Gene Techno Science Co.,Ltd.

4584 TSE Mothers

8-Feb.-16

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FISCO Ltd. Analyst
Yuzuru Sato

To be the world's leading biosimilar company

Gene Techno Science <4584> (hereafter, also "the Company") is a drug discovery venture company originating from Hokkaido University specialized in biologics and biosimilars. In the field of biosimilars, it was the first company in Japan to launch filgrastim biosilimar, under the Japanese biosimilar guidelines. The potential market value of the Company`s main development pipeline candidates are considered to be worth ¥90 billion domestically and ¥1.2 trillion globally. Net sales is expected to expand up to ¥20 billion in 10 years' time if the candidates in the pipeline were steadily commercialized, and the Company is aiming to become "the world's leading biosimilar company".

The ratio of biologics in the pharmaceutical market rose from 18% to 23% from 2010 to 2014, and it is anticipated to continue expanding. The patents of the main biologics are set to expire by 2020, by when the biosimilar market is expected to rapidly expand. Biosimilar products are expected to reduce the expense of biologics, which is the major factor behind the expanding medical expenditures. Following Japan and Europe, the United States also approved the manufacture and sale of biosimilars in 2015, and there is little room for doubt that it is a growing market worldwide.

The Company has been attracting attention for its track record of launching biosimilars and its expertise in this field, from development to commercial production. In 2015, it announced that it had entered into basic agreements for joint development and sales with Mochida Pharmaceutical Co., Ltd. <4534> in the anti-cancer field in August, and with Senju Pharmaceutical Co., Ltd., in the ophthalmology field in November.

The forecasts for FY3/16 are for net sales to increase approximately 4 times year-on-year (y-o-y) to ¥1,132mn and for an operating loss of ¥1,045mn (compared to a loss of ¥824mn in the previous fiscal year). In addition to net sales of the filgrastim biosimilar increasing by more than 3 times, the lump-sum payments received upon entering into basic agreements will contribute ¥50mn. Due to the acceleration in developments with the said collaborations, R&D costs will increase ¥500mn, which is the main reason of slightly higher expected operating loss.

There are many candidates in the Company's biosimilar development pipeline that will enter the clinical trials from 2016 and beyond, and the earliest target for the market launch is 2019 onwards. For the time being, the situation will continue where the development costs are covered mainly by earnings from the filgrastim biosimilar, milestone payments in the pipeline with joint development and from new agreement-related payments. However, considerable growth is expected from 2020 onwards and we will be paying close attention to the progress that the Company makes in its developments, as well as movements toward concluding new agreements with joint-development partner companies.

Check Point

- Currently developing 11 biosimilar products and the potential global market for just the main 6 products is ¥1.2 trillion
- The filgrastim biosimilar is contributing to the major increase in sales, while the extent of the loss is also shrinking
- Aiming to grow the biosimilar business to a scale of ¥10bn by around 2021

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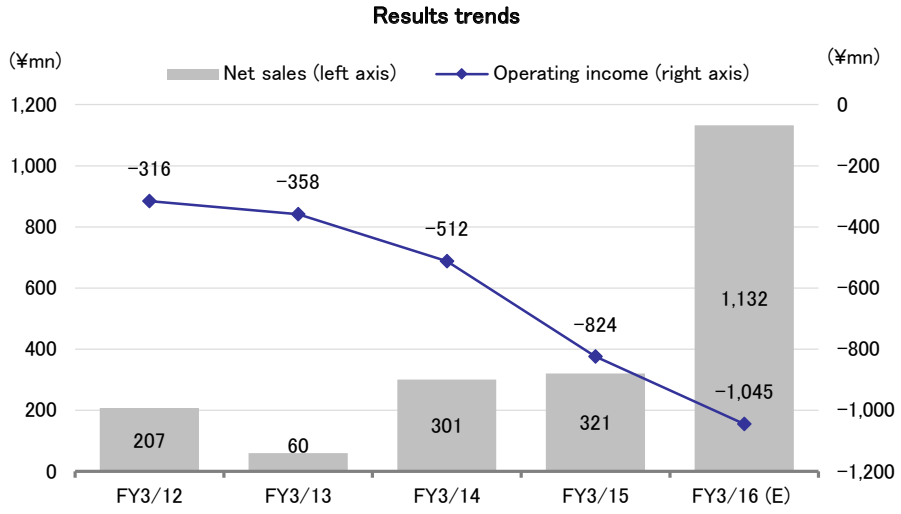

■ Company outline and the biologics market

A bio-venture company originating from Hokkaido University that is strengthening its development of biosimilars

(1) Company history

The Company is a bio-venture company that was established within Hokkaido University in 2001 with the objective of developing diagnostic and therapeutic agents based on the research of the University's Division of Molecular Interaction, Institute for Genetic Medicine. In terms of research and development of new biologics, in 2007 it licensed-out to Kaken Pharmaceutical Co., Ltd. <4521> anti-integrin alpha 9 antibodies. In addition, in order to build a stable earnings foundation, it began developing biosimilars, which are the follow-on products of innovator drugs. In 2007 it entered into a joint-development agreement with Fuji Pharma Co., Ltd. <4554> for a filgrastim biosimilar *, and in 2012 it was the first company to obtain approval for manufacturing and sales under the domestic biosimilar guidelines for biosimilars. This product has been marketed by Fuji Pharma and Mochida Pharmaceutical since 2013.

