&D partners

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This slide shows comparisons with the same period of the previous fiscal year. Sales rose 9.3% year on year. Details will be available later in this report. As a result of a one-point improvement in the cost of sales ratio, gross profit increased by approximately 780 million yen, or 10.8%, compared with the same period of the previous fiscal year.

However, R&D expenses rose 78.4%, or 1.4 billion yen, compared with the previous fiscal year. This resulted in a decrease in operating income of 48.7%, or just under 1 billion yen. The same trend applies to ordinary income and net income. The increase in sales and the decrease in profits were in line with the initial forecast.

Consequently, we have left our initial forecasts unchanged for the full-year profit and loss forecast. As mentioned earlier, in the second quarter of the fiscal year under review, operating income and ordinary income exceeded expectations of 350 million yen. However, we are working to accelerate our R&D activities to the extent possible in the current situation, especially in the area of research. For this reason, we have been reviewing our plans to carry out some of the activities planned for the next fiscal year ahead of schedule. As a result, there is a possibility that our annual R&D expenses will exceed our forecasts of 6.3 billion yen. Accordingly, to retain a little room to maneuver, the operating income and income figures have not been revised.

This concludes the summary of profit and loss.

Sales by business Segments (Consolidated)

(Unit: Million yen)

Number of business segment	Six Months Ended Sep. 30, 2018		Six Months Ended Sep. 30 2019			FY2019 (Apr. 1, 2019- Mar. 31, 2020)		Reference
		Composition ratio	A	Composition ratio	Year-on-Year	Forecast (after fixing) B	Expected progress rate A/B	Forecast (before fixing)
Growject®	5,845	56.8%	**6,235**	55.5%	+6.7%	12,580	49.6%	12,580
Epoetin Alpha BS Inj. [JCR]	2,166	21.1%	**2,272**	20.3%	+4.9%	3,900	58.3%	3,410
TEMCELL®HS Inj.	989	9.6%	**1,527**	13.6%	+54.3%	2,800	54.5%	2,050
Agalsidase Beta BS I.V. Infusion [JCR]	–	–	**123**	1.1%	–	450	27.3%	990
Urine-derived products	27	0.3%	**9**	0.1%	(63.5%)	1,000	0.9%	1,080
License Revenue	1,054	10.3%	**1,002**	8.9%	(4.9%)	4,200	23.9%	4,200
Other	–	–	**26**	0.2%	–	1,400	1.9%	2,020
Total sales of Finished Goods	**10,083**	**98.1%**	**11,197**	**99.7%**	**+11.0%**	**26,330**	**42.5%**	26,330
Medical devices & laboratory equipment	**192**	**1.9%**	**39**	**0.3%**	**(79.6%)**	**70**	**55.7%**	70
Total Net Sales	**10,275**	**100%**	**11,236**	**100%**	**+9.3%**	**26,400**	**42.6%**	26,400

This slide shows net sales by product category. This information is also available on the website. First, compared with the same period of the previous fiscal year, sales of GROWJECT and Epoetin Alfa BS continued to be solid. As a result, sales rose 6.7% for GROWJECT, and 4.9% for Epoetin Alfa BS.

As I mentioned earlier, TEMCELL sales increased by over 500 million yen, a 54.3% year-on-year increase. This reflects higher than expected growth. Sales of Agalsidase Beta BS, which launched last fall, totaled 123 million yen in the first half of the year. Contract revenue has seen very little change, amounting to 1.0 billion, compared with 1.05 billion in the previous fiscal year.

As a result, net sales for the fiscal year under review totaled 11.23 billion yen, an increase of 9.3% from the same period of the previous fiscal year.

Next, with regard to the full-year forecast, the figure for total net sales was 26.4 billion yen, the same as the initial forecast. However, some adjustments have been made for individual products, as shown here. Firstly, in light of the results of the first half of the fiscal year under review and current trends, the Company has upwardly revised its forecast of 2.0 billion yen for TEMCELL to 2.8 billion yen, while its forecast of 990 million yen for Agalsidase Beta BS has been downwardly revised to 450 million yen.

In addition, Darbepoetin Alfa BS, which was approved in September, has been included in other items. In light of the situation with Nesp AG, we have revised our total forecast for other items from 2.0 billion yen to 1.4 billion yen.

On the other hand, the forecast for Epoetin Alfa BS has been upwardly revised from 3.4 billion yen to 3.9 billion yen. Therefore, the total sales figure for ESA formulations is expected to be roughly the same as the

initial forecast. GROWJECT sales and subscription revenue forecasts are unchanged from the initial forecast. This gives a forecast total of 26.4 billion yen. This is the same figure as the initial forecast.

We have seen a breakdown of net sales above.

On the next page, we have plotted sales trends by product, so please refer to it again.

Balance Sheets (Consolidated)

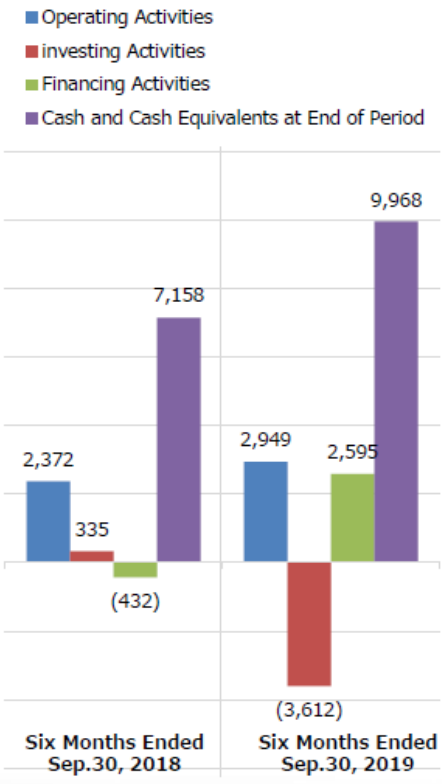
(Unit: Million yen)

	Mar. 2019	Sep. 2019	Main increase/decrease		Mar. 2019	Sep. 2019	Main increase/decrease
Current assets	27,368	**27,635**	Cash and deposit +2,176 Notes and accounts receivable-trade (2,098) Inventories +858 Securities (230)	**Current liabilities**	8,684	**9,686**	Short-term loans payable +1,350 Income taxes payable (229)
				Non-current liabilities	2,957	**4,663**	Long-term loans payable +1,850
Non-current assets	15,147	**17,990**	Deferred tax assets +363 Property, plant and equipment +2,555 Investment securities (301)	**Total liabilities**	11,642	**14,350**	+2,707
				Total net assets	30,874	**31,276**	Net income +922 Dividend (525)
Total	42,516	**45,626**	+3,109	**Total**	42,516	**45,626**	+3,109
Capital investment	1,517	**3,376**		**Equity ratio**	71.1%	**66.9%**	

The next page shows a summary of the balance sheet. Total assets increased 3.1 billion yen from the end of the previous fiscal year. This was mainly due to an increase of 2.5 billion yen in property, plant and equipment. The majority of this 2.5 billion yen was released in June of this year, and we acquired land and buildings near our existing research facilities to augment our research facilities. Most of the increase in property, plant and equipment is due to the expansion of research facilities, since the acquisition price was approximately 2.3 billion yen. Total short-term and long-term loans payable increased by 3.2 billion yen as a result of this capital investment.

Please refer to the next page for a graph of assets and net liabilities.

Cash Flows (Consolidated)



(Unit: Million yen)

	Six Months Ended Sep.30, 2018 A	**Six Months Ended Sep.30, 2019 B**	Year-on-year B - A
Income before income taxes	1,855	1,098	(757)
Depreciation and amortization	642	658	16
Accounts receivable-trade	462	2,098	1,636
Inventories	115	(860)	(975)
Other	(702)	(45)	657
Operating Activities	2,372	**2,949**	577
Securities	613	239	(373)
Capital investment	(280)	(3,852)	(3,571)
Other	3	0	(3)
Investing Activities	335	**(3,612)**	(3,947)
Loans payable	86	3,200	3,114
Dividends·treasury stock	(418)	(515)	(97)
Other	(100)	(89)	11
Financing Activities	(432)	**2,595**	3,027
Cash and Cash Equivalents at End of Period	7,158	**9,968**	2,810

Moving on to cash flows. The increase in inventories was one of the major expenditures during the first half of the fiscal year under review. This was due to an increase in production in anticipation of the launch of Darbepoetin Alfa. In addition, including the 2.3-billion-yen expansion of research facilities I just mentioned, capital expenditure is 3.8 billion yen, and dividend payments will be over 500 million yen. Cash provided by operating activities was 2.9 billion yen, and borrowings of 3.2 billion yen were used to cover these payments. Cash and cash equivalents at the end of March of the previous fiscal year totaled approximately 8 billion yen, so cash equivalents increased by approximately 2 billion yen in the first half of the fiscal year.

The following pages show trends in cash flow, gross profit margin, cost of sales and expense ratios, and so on. Please refer to the chart below for more information.

This concludes the results summary for the second quarter. That's all from me. Thank you very much.

Moderator: Next, Mr. Tanizawa will discuss our R&D activities.

Tanizawa: Good morning everyone. I would like to explain the current status of R&D.

Today, I will explain the highlights of our press releases, and then discuss the current development status of lysosomal disease treatments. Finally, I will explain our other R&D pipelines.