Whilest strengthening its biosimilar development pipeline, the Company has been actively forming collaborations with other companies for joint development. It entered into joint-development agreements with ITOCHU CHEMICAL FRONTIER Corporation in 2013 and with Sanwa Kagaku Kenkyusho Co., Ltd., in 2014, and most recently, it concluded basic agreements for joint development and sales with Mochida Pharmaceutical in the anti-cancer field in August 2015, and with Senju Pharmaceutical in the ophthalmology field in November of the same year. At the same time as entering-into the basic agreement, Senju Pharmaceutical acquired 5.26% (as of November 12, 2015) of the Company's shares from its largest shareholder, Whiz Healthcare PE1 Limited Partnership (a healthcare sector specialized investment fund), making it the second largest shareholder.

The Company has started initiatives for the healthcare-related field. In 2014, It entered into a capital and business partnership with venture company ORTHOREBIRTH Co., Ltd., which is conducting research and development on synthetic bones, and in 2015, DyDo Drinco, Inc. <2590> acquired 3.79% of the Company's shares (as of November 12, 2015), and the companies are working to collaborate in the healthcare field.

* filgrastim: a granulocyte growth factor drug product (G-CSF). Following chemotherapy (dosages of anti-cancer agents), white blood cells decrease and immunity is weakened, which can cause various symptoms. Filgrastim is a drug product which helps the cell growth of the white blood cells.

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Company history

Date	Main events in the Company's history
March 2001	Established in Sapporo City with the objective of developing diagnostic and therapeutic agents based on the research in the Division of Molecular Interaction, Institute for Genetic Medicine, Hokkaido University.
June 2002	As a venture company certified by the National Institute of Advanced Industrial Science and Technology (AIST), it newly established research facilities within the Hokkaido Center of AIST and reinforced its research and development into new biologics.
June 2007	Licensed-out the anti-integrin alpha 9 antibody to Kaken Pharmaceutical Co., Ltd.
October 2007	Entered into a joint-development agreement with Fuji Pharma Co., Ltd. for a filgrastim (G-CSF) biosimilar
January 2008	Licensed-in filgrastim biosimilar cell line and basic production technology from Dong-A Pharmaceutical Co., Ltd.
November 2012	Fuji Pharma Co., Ltd. and Mochida Pharmaceutical Co., Ltd. domestically acquired manufacturing and sales approval for the filgrastim biosimilar (launch in May 2013)
November 2012	Listed on the Tokyo Stock Exchange (TSE) Mothers (market of the high-growth and emerging stocks)
August 2013	In the biosimilar business, entered into a capital and business partnership with ITOCU CHEMIAL FRONTIER Corporation.
September 2013	Research facilities were moved to the Center for Promotion of Platform for Research on Biofunctional Molecules, The Creative Research Institute, Hokkaido University
January 2014	Entered into a joint-development agreement with Sanwa Kagaku Kenkyusho Co., Ltd., for a darbepoetin α biosimilar
June 2014	Entered into a nucleic-acids joint business agreement with Gene Design Inc. with the objective of commercializing a nucleic-acid pharmaceuticals development platform
November 2014	Entered into a capital and business partnership with ORTHOREBIRTH Co., Ltd., which is conducting research and development on synthetic bones
July 2015	Capital participation in the Company by DyDo Drinco, Inc. toward a collaboration in the medical and healthcare related business
August 2015	Entered into a basic agreement for a business-partnership agreement with Mochida Pharmaceutical Co., Ltd. toward the joint development and sales of a biosimilar in the anti-cancer field
November 2015	Entered into a basic agreement for capital and business partnership agreement with Senju Pharmaceutical Co., Ltd. toward the joint development and sales of a biosimilar in the ophthalmology field

Specializing in biologics manufactured by applying gene recombination technology and cell culture techniques

(2) Biologics and biosimilars

The biologics developed by the Company refers to pharmaceuticals manufactured utilizing the ability of microorganisms and cells to create specific proteins (hormones, enzymes, antibodies, etc.) useful for pharmaceuticals. Well-known biologics include insulin (a diabetes therapeutic agent) and interferon (a hepatitis C therapeutic agent). General pharmaceuticals (low molecular weight drugs) are mass-produced by chemosynthesis on a molecular level. But the manufacturing process of biologics is very different utilizing gene recombination technology and cell culture techniques to synthesize in a large scale volume of microorganisms and cells. One of the characteristics of biologics is that major costs must be undertaken for the development and the manufacturing facilities for mass production. Biologics also tend to have shorter expiry than that of general pharmaceuticals, leading to higher product price.

In the same way that general pharmaceuticals have innovator drugs that were developed first and then followed by generic pharmaceuticals that use the same molecules as of the innovator drugs, biosimilars are the follow-on products of biologics.

However, in case of biosimilars, the drug efficacy and safety do not change compared to the innovator drugs because the type of protein is the same as the innovator drugs, however, the sugar chain attached to the protein has slight difference, thus biosimilars are not identical to the innovator drugs. Therefore in order to pursue the similarity between innovator drugs and its biosimilars, it is necessary to establish an independent manufacturing process and accumulate physicochemical data to prove its similarity. It is also necessary to conduct clinical trials to prove the safety and the efficacy. Approvals are given based on these requirements, therefore the R&D costs of biosimilars are much higher than those of generic pharmaceuticals.