Development Pipeline

■ Lysosomal Storage Disorders (LSDs) ■ Other Recombinant Protein Therapeutics
■ Regenerative Medical Product

As of Nov. 6, 2019

Code	Indication	Preclinical / Clinical trials / Filed / Approved	Remarks
JR-141	Hunter syndrome	Phase 3 (Japan) Phase 2 (Brazil)	• ERT • J-Brain Cargo®
JR-162	Pompe disease	Preclinical	• ERT • J-Brain Cargo® • J-MIG System®
JR-171	Hurler syndrome Hurler-Scheie syndrome Scheie syndrome	Preclinical	• ERT • J-Brain Cargo® • J-MIG System®
JR-441	Sanfilippo syndrome type A	Preclinical	• ERT • J-Brain Cargo® • J-MIG System®
Darbepoetin Alfa BS Inj. [JCR] (JR-131)	Renal anemia	Approved	• Co-developed with Kissei Pharmaceutical Co., Ltd. • Biosimilar
JR-401X	SHOX deficiency	Phase 3	• Expanded indication of GROWJECT®
JR-041	Infertility	Phase 1/2	• Out-licensed to ASKA Pharmaceutical Co., Ltd.
JR-142	pediatric growth hormone deficiency	Phase 1	• Long-acting human growth hormone product • J-MIG System®
JR-031EB	Epidermolysis bullosa	Suspended (Application withdrawn)	• Expanded indication of TEMCELL®HS Inj.
JR-031HIE	Hypoxic ischemic encephalopathy in neonates	Phase 1/2	• Expanded indication of TEMCELL®HS Inj.
JTR-161/ JR-161	Acute cerebral infarction	Phase 1/2	• Co-developed with Teijin Limited

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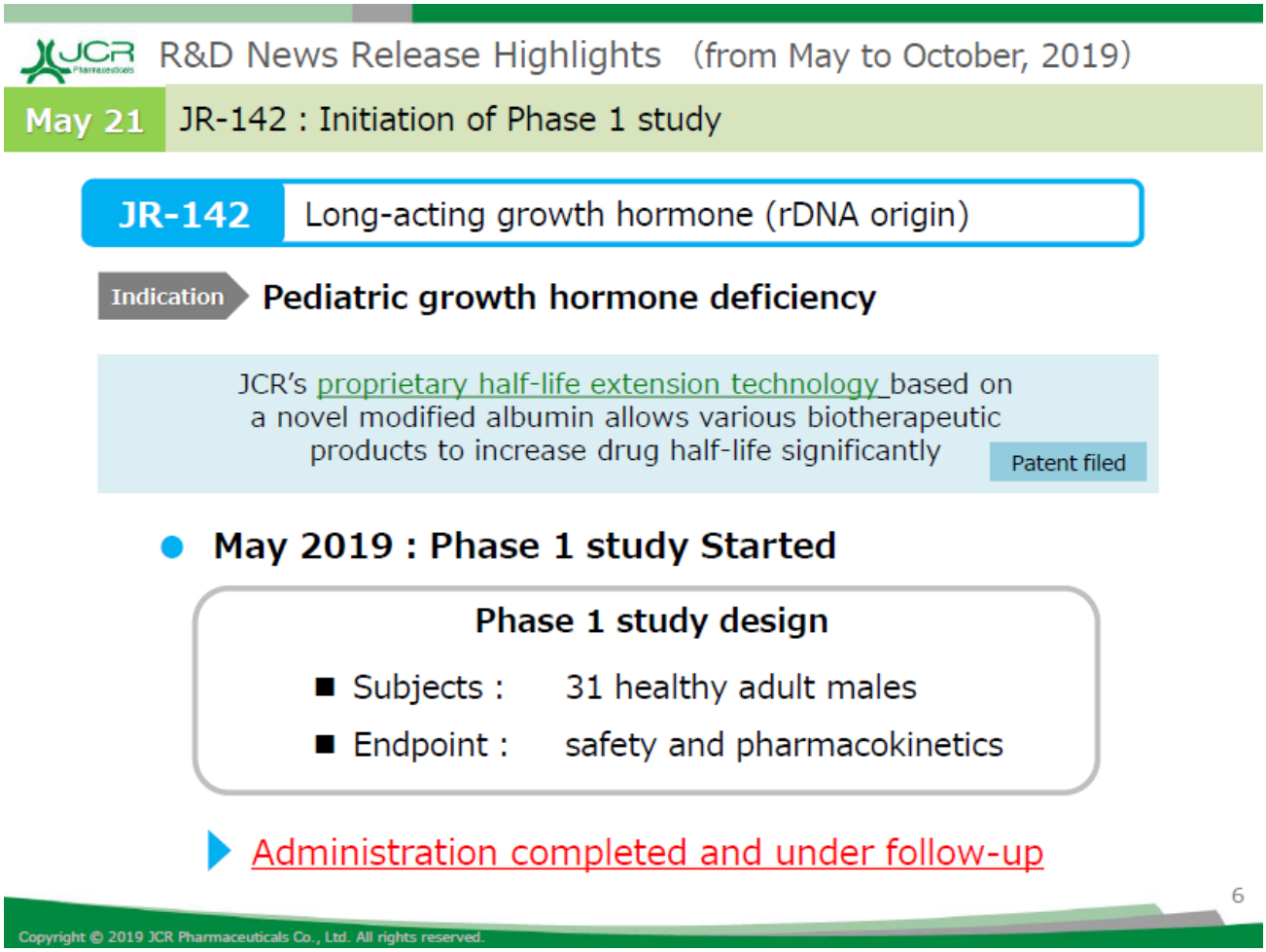
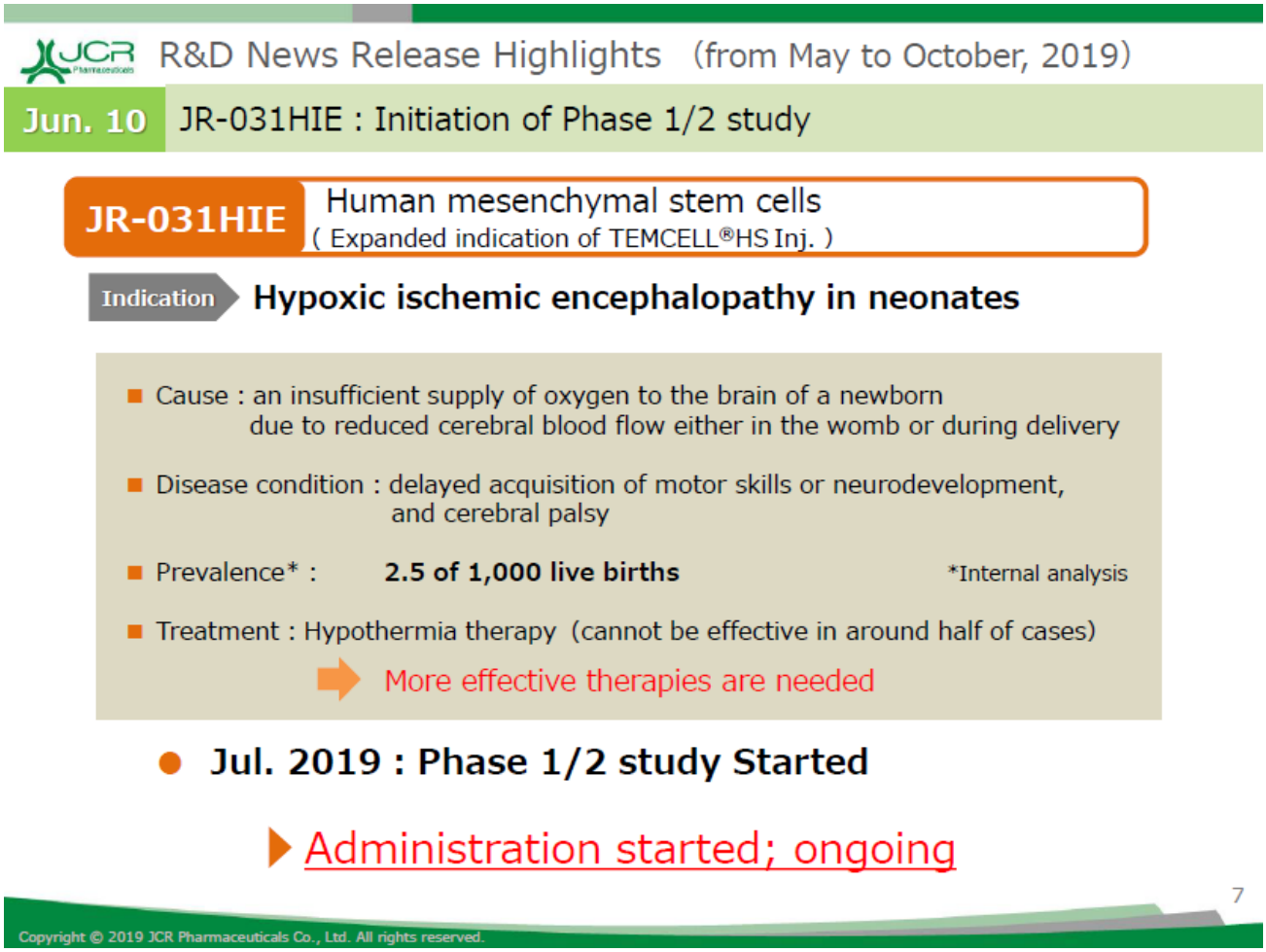
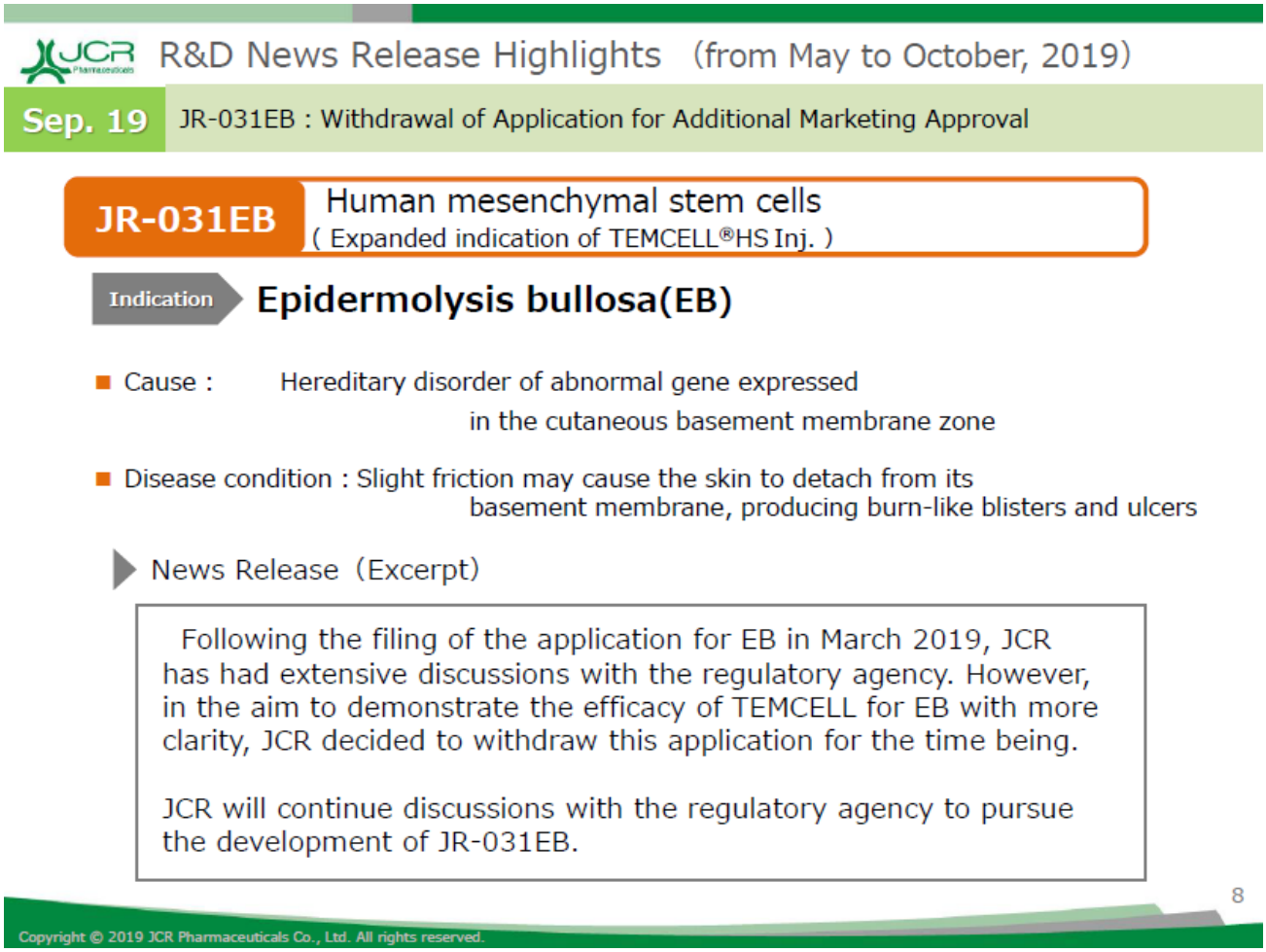
This is a summary of the pipeline, and currently 11 projects are proceeding in parallel. Broadly speaking, these green bars represent treatments for lysosomal disease, which are all based on J-Brain Cargo. Lysosomal disease, regenerative medicine, and other biopharmaceuticals together form the three pillars of our development pipeline. The stars marking some bars indicate recent progress in that area.



First, let me explain the highlights for JR-142. This is a genetically modified, sustained-growth hormone formulation that uses our proprietary modified albumin. This will greatly extend its blood half-life. phase I clinical trials were launched in May this year, and at present, all 31 healthy adult men who participated have received the compound. We are currently conducting follow-up examinations, and will move forward based on the results.

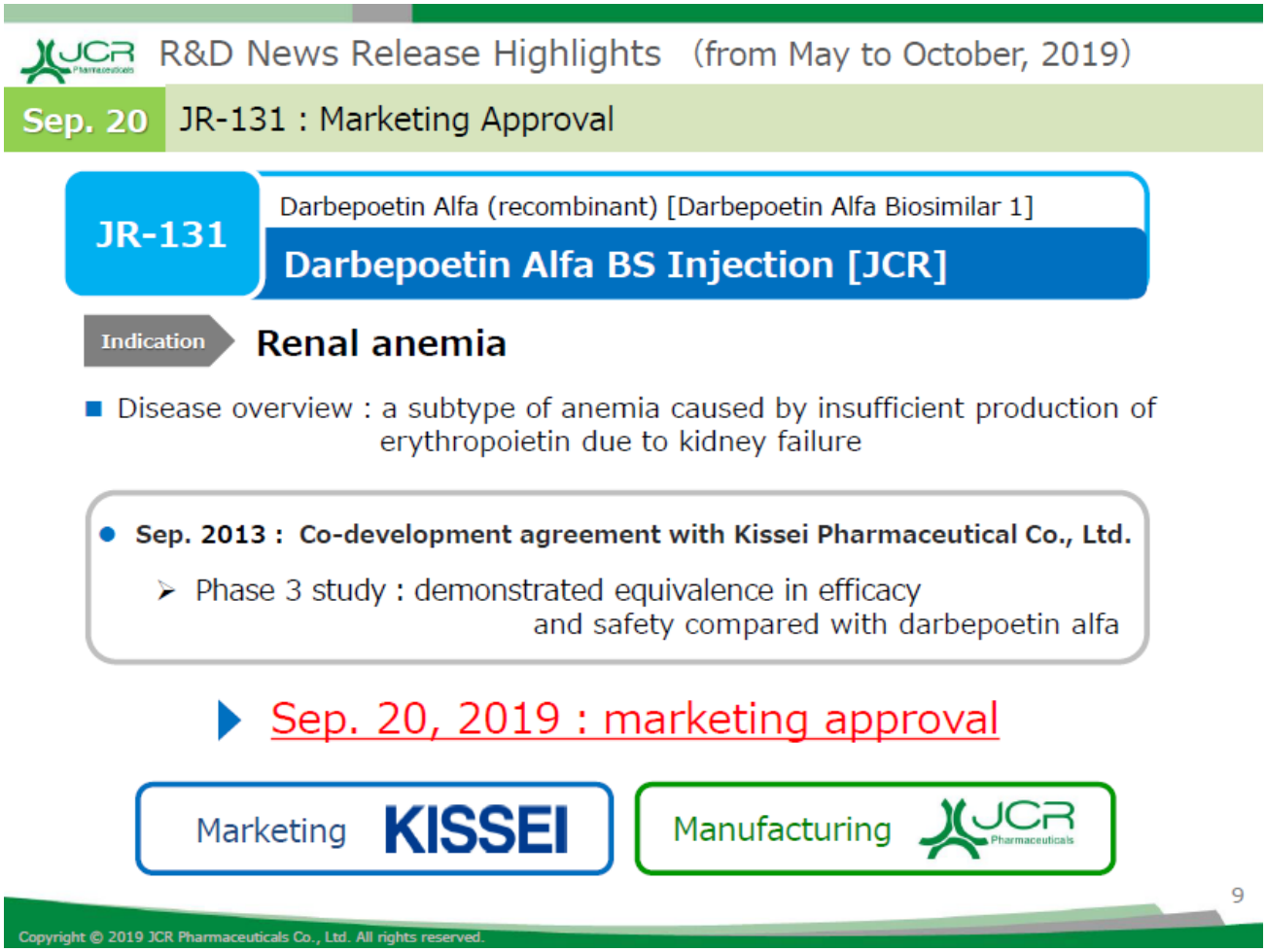


We will continue to expand the indications of TEMCELL. This slide shows progress in expanding the indications to include Newborn Hypoxic Ischemic Encephalopathy, or HIE. This disease occurs as a result of neonatal asphyxia, and is a very serious disorder linked to cerebral palsy. Currently, there is a long-standing need for effective treatment methods. We have chosen this disease as an indication expansion for TEMCELL, and trials have been underway since July. We have already begun administration to patients, and recruitment is ongoing. We will continue to monitor progress in the future.



This is a press release released in September. We are currently expanding the indication of TEMCELL for the treatment of Epidermolysis Bullosa. As stated in the release, we applied for approval in March, but as we proceeded with negotiations with the authorities, we felt it was important to demonstrate the effectiveness more clearly. Therefore, we decided to withdraw the application for approval.

Currently, we are in discussions with the PMDA on this matter, and we are in the process of discussing how to clearly demonstrate its effectiveness in the future. Once that policy has been finalized, I would like to discuss it again.

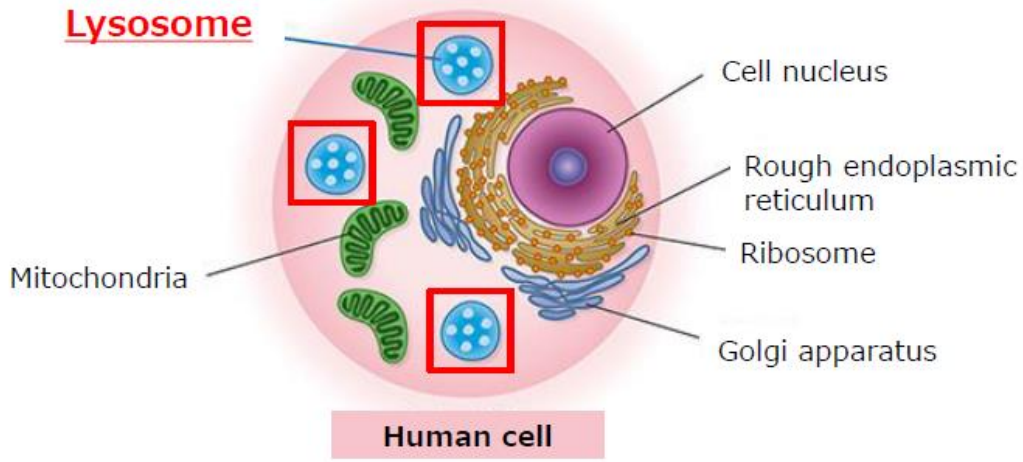


This concerns the September 20th marketing approval for Darbepoetin Alfa BS Injection. This was approved as planned. The product is to be manufactured by our Company, and sold by Kissei Pharmaceutical Co., Ltd.

R&D for Lysosomal Storage disorders (LSDs)

Lysosomal Storage Disorders (LSDs)

LSD is a group of rare inherited disorders in which one of enzymes in the lysosomes is congenitally missing or its function is deficient, resulting in the accumulation of metabolic wastes which fail to dissolve. Its symptoms vary depending on the affected enzymes and the accumulating substrates.
It is designated by MHLW as an intractable disease as well as a specific pediatric chronic disease.