As the drug price of biosimilars are set at around 70% of the innovator drugs, high productivity in development and manufacturing process is important for commercialization of biosimilars. In particular, there are not many companies in Japan that possess the expertise necessary to establish the required manufacturing process, or to analyze the characteristics and the quality of developed biosimilars. The Company specializes in biologics/biosimilars and has accumulated track records in this field from conducting research and development for more than 10 years, and it has established a position as a leading expertise in the development of biologics/biosimilars field in Japan.

When new biologics and biosimilars are compared, it takes around 15 to 17 years from the start of the research to launch of the new biologics, where it takes from 4 to 7 years to develop and launch biosimilars. In case of a new biologics, it takes two to three years to search for genes (functional analysis), and further two to four years to screen the candidate compounds. After that, a long period of time is required from the non-clinical trials through to the clinical trials. The R&D costs for a new biologics will therefore be in the range of ¥20bn to ¥30bn. In contrast, the cost for biosimilars will be from ¥2.5bn to ¥6bn, and has higher probability to succeed at each stage from development to market launch compared to new biologics. The Company is utilizing its expertise to develop its business with the focus placed on the biosimilar business, while also developing new biologics.

Characteristics of biologics

- Biologics refers to pharmaceuticals manufactured through the application of gene recombination technology and cell culture techniques, utilizing the ability of microorganisms and cells to create specific proteins (hormones, enzymes, antibodies, etc.) in a large scale volume.
- Main biologics include insulin (a diabetes therapeutic agent), interferon (a hepatitis C therapeutic agent), and rituximab (an anti-cancer agent, etc.)

	Biologics	General pharmaceuticals
Size (molecular weight)	Approx. 10,000	100~
Manufacturing method	Synthesized within microorganisms and cells	Chemosynthesis
Production	Unstable (the product can change depending on the conditions of the microorganisms and cells)	Stable

Biosimilars

- Biosimilars are approved pharmaceuticals that have demonstrated the equivalent efficacy and safety compared to previously approved biologics.

Differences between biosimilars and other generic pharmaceuticals

	Biosimilars	Other generic pharmaceuticals
Molecular structure	Enormous and complex	Small and simple
Efficacy and safety	Practically the same as the innovator drugs (the amino acid sequence is the same, but the molecular structure and manufacturing process are different)	Same as the innovator drug (the molecular sequence and structure are the same)
Costs of development and manufacturing facilities	High (¥20bn to ¥30bn) * Innovator drug, ¥100bn	Low (around ¥100mn) * innovator drug, ¥30bn to ¥100bn
Price difference with innovator drugs	70% of the innovator drug price * For medicines for internal use, 60% when more than 10 biosimilar products of a certain innovator drug are launched.	60% of the innovator drug price * For medicines for internal use, 50% when more than 10 genetic products of a certain innovator drug are launched.
No. of products listed in the standard prices for medicines (as of June 2014)	27 (5 components)	9,478

Source: extracted from “Current conditions of biosimilars” by the Ministry of Health, Labour and Welfare (July, 2014)

The global biologics market is expected to expand to $300 billion by 2020

(3) The environment of biologics market

The biologics market is continuing to expand year by year. In 2014, the global pharmaceutical market was worth approximately $800bn, where the biologics market was estimated to be worth around $180bn, or 23%, and it is expected to grow to be worth around $300bn by 2020.

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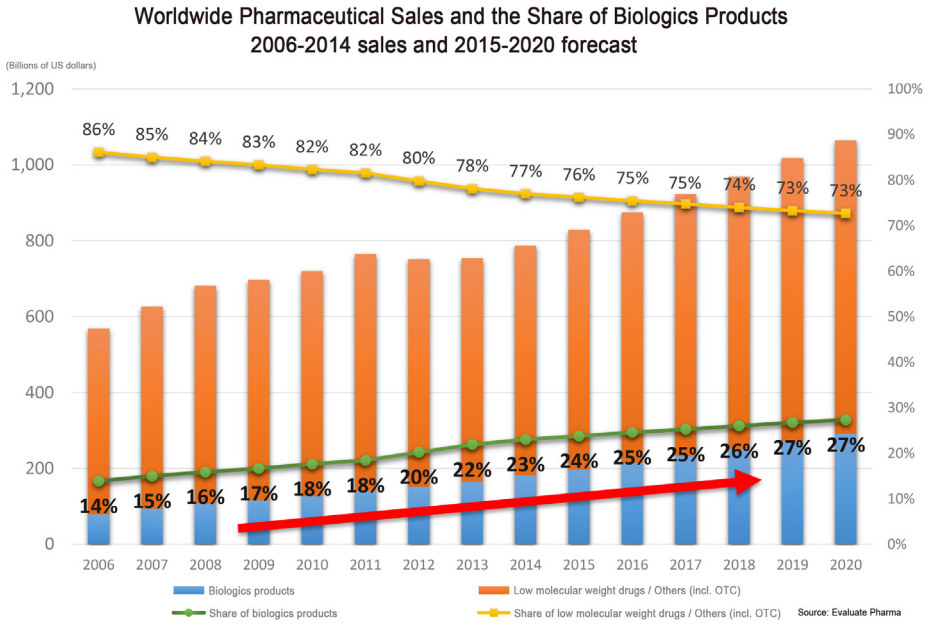
Growth of Global Pharmaceutical Sales



The biologic market is expanding year after year

Source: Company materials

High percentage of large-scale selling pharmaceuticals (so-called block busters) is a characteristic of this field, 7 products out of top 10 pharmaceutical sales ranking were biologics in 2014.