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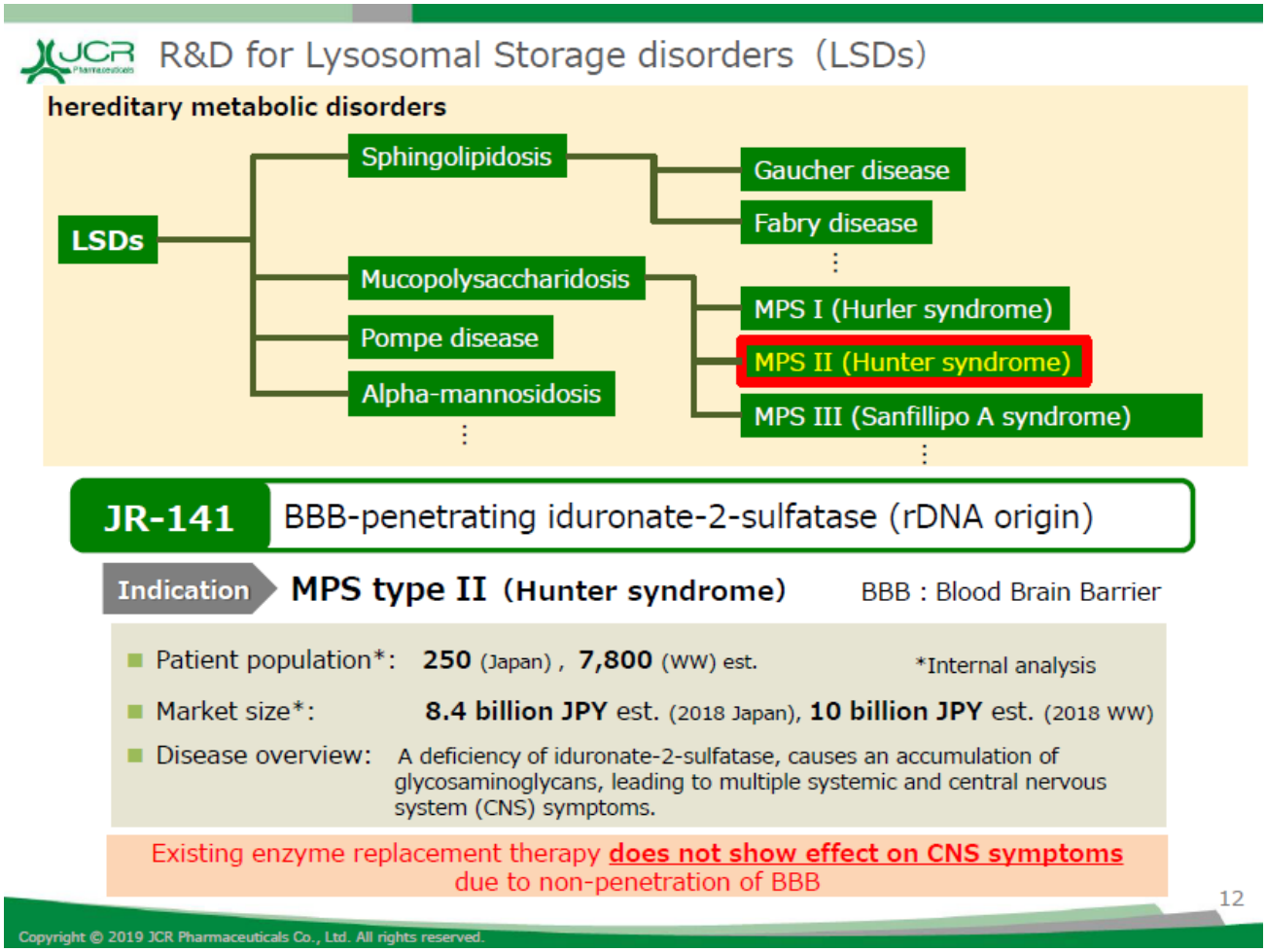
Let me now explain the status of research and development for the treatment of lysosomal disease. As you know, lysosomal diseases make up a group of congenital metabolic disorders. Lysosomes, which are a type of endogenous organelle, contain a large number of enzymes, and in lysosomal diseases, malfunctions in the enzymes result in a buildup of their target molecules in the cell. These diseases occur when cells throughout the whole body become impaired.

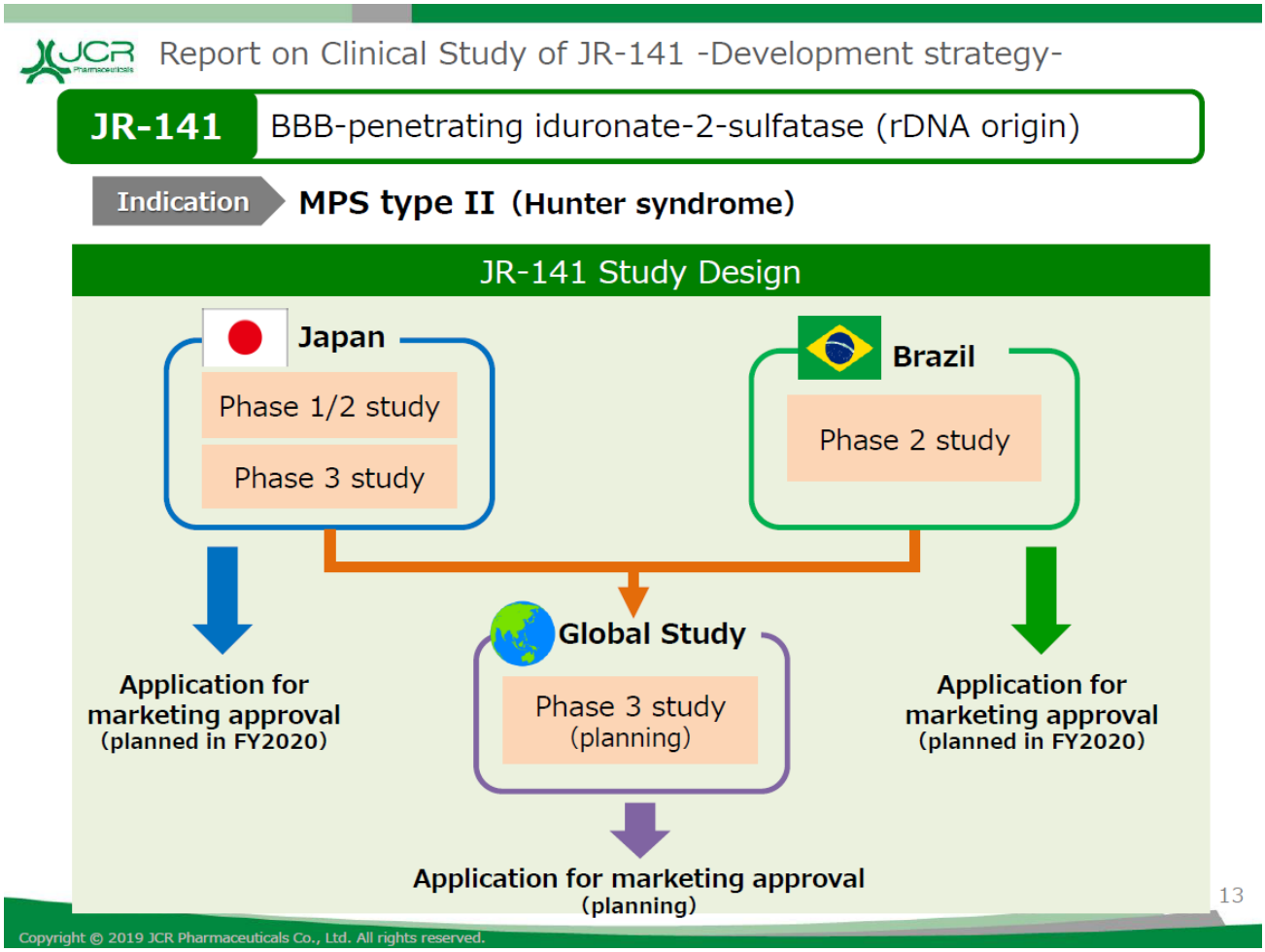


In addition to lysosomal disease, other congenital metabolic disorders include amino acid metabolism disorders, organic acid metabolism disorders, and metal metabolism disorders. Some of these diseases are also lysosomal diseases, and their classification is mainly based on the type of accumulated substance.

For example, Lipidosis refers to lipid accumulation, and this occurs in diseases such as Gaucher disease and Fabry disease. Mucopolysaccharides, which are often found in connective tissue, accumulate in diseases known as mucopolysaccharidoses. Others include Pompe disease and Mannosidosis.

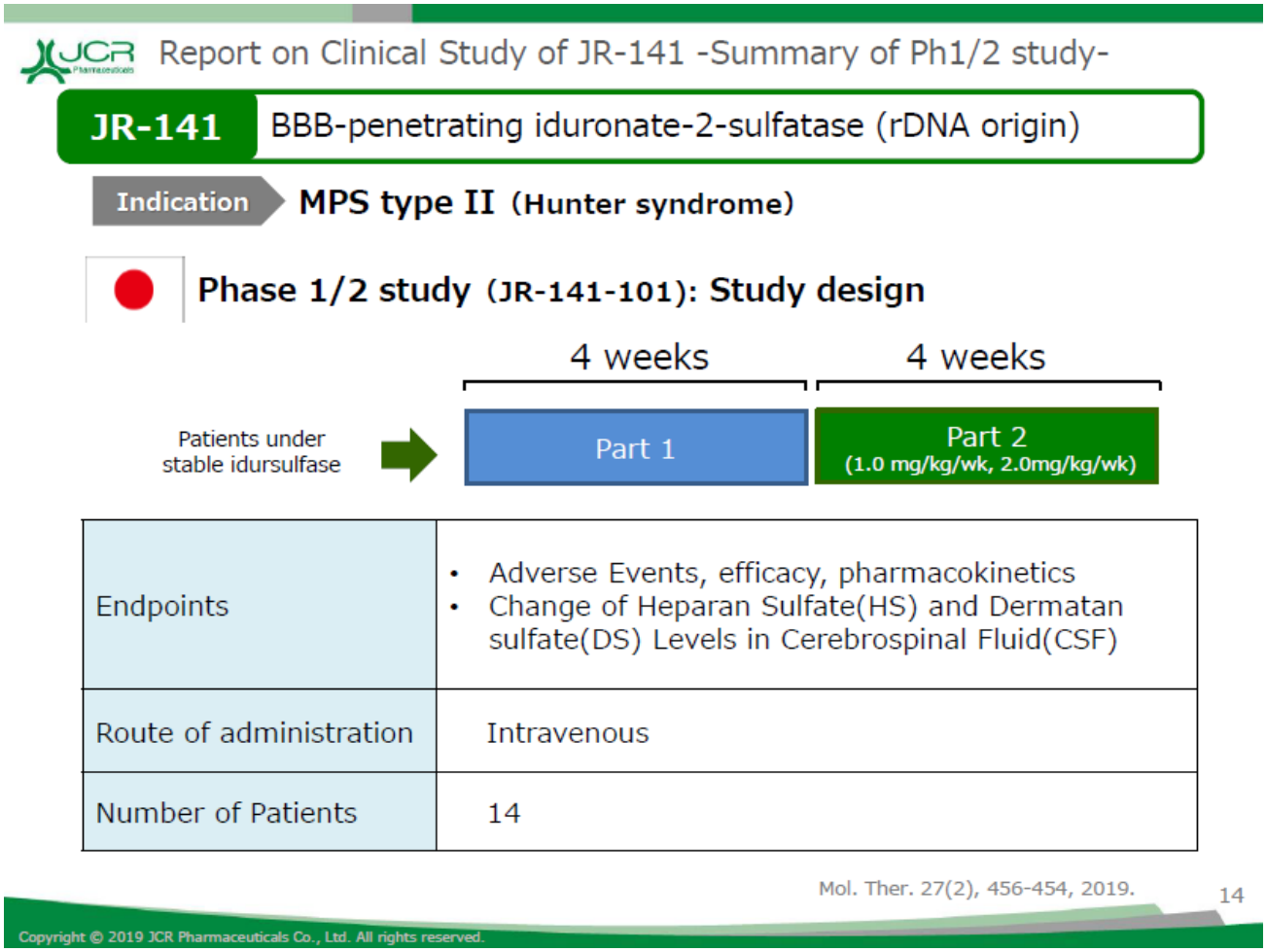
JR-141, which we are currently focusing on, targets Hunter syndrome, which is a Type II Mucopolysaccharidosis. We believe that there are 250 affected patients in Japan and 7,800 affected patients worldwide.

There is an extremely large problem with existing treatments. That is, current enzymes are not effective in addressing central nervous system problems.



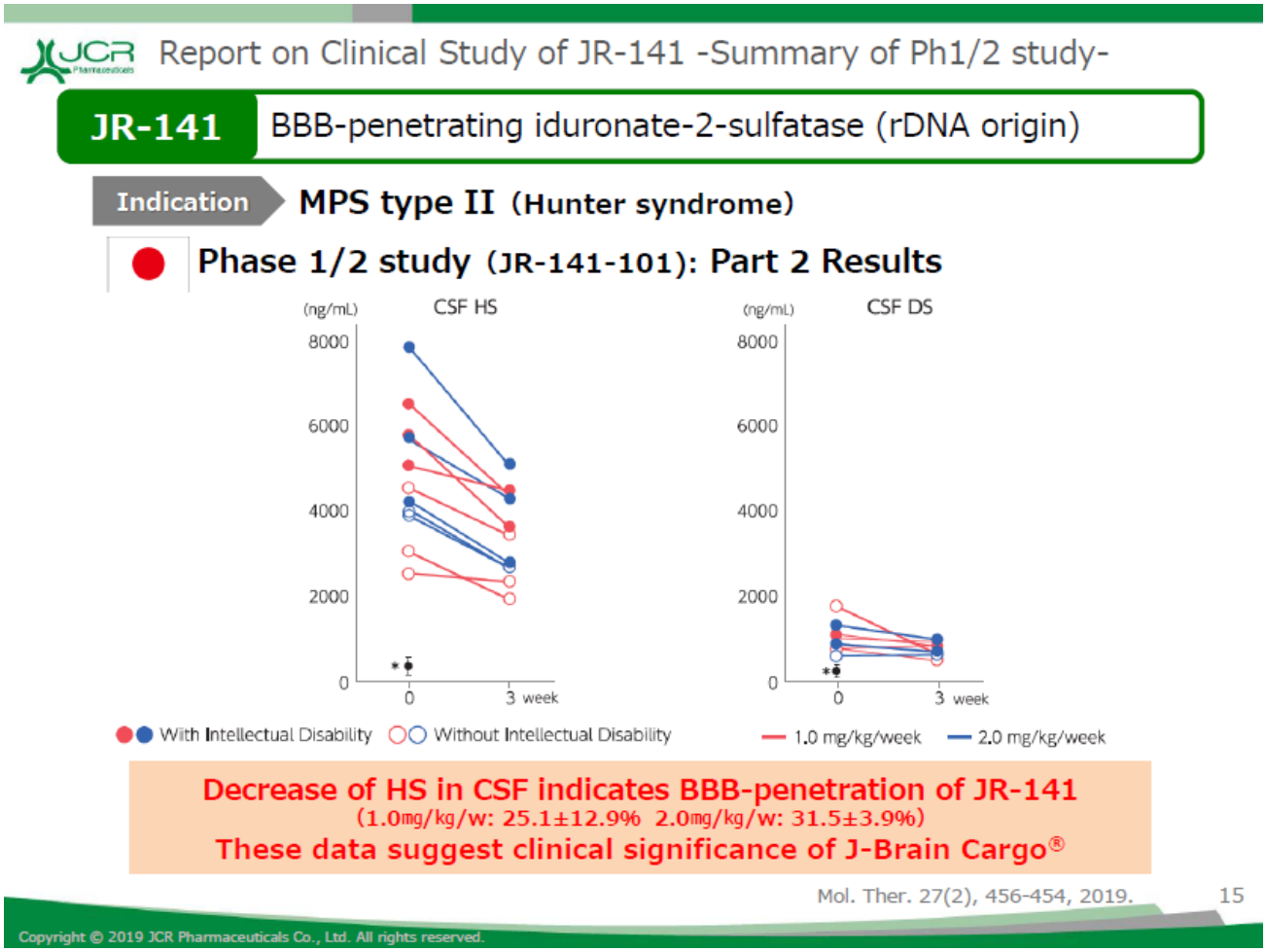
This is an overall picture of our R&D plans for JR-141. phase I/II trials have already been completed in Japan. Subsequently, we are currently conducting phase III trials. In parallel, in Brazil, we are conducting phase II trials with different administration routes and dosages. Once this study is completed, we will apply for marketing approval for each product.

We are currently in discussions with the FDA, and based on the results of the Japanese and Brazilian trials, we are planning a global phase III study, including the US and Europe.



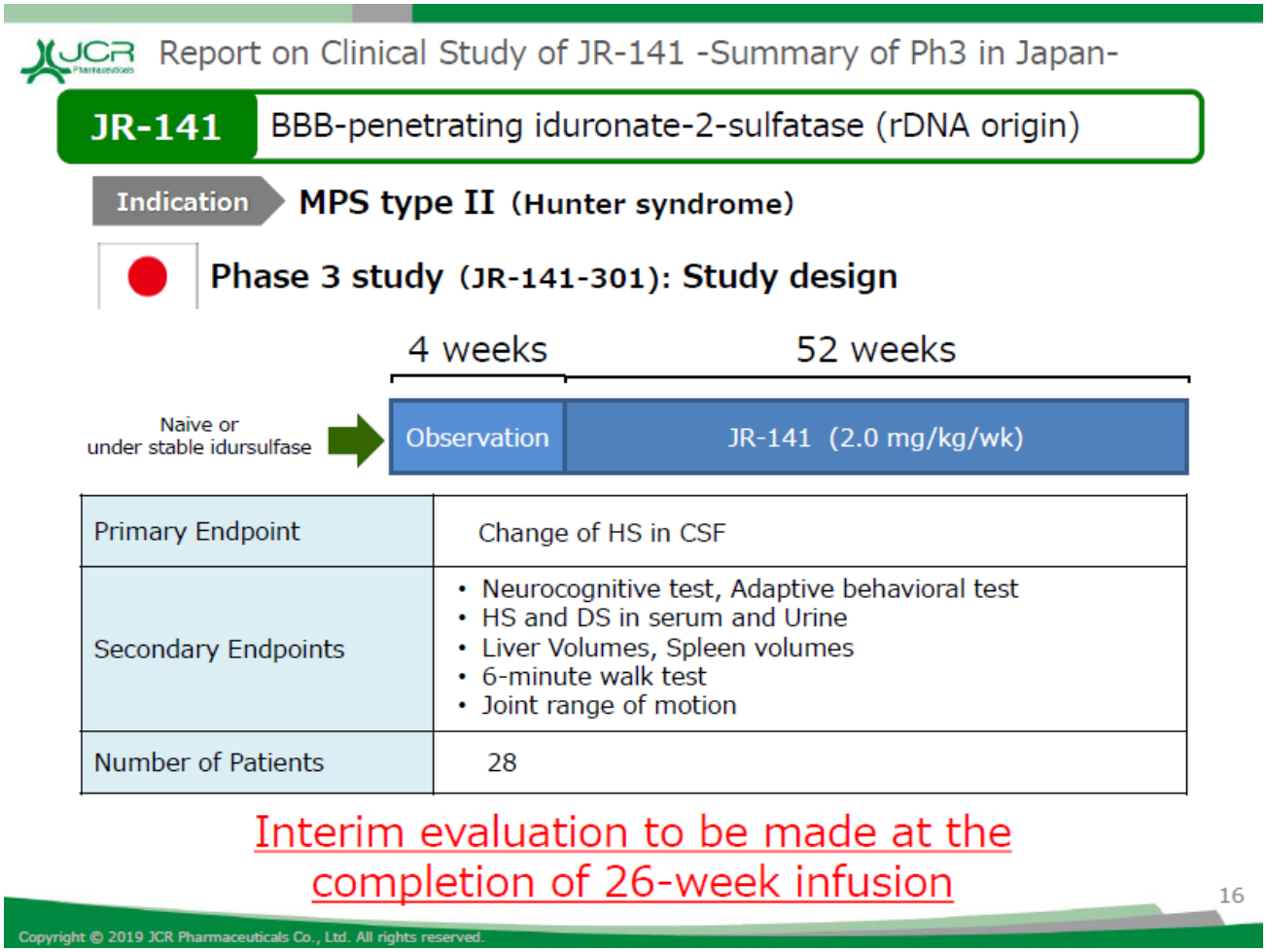
This is the design of the phase I/II study. First, I would like to talk about the details. Patients who were treated with Idursulfase, an innovator drug, were enrolled in this study first. As it was the first administration of the drug, part one of the trial involved gradually increasing their dosage and changing administration route. After that, we moved on to the four-week part two. We created a one milligram and a 2-milligram group, and compared results between the two groups.

The main goal was to ascertain safety, and in the course of this study, the substance that accumulates in Hunter syndrome and affects the central nervous system (CNS) was measured in the cerebrospinal fluid.