In this environment, the biosimilar market is also expected to rapidly expand in the future. Within the 10 biological products out of top 20 products in terms of sales, the patent of 8 biologics will expire by 2020.The scale of patent expired biologics market by 2020, is forecasted to reach US$62.2bn.

Sales of the top twenty products and the biologics market scale

	2008	2014	2020 (E)
Sales of the top twenty products ($bn)	111.0	131.5	135.0
Within which, the number of biologics (products)	7	10	12
Within which, biologics whose patents are expiring (products)	0	0	8
Within which, biologics net sales ($bn)	36.2	73.7	85.4
Within which, net sales of biologics whose patents are expiring ($bn)	0	0	62.2

Source: Company briefing materials

In the biosimilar market, a human growth hormone pharmaceutical was first launched in Europe (EU) in 2006, and currently sold in Europe and Japan. Finally in 2015, the United States published biosimilar guidelines and opened-up the biosimilar market. In March 2015, Sandoz Inc. was the first to receive manufacturing and sales approval for a filgrastim biosimilar in U.S, opening a door for the U.S. market, the world's largest market for pharmaceuticals. This event set 2015 as the Year One of the biosimilar market, and biosimilar market is expected to expand and enter a full-fledged growth stage. In countries other than Japan, the United States, and in Europe, it is likely that the approval may be obtained if the biosimilar product was already approved in at least one or two counties of either Japan, the United States, or Europe.

The increased use of biosimilars can be described as one key to keep the medical costs down. Due to their efficacy, demand for biologics is increasing year by year to the extent that biologics occupy nearly all of the top positions in the sales ranking. As their drug prices are expensive, they are pressuring the national healthcare expenditure. The drug prices of biosimilars are around 70% of the prices of innovator drugs, so the difference is smaller compared to the generic pharmaceuticals, which are around 60% of the price of their innovator drugs. But as the drug prices of biologics themselves are high, the effect of increased use of biosimilars will have significant effect in reducing medical cost. The reduction in medical costs not only decrease the financial burden on the individual patients, but also helps to alleviate the burden on national healthcare expenditure. In order to reduce government spending on healthcare, institutional reforms are hiking-up the use of generic pharmaceuticals, but so far biosimilars have not been the subject of these reforms. In March 2015, the Parliamentary Association for Promoting Biosimilars, which is a cross-party alliance of members of the Diet, was established and it is expected that there will be institutional reforms to promote the use of biosimilars, which will be very beneficial to the Company.

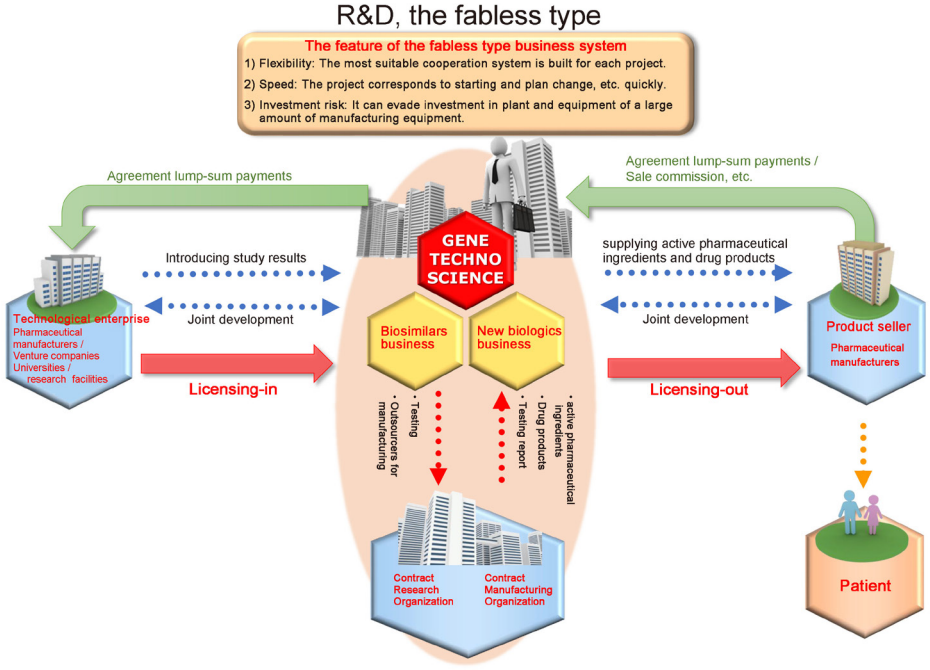
The Company's domestic biosimilar competitors include JCR Pharmaceuticals <4552> and Kyowa Kirin Fujifilm Biologics Co., Ltd., which is a subsidiary of Kyowa Hakko Kirin <4151>.