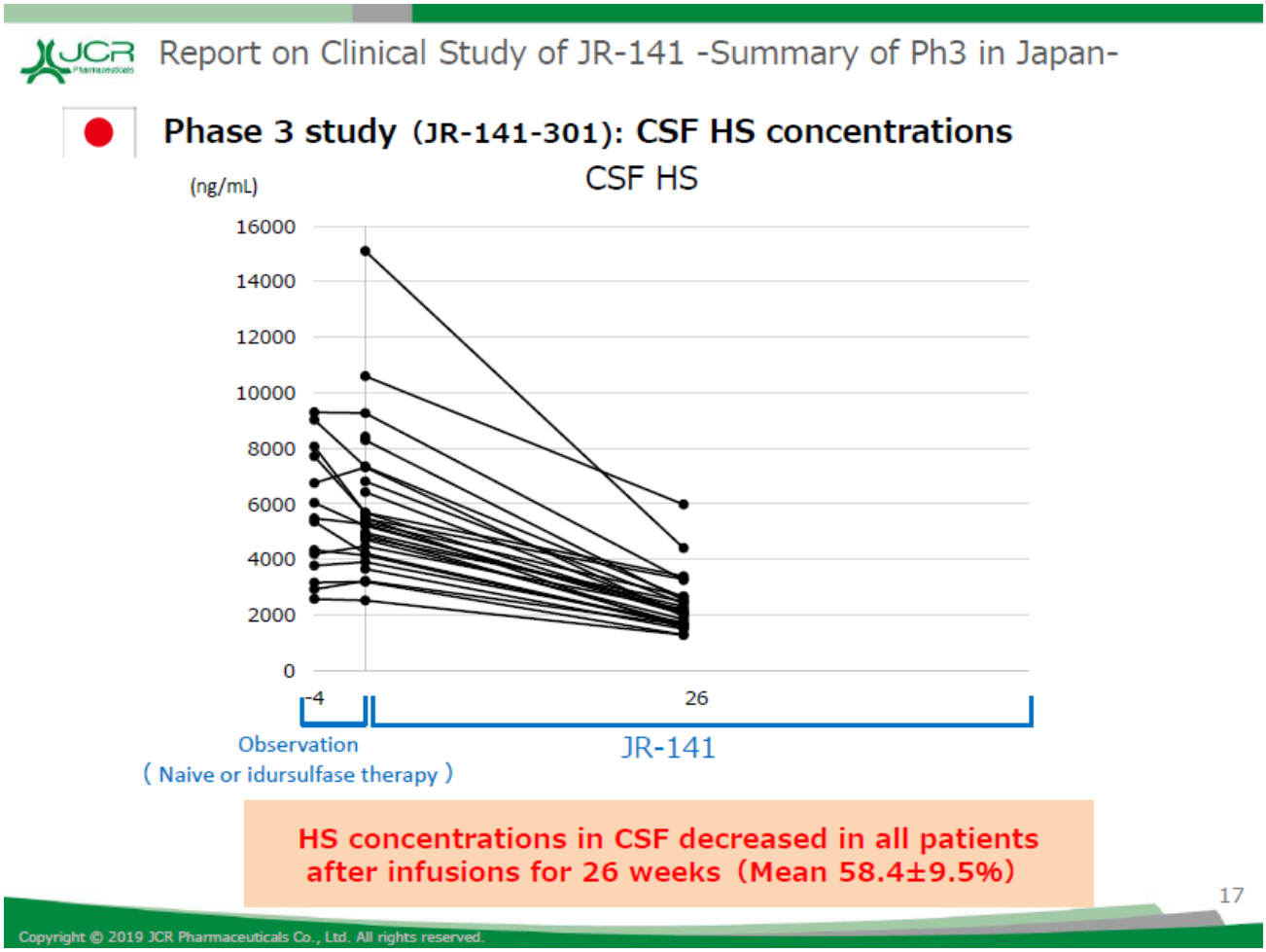
This paper has already been published, and I think some of you have read it, but the results of this phase I/II trial are as follows. The concentration of heparan sulfate in CSF decreased in all subjects after three doses. This data is crucial, as it is the first result showing that a compound employing J-Brain Cargo went through the blood-brain barrier.

We would like to draw your attention to two points: these filled and unfilled circles. The unfilled circles indicate participants without intellectual disability, which is the baseline data for those without CNS problems. Therefore, as we have seen this data, we can confirm that those with a large amount of accumulation are suffering from central nervous system symptoms. Therefore, I think that this biomarker, heparan sulfate, is extremely important in assessing central nervous system symptoms.



Following on from this, we are currently conducting phase III trials. Although the trial design is very similar, we are dividing participants into those receiving the innovator drug and those who have not been treated with it. The study period is 52 weeks and the dose is 2 milligrams. The primary endpoint is the change in concentration of heparan sulfate in the CSF, as I just mentioned. This will be assessed at week 52.

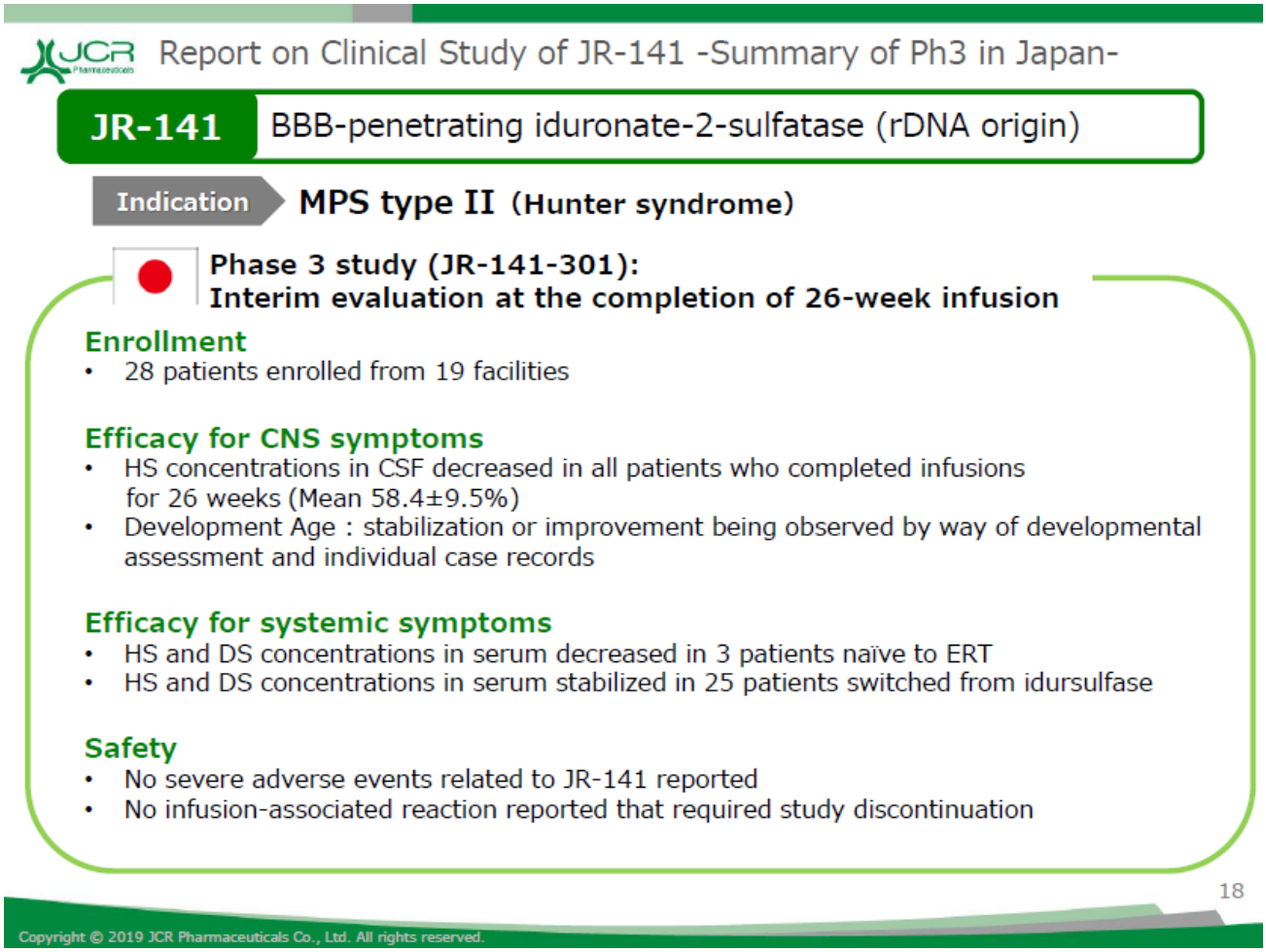
We are also conducting development assessments, which is an important point, and we are also conducting blood and urine analysis to assess biomarker levels. Since there is also a question about the effects on the body as a whole, we also evaluate liver and spleen volume, six-minute walking, joint mobility, and so on. The target number of cases was 20, but 28 patients are participating. The week-26 administration has been completed, and we have conducted an interim evaluation.



This is the most important figure. It is part of the preliminary report. As you can see, in all patients who have completed 26 weeks of treatment, the level of heparan sulfate in the cerebrospinal fluid has decreased. On average, the level was 58.4% lower. There are, of course, differences among patients, with reductions between roughly 40% to 70% observed after 26 weeks.

This implies that although in the phase I/II study mentioned above, the level was 25% to 30% lower after three doses, it was confirmed that the level was lower still after a longer administration period.

As I mentioned earlier, the main evaluation item is the decrease at the 52-week timepoint. Therefore, we believe that it is extremely significant to obtain such data at the mid-term stage.



Here is a summary of the interim evaluation, and some other parts are also shown in bullet points. Professors from 19 facilities nationwide have endorsed and cooperated in this study. As I said, we aimed for 20 patients, and 28 patients enrolled in the trial. Three of them are patients who had not been treated. As I mentioned earlier, the concentration of heparan sulfate in the cerebrospinal fluid was decreased in all patients at the time of administration at week 26.