A hybrid business structure; stable business structure with a profit at early stage of development for biosimilars and high growth through new biologics business

(4) Business model

For its business model, the Company adopts a hybrid business structure consisting of the biosimilar business, which is highly stable and expected to become profitable at an early stage, and the new biologics business, aiming for high growth.

R&D system



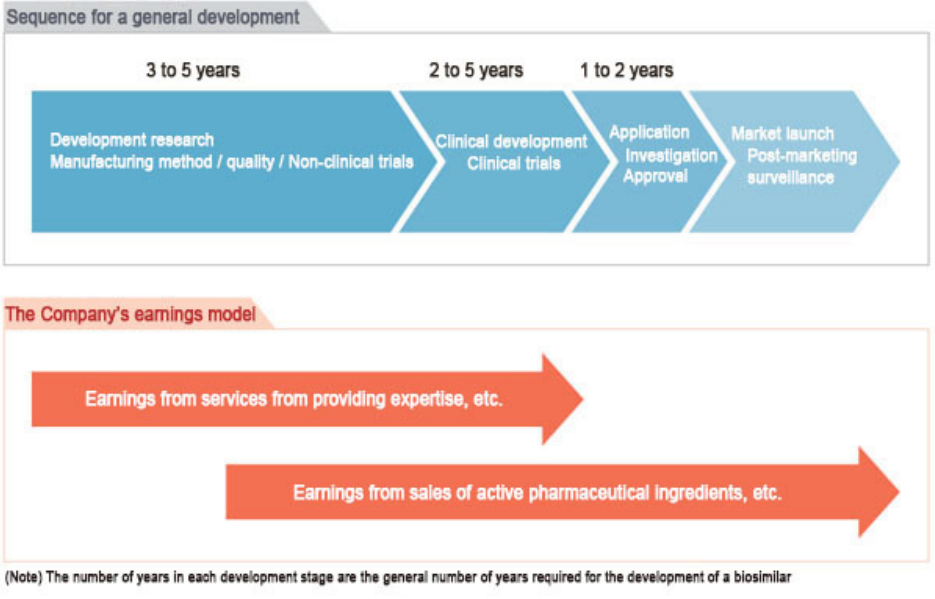
Source: Company materials

○The biosimilar business

The earnings model in the biosimilar business is comprised of sales earnings at the research-and-development stage and post-market-launch stage from supplying the active pharmaceutical ingredient that will be the main raw material for the drug product developed by the collaborating pharmaceutical company. Earnings are also from the development expertise and other such services it provides to the collaborating company after entering into the joint research and development agreement. The Company adopts a fabless system and outsources all of the tasks of manufacture, analysis, evaluation, and testing of the active pharmaceutical ingredient.

As an example, for the commercialized filgrastim biosimilar, the Company paid royalties to introduce the cell line from Dong-A Socio Holdings (formerly, Dong-A Pharmaceutical Co. Ltd.) of South Korea and sells the developed active pharmaceutical ingredient to its partner, Fuji Pharma. Fuji Pharma manufactures and sells the drug product, and also supplies the drug product to Mochida Pharmaceutical. The filgrastim biosimilar developed by the Company takes approximately 30% of filgrastim sales in Japan since the filgrastim biosimilar was launched in 2013, and this ratio is expected to rise even further. Filgrastim biosimilars are sold by a number of pharmaceutical manufacturers other than Fuji Pharma and Mochida Pharmaceutical, including Nippon Kayaku Co., Ltd. <4272>, Teva Pharma Japan Inc., and Sawai Pharmaceutical Co., Ltd. <4555>. Since Fuji Pharma and Mochida Pharmaceutical started the sales in advance, they together hold a considerable market share of filgrastim biosimilars.

Biosimilar development schedule and earnings model



(Note) The number of years in each development stage are the general number of years required for the development of a biosimilar

Source: Company materials

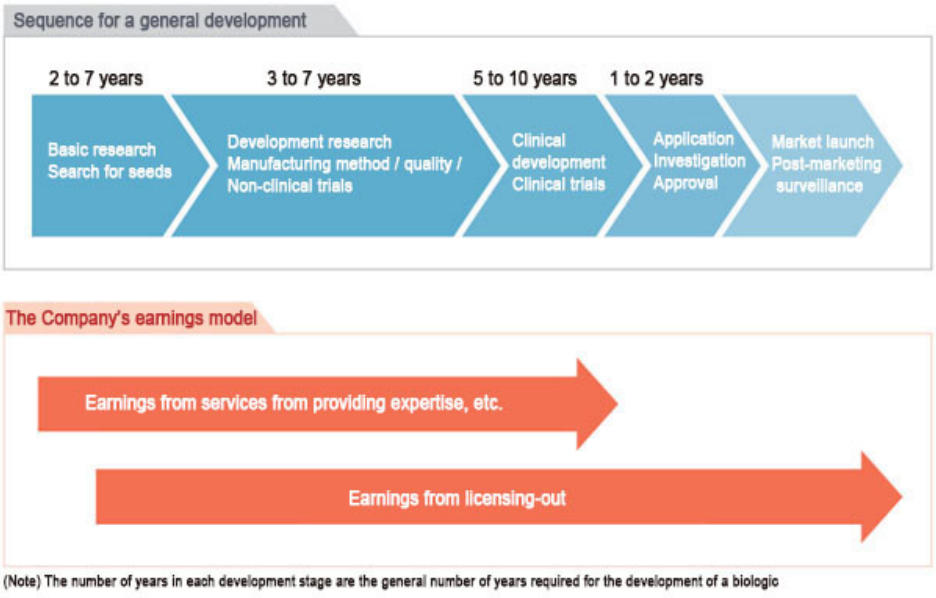
○**The new biologics business**

The Company implements its new biologics business from the basic research for drug discovery. It conducts research not only in-house, but also jointly with universities and other research facilities. Manufacturing, quality testing and non-clinical trials for drug-discovery of drug candidates are outsourced both domestically and overseas. As enormous costs will be subsequently incurred at the clinical trials stage, in principle its basic policy is to license-out to a pharmaceutical manufacturer at this stage.

For its earnings model, the Company enters into joint research and development agreements or license agreements and obtains earnings from agreement lump-sum payments, milestone payments according to the progress of the research and development, followed by royalties after launching the product.

In 2007 the Company provided the exclusive development, manufacture, and sales rights of an anti-integrin alpha 9 antibody to Kaken Pharmaceutical and as the compensation, it received an agreement for lump-sum payment, while it is also currently providing support and advice to advance its development. In terms of the other candidate drugs in the development pipeline, it is currently conducting basic research for a total of six candidates in fields such as cancer, immune disorders, and circulatory diseases.

New biologics development schedule and earnings model



(Note) The number of years in each development stage are the general number of years required for the development of a biologic

Source: Company materials

■ The biosimilar development pipeline

The Company is currently progressing the development of 11 biosimilar products, and the potential global market for just the main 6 products is ¥1.2 trillion

Currently, the Company has 11 biosimilar products that has been launched and marketed, or currently under development. The potential market for the main 6 products has been provisionally calculated to be ¥1.2 trillion globally and even ¥90bn for Japan alone (biologics market ×biosimilar penetration volume rate 60% ×70% of the innovator drug price). Among these six, the filgrastim biosimilar has already been launched in the domestic market. The Company also plans to launch filgrastim bosimilar overseas and currently is at the stage of searching business partners, and at the earliest, it is aiming for a market launch in around 2019.

Other candidates in the pipeline for which the Company has entered into a joint-development agreement or basic agreement are biosimilars in the fields of renal anemia, anti-cancer, and ophthalmology field for treatment of age-related macular degeneration and other indications. The Company entered into agreements for a biosimilar in the renal anemia field with Sanwa Kagaku Kenkyusho in January 2014, in the anti-cancer field with Mochida Pharmaceutical in August 2015, and in the ophthalmology field with Senju Pharmaceutical in November 2015, and these agreements are accelerating the development of each respective biosimilar. The most progress has been made for the development of the renal anemia biosimilar, which is a Nesp (darbepoetin alfa) biosimilar. Steady progress is being made for this product and it is expected to enter clinical trials soon.

Also, with regards to PEG-filgrastim that has superior longevity than filgrastim, which reduces the burden on the patient in terms of taking the drug and going to the hospital, the non-clinical trials have been completed and currently the stage is being shifted to establishing the production technology toward its commercial production. PEG-filgrastim is manufactured using filgrastim as the raw material, so it could be an advantage for companies that have already commercialized filgrastim biosimilar to enter this market. It is targeting market launches of 2019 overseas and 2023 domestically, and currently it is searching for companies to collaborate with both domestically and overseas.

The Company is jointly developing a biosimilar in the ophthalmology field with Senju Pharmaceutical. As the price of the innovator drugs for the treatment of age-related macular degeneration, the largest market in the ophthalmology field, is expensive, there is demand for an inexpensive biosimilar. The basic research has been completed and it is expected to enter clinical trials soon.

The Company is also currently developing a biosimilar of Humira (biologics for rheumatoid arthritis), which has the largest sales of all pharmaceuticals. Global sales of Humira is on the scale of ¥1.3 trillion, and the potential market for Humira biosimilar has been provisionally calculated as around ¥520bn. As the market scale is so large, many competitors are also developing Humira biosimilar, but it seems that the Company holds the key to this market with high levels of quality and productivity for its Humira biosimilar. It is currently progressing non-clinical trials and aiming to enter into agreements with pharmaceutical manufacturers domestically and overseas. It is considered at the earliest to enter phase 1 clinical trials in 2016 aiming for market launch in Japan in around 2020.