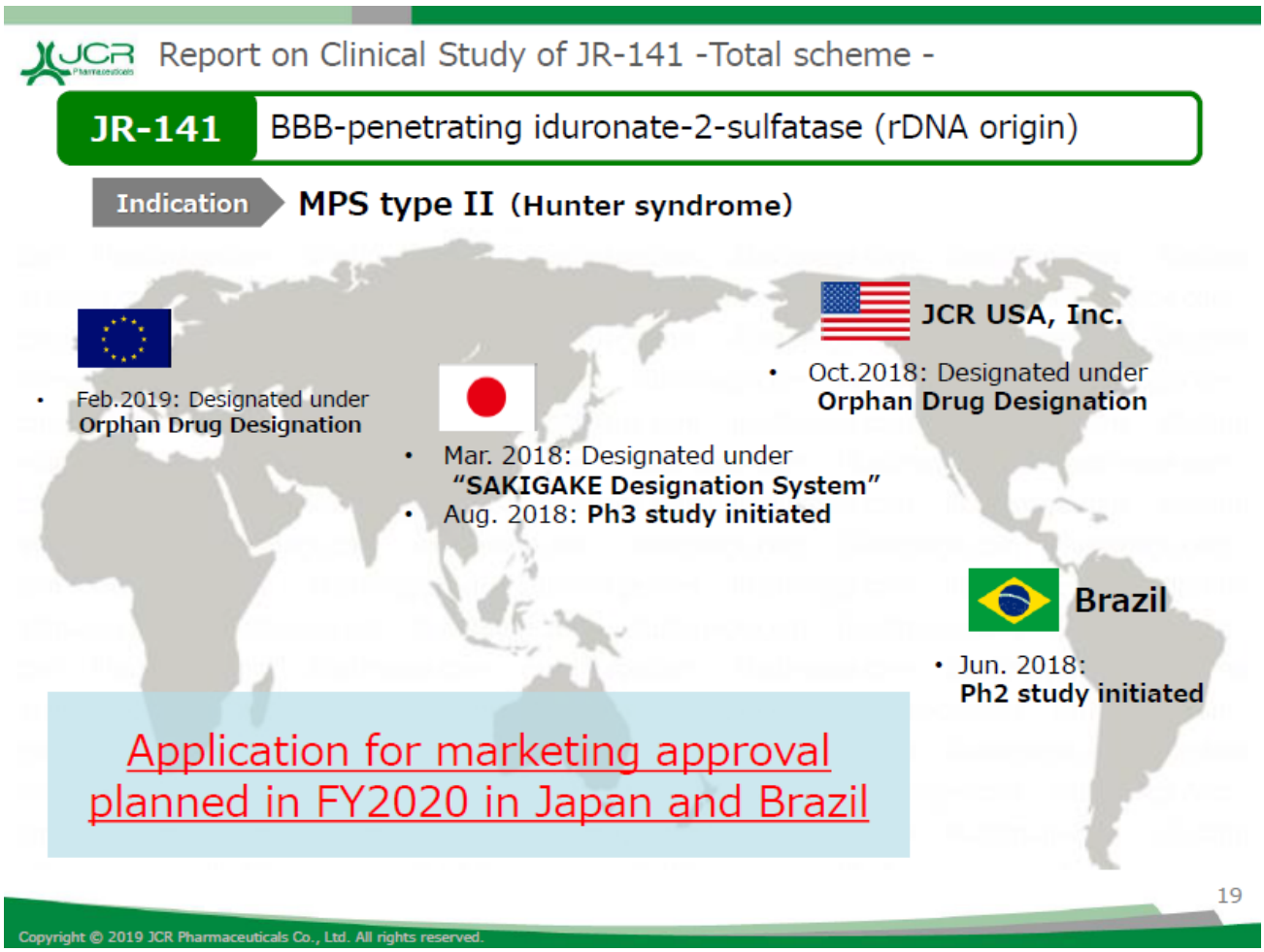
Another point of great importance is that a development test is being conducted in this study. Developmental testing is evaluated using the most commonly used development questionnaire, the new-edition K-type developmental test. By doing this, we can get the developmental age of the patients. From this data, the development age has been maintained or has improved, and we can consider this data in relation to the reduction in biomarker levels.

This is also described in the paper on the phase I/II study, but there have also been behavioral improvements, such as skipping or responding to one's surroundings. In this study, we conducted a survey by collecting the data from the investigators in the form of a questionnaire. Therefore, we are currently considering how to integrate this data as well.

In this case, intravenous administration is used, and the efficacy against systemic disease is extremely important. As shown here, for the most part, heparan sulfate and dermatan sulfate are very important points for the body in terms of changes in biomarkers. In the new patients, they have been declining, and in patients switched from other medications, they have been maintained, as of week 25. This is the result with the 2-milligram dose.

As for safety, there were no serious adverse events related to the investigational drug. Dosing-related reactions were expected because they the investigational product is an enzyme formulation. However, these reactions need not lead to treatment discontinuation, and doctors believe that it is possible to control them.

To summarize our results as of the 26th week, the drug has met our expectations in terms of efficacy against both CNS and systemic symptoms.



Future development has been subject to designation according to the Japanese "Sakigake" breakthrough medication system. Based on the current data, we are currently in the process of conducting discussions with the authorities for early application. Phase II trials are currently underway in Brazil, and as soon as the results are obtained, we will proceed with the application for marketing approval in Japan and Brazil as planned. In the US and Europe, in addition to designating orphan drugs, meetings with the FDA are underway, and we are currently planning future trials.

Progress of Other LSDs Pipeline

JR-171 BBB-penetrating α-L-iduronidase (rDNA origin)

Indication **MPS type I**
(Hurler syndrome, Hurler-Scheie syndrome, Scheie syndrome)

- Disease overview: A deficiency of **α-L-iduronidase**, causes an accumulation of Mucopolysaccharide, giving rise to multiple systemic and **CNS symptoms**.
- Patient population*: **60** (Japan), **3,600** (WW) est. *Internal analysis
- Market size*: **1.5 billion JPY** est. (2018 Japan) , **24 billion JPY** est. (2018 WW)

- Sep. 2019: Meeting with FDA
  about the design of Phase 1/2 study (JR-171-101)

▶ Phase 1/2 study is planned in 2020

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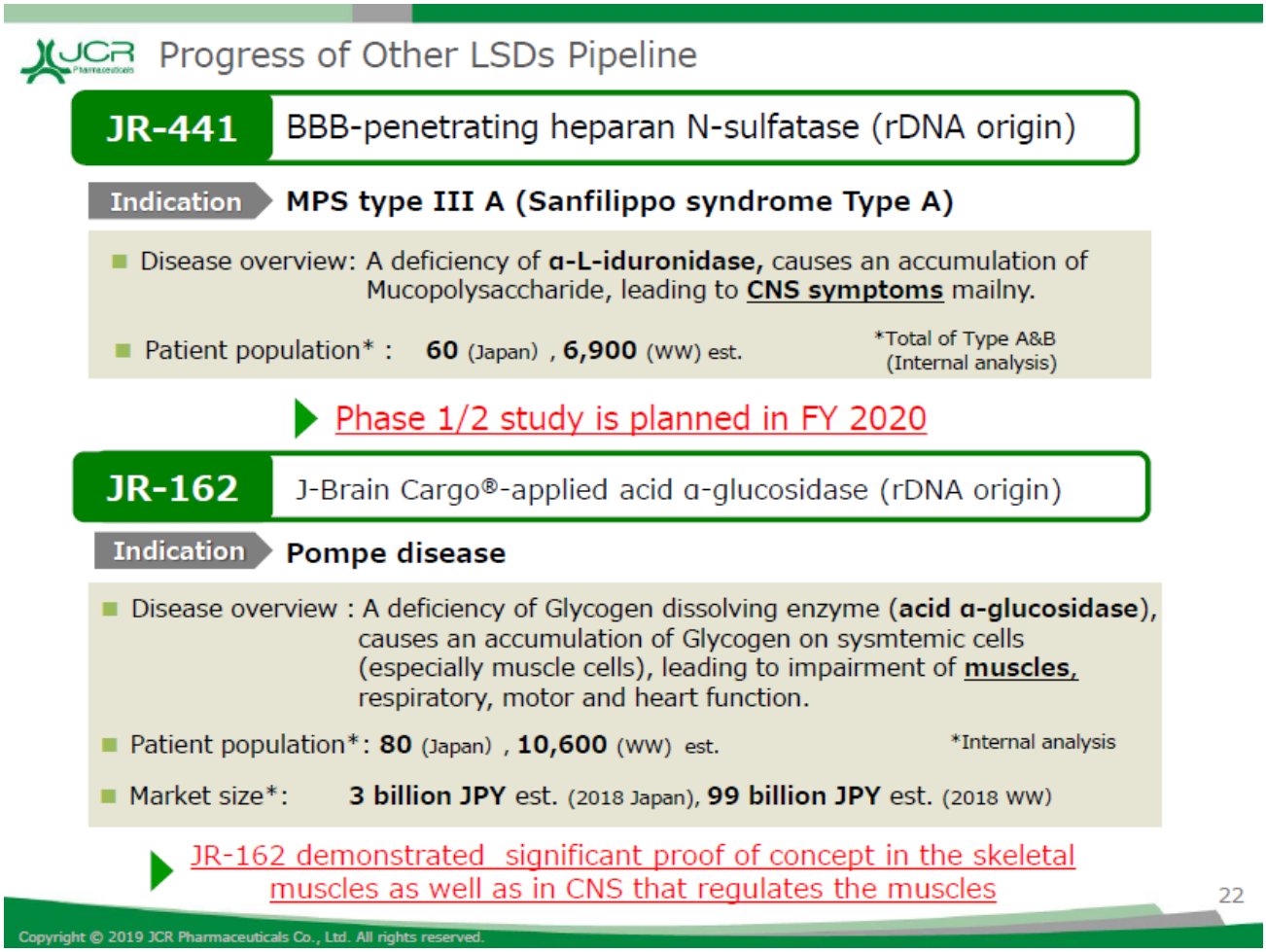
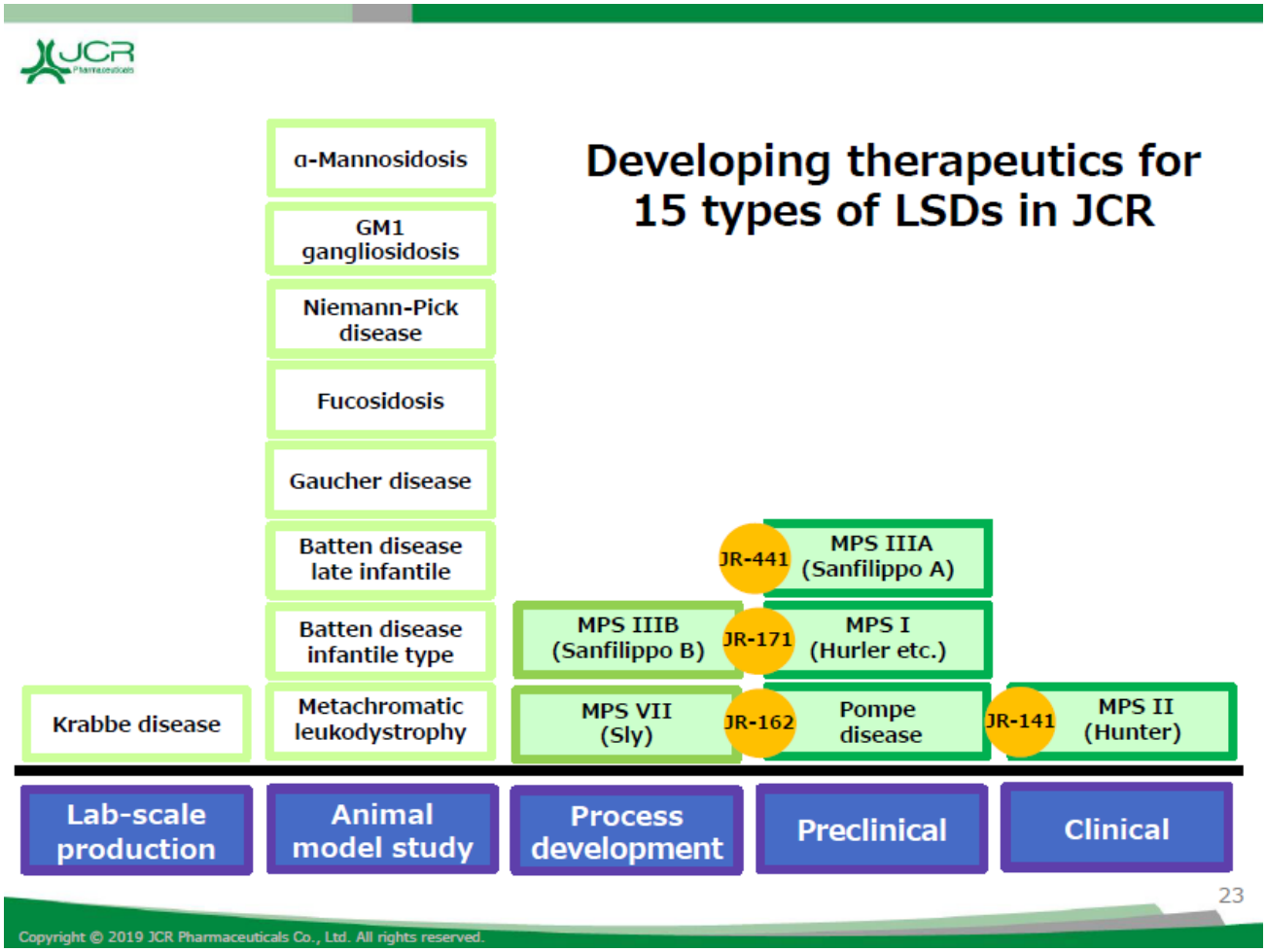
Next is JR-171. This is a treatment for Type I Mucopolysaccharidosis, a disease with very similar symptoms to Type II Mucopolysaccharidosis. Regarding this issue, we have held a meeting with the FDA. First of all, we plan to start phase I/II trials. We have received some specific advice from the FDA. Currently, we are working to reflect this content in the protocol, so we are making steady progress in preparations for the start of clinical trials in 2020.