Main biosimilars in the pipeline

Pipeline biosimilar (common name)	innovator drug / product name	Potential scale of the biosimilar market		The estimated market launch period		Current development situation
		Japan	The world	Japan	The world	
GBS-001 (filgrastim)	Gran / Neupogen (biologics for neutropenia caused by chemotherapy)	¥8bn	¥40bn	Market launched	2019	Market launched domestically, searching for partner companies overseas.
GBS-010 (PEG-filgrastim)	G-Lasta / Neulasta (biologics for neutropenia caused by chemotherapy)	¥8bn	¥208bn	2023	2019	Non-clinical trials have been completed. Now at the stage of establishing production technology toward commercial production and searching for partner companies.
GBS-011 (darbepoetin alfa)	Nesp / Aranesp (biologics for renal anemia)	¥22.4bn	¥92bn	2020	-	Joint development with Sanwa Kagaku Kenkyusho.
GBS-005 (adalimumab)	Humira (biologics for rheumatoid arthritis)	¥14.4bn	¥520bn	2020	2021	Currently searching partner companies for joint development. Scheduled to start phase 1 clinical trials from 2016..
(ophthalmic biologics)	Ophthalmic biologics for age-related macular degeneration, etc.	¥25.2bn	¥307bn	-	-	Joint development with Senju Pharmaceutical.
GBS-008 (palivizumab)	Synagis (biologics for respiratory syncytial virus (RSV))	¥15bn	¥59bn	-	-	Non-clinical trials stage.
Total		¥93bn	¥1,226bn			
In terms of the other candidates in the pipeline, the Company is currently developing drugs on a number of themes, cancer, immune disorders, and circulatory disease.						

Note: the potential market scale is calculated as approximately 40% of the innovator drugs (innovator drugs net sales × biosimilar penetration volume rate 60% × 70% of the innovator drug price)
Source: prepared by FISCO from Company materials

■ Results trends

The filgrastim biosimilar is contributing to the major increase in sales, while the extent of the loss is also shrinking

(1) FY3/16 Q2 cumulative results

In the FY3/16 Q2 cumulative results, net sales increased 443.7% y-o-y to ¥791mn, while the operating loss was ¥116mn (compared to a loss of ¥396mn in the previous fiscal year). In the biosimilar business, sales of the filgrastim biosimilar trended strongly, while the lump-sum payment of ¥50mn upon entering into a basic agreement with Mochida Pharmaceutical also contributed. In the new biologics business, the Company is progressing research and development of a next generation antibody pharmaceutical, while it is also implementing initiatives toward the development of a nucleic-acid drug development platform with its business partner, Gene Design Inc. It is also focusing on acquiring new technologies, including Exosome for which it has jointly applied for a patent with the National Cancer Center. In July, it began a business collaboration in the healthcare-related field with DyDo Drinco following a capital participation by this company.

In terms of year-on-year profits, the extent of the loss was greatly reduced (improved ¥280mn) due to the increase in sales of the filgrastim biosimilar. The result has exceeded the initial target (improved ¥34mn).

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FY3/16 Q2 cumulative results

(unit: ¥mn)

	FY3/15 2Q cumulative		FY3/16 2Q cumulative				
	Result	% of sales	Initial target	Result	% of sales	y-o-y change	Change vs. target
Net sales	145	-	681	791	-	+646	+110
Gross profit	78	53.9%	-	458	57.9%	+380	-
SG&A expenses	474	325.9%	-	575	72.6%	+100	-
Operating income	-396	-272.1%	-150	-116	-14.7%	+280	+34
Ordinary income	-369	-253.9%	-136	-99	-12.6%	+270	+37
Net income	-370	-254.6%	-137	-100	-12.7%	+270	+37

¥1bn sales of filgrastim biosimilar forecast in FY3/16, and acceleration in market launches through increased spending on R&D.

(2) FY3/16 outlook

The outlook for the FY3/16 results is for net sales to increase 252.1% y-o-y to ¥1,132mn, on operating loss of ¥1,045mn (compared to a loss of ¥824mn in the previous fiscal year), an ordinary loss of ¥1,019mn (a loss of ¥790mn), and a net loss of ¥1,021mn (a loss of ¥792mn).

Net sales of the filgrastim biosimilar are expected to trend strongly and increase by more than three times y-o-y for a major increase in net sales. However, based on the agreement with Senju Pharmaceutical, R&D costs will also rise from ¥689mn in the previous fiscal year to ¥1,200mn in order to advance the development aggressively towards earlier market launch. As a result, the operating loss will increase.

The level of R&D costs is expected to hit the peak in this fiscal period. This is because majority of the non-clinical trials have been completed for the main drugs in the pipeline, and further development (i.e. the clinical trials) will be carried out by the business partners. On the other hand, the operating loss is forecasted to shrink in FY3/17 as the sales of the filgrastim biosimilar is expected to increase being introduced to more medical facilities.

FY3/16 results outlook

(unit: ¥mn)

	FY3/15		FY3/16				
	Result	% of net sales	Initial target	Revised target	% of net sales	y-o-y change	Change vs. initial target
Net sales	321	100.0%	1,022	1,132	100.0%	811	110
(R&D costs)	689	214.4%	700	1,200	106.0%	511	500
Operating income	-824	-256.2%	-602	-1,045	-92.3%	-221	-443
Ordinary income	-790	-245.7%	-573	-1,019	-90.0%	-229	-445
Net income	-792	-246.3%	-575	-1,021	-90.2%	-229	-445

Plans to raise funds through the execution of subscription rights to share and forming collaborations with capital tie-ups

(3) Financial position

Looking at the Company's financial position at the end of September 2015, total assets had increased ¥150mn y-o-y to ¥1,296mn. Income generated from the issue of stocks in conjunction with the execution of subscription rights to share was ¥190mn, which was the main reason why cash and deposits rose ¥158mn. Conversely, liabilities increased ¥58mn y-o-y to ¥934mn. Outstanding payments, consumption tax payable, and advances received each increased to ¥14mn, ¥23mn, and ¥20mn respectively. Net assets rose ¥91mn y-o-y to ¥362mn. Although a net loss of ¥100mn was recorded, capital and the capital reserve both increased ¥96mn due to the execution of subscription rights to share.

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4584 TSE Mothers

8-Feb.-16

In fixed liabilities, there are ¥775mn convertible corporate bonds with subscription rights to share issued under third party allocation. The entire amount is owned by the leading shareholder, Whiz Healthcare, and is scheduled for redemption in April 2018. If the business plan proceeds smoothly, the bonds are expected to be converted into stocks.

Balance sheet

(unit: ¥mn)

	FY3/13	FY3/14	FY3/15	FY3/16 2Q	Change
Current assets	919	1,881	1,092	1,237	144
(cash and deposits)	887	1,610	599	757	158
Fixed assets	3	4	54	59	5
Total assets	922	1,886	1,146	1,296	150
Current liabilities	24	50	92	150	58
Fixed liabilities	9	783	783	783	-
(convertible-type corporate bonds with subscription rights to share)	-	775	775	775	-
Total liabilities	34	833	876	934	58
Capital	1,239	1,571	1,576	1,673	96
Capital reserve	1,143	1,474	1,479	1,576	96
Retained earnings	-1,495	-2,014	-2,806	-2,907	-100
Total net assets	888	1,052	270	362	91
Management indicators (financial strength)					
Equity ratio	96.3%	54.7%	21.7%	26.4%	
Interest-bearing debt ratio	-	-	-	-	

■ Medium- to long-term vision

Aiming to grow the biosimilar business to the scale of ¥10bn by around 2021

The Company is aiming to supplement and accelerate development in the biosimilar business through swift collaboration with pharmaceutical manufacturers. Its strategy is also to develop its business globally (through collaborations with pharmaceutical manufacturers in the United States and Europe and opening-up markets in newly emerging countries).

In the new biologics business, in addition to advancing in-house research and development and improving added-value, its policy is to build alliances at an early stage with pharmaceutical manufacturers. To strengthen its technological foundations, it is jointly developing a technological foundations for a next generation antibody pharmaceutical with Hokkaido University. As a supplementary business, it is implementing various initiatives including national projects, such as developing the technological foundations for the discovery of next generation drugs for personalized medicine, and the trial production of antibody drug cell line and active pharmaceutical ingredients.

The Company's medium- to long-term target is considered to grow net sales to a scale of ¥10bn by around 2021 by using the filgrastim biosimilar as a stable source of earnings. From 2019 onwards, it is aiming for net sales of around ¥20bn in the next decade with biosimilar alone by steadily launching biosimilars for PEG-filgrastim, Humira, Nesp, and in the ophthalmology field. If the biologics and healthcare related businesses contribute to earnings, it is expected to accelerate the growth to an even greater extent.

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Medium- to long-term sales vision

Sales of biosimilar pharmaceutical preparations and active pharmaceutical ingredients, and lump-sum and milestone payments for new biologics

Source: Company materials

Looking at the development pipeline, if steady progress is made it could become profitable in around 2018-2019.

As previously explained, the biosimilar market is expected to rapidly expand due to the world largest biosimilar market opening in the United States in 2015, and the expiry of number of large-scale biologics patents by 2020. Consequentially, next two to three years will be of the utmost importance for the Company making it a turning point to decide whether it can realize its goal of becoming “the world’s leading biosimilar company.”

The candidates in the pipeline for which the joint-development partners have already been decided are a Nesp biosimilar (Sanwa Kagaku Kenkyusho), a biosimilar in the anti-cancer field (Mochida Pharmaceutical), and a biosimilar in the ophthalmology field (Senju Pharmaceutical), and we will be paying attention on the progress in the clinical trials of these biosimilars, which are planned to start from 2016 onwards. For the PEG-filgrastim and Humira biosimilars, which partners are yet to be decided, the points to focus on would be the collaborating partners for joint development, both domestically and overseas, and when and in what form these joint developments will take place.

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Income statement

(units: ¥mn, %)

	FY3/13	FY3/14	FY3/15	FY3/16
Net sales	60	301	321	1,132
(y-o-y)	-70.8	397.8	6.7	252.1
Cost of sales	15	141	147	
(% of sales)	24.9	47.1	45.9	
SG&A expenses	403	671	998	
(% of sales)	666.6	222.9	310.3	
Operating income	-358	-512	-824	-1,045
(y-o-y)	-	-	-	-
Ordinary income	-373	-516	-790	-1,019
(y-o-y)	-	-	-	-
(% of sales)	-617.3	-171.5	-245.7	-90.0
Pretax profit	-373	-516	-790	
(y-o-y)	-	-	-	
Income taxes	3	2	1	
(effective tax rate)	-0.9	-0.5	-0.2	
Net income	-377	-519	-792	-1,021
(y-o-y)	-	-	-	-
(% of sales)	-622.9	-172.3	-246.3	-90.2
(main indicators)				
Average number of shares during the fiscal period (thousands)	2,081	2,384	2,394	2,501
Earnings per share (¥)	-238.20	-240.15	-331.86	-404.73
Dividend per share (¥)	-	-	-	-
Book value per share (¥)	426.70	441.61	104.14	-
No. of employees	8	13	14	-

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