JR-441 is the proposed treatment for Sanfilippo syndrome, or Mucopolysaccharidosis Type IIIA. No treatment is currently available. This is why very new treatments are required. In this regard, we are preparing for an early start of clinical trials after 171.

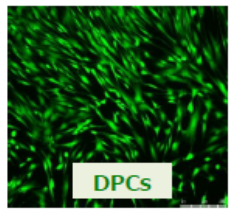
JR-162 is a proposed treatment for Pompe disease that uses J-Brain Cargo. We recognize that it is a very unique drug that can be effectively distributed throughout the body, as well as throughout the central nervous system. In order to maximize this unique profile, we are currently proceeding with development plans and are in discussions with professors in Japan and overseas.



Next, lysosomal disease. This is a list of items that are using the J-Brain Cargo system. As I mentioned earlier, we have obtained very important data with respect to JR-141, and we have received a lot of advice from the authorities regarding biomarkers and endpoints. While utilizing this know-how, we would like to proceed with the plan for mucopolysaccharidoses as soon as possible. I believe that the results of the current plan will support the accelerated development of other compounds.

Progress of Other R&D Pipeline

JTR-161/JR-161 Human dental pulpstem cells (DPCs)



Indication **Acute cerebral infarction**

- Cause : hypertension, diabetes mellitus, smoking, obesity, and dyslipidemia
- Prevalence* (Japan): **300,000** est. per year. *Internal analysis
- Treatment : "thrombolytic therapy" and "endovascular treatment" are performed within several hours of onset, followed by "brain protection therapy", "antiplatelet therapy", and "anticoagulation therapy" are performed

TEIJIN **Jul. 2017 : Co-development and license agreement with Teijin Limited** Indication : Acute cerebral infarction

▶ Jan. 2019 : Administration started for patients in Phase1/2

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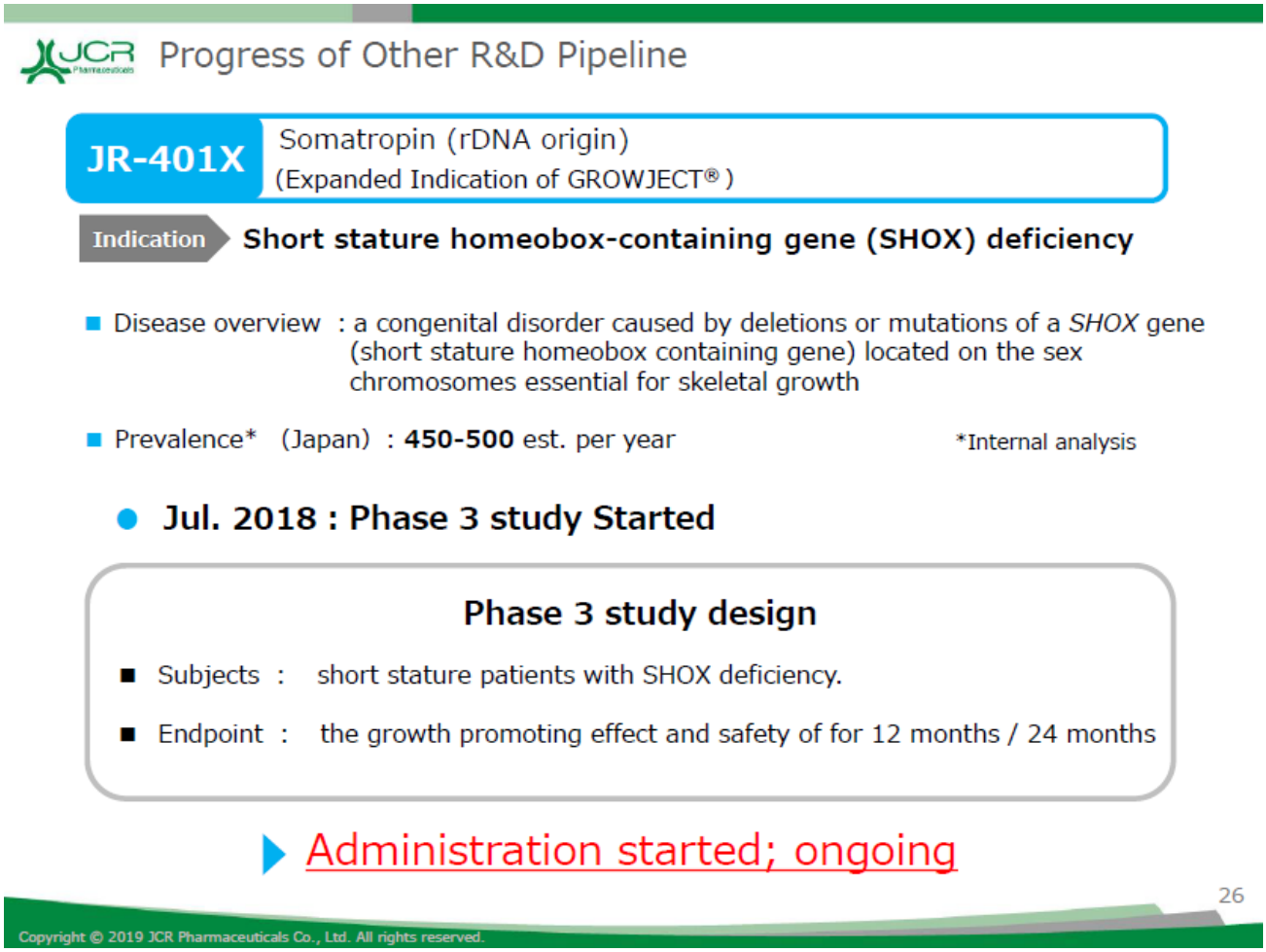
Finally, this is the R&D pipeline for other biopharmaceuticals. As explained, we have already begun a joint study into dental pulp-derived stem cells with Teijin Pharma Limited. We are at the stage of monitoring the progress of the trial.



Regarding new indications for GROWJECT, we are conducting development in various areas. A trial to assess the use of GROWJECT in treating SHOX-deficiency disorders has been progressing for over a year. Administration to subjects has started, and the trial is progressing smoothly. We are continuing to recruit patients for this study.

So far, I have explained about five compounds in total. Looking ahead, we will continue to steadily develop world-first new drugs in line with our three development pillars, using technologies such as genetically modified cell therapy and genetic therapy.

This is the end of my presentation. Thanks.

Moderator: Lastly, Mr. Ashida will give a speech.

Shin Ashida: Thank you very much for your time today.

We have heard from Mr. Haguchi and Mr. Tanizawa. We are focusing on biopharmaceuticals and cell-based pharmaceuticals. As Mr. Tanizawa said, the results for 141 were extremely favorable, and I believe that in the future we can be very confident in moving forward with treatments for other lysosomal diseases.

Year-on-year, first-half R&D expenditures have increased by 1.4 billion yen. This increase reflects the fact that we have invested heavily in R&D in order to maximize profits in the future, and is part of our process of globalizing. That is the background behind this increase.

Going forward, as our products emerge on the global stage, we know that it is impossible to sell on our own. However, we have been making various efforts to maximize our profits, and I am confident that the time will come when we will be reporting these profits to you all. We would like to ask for your continued support.