Gene Techno Science Co.,Ltd.

4584 TSE Mothers

8-Sept.-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 bioventure originating from Hokkaido University specialized in biologics and biosimilars. In the field of biosimilars, it was the first company in Japan to launch a filgrastim biosimilar of all the biosimilars launched in accordance with the Japanese biosimilar guidelines. The potential market values of the Company’s main development pipeline are considered to be ¥90 billion domestically and ¥1.2 trillion globally. Net sales is expected to expand up to several billions of yen in 10 years’ time if the candidates in the pipeline are steadily commercialized, and the Company is aiming to become “the world’s leading biosimilar company.”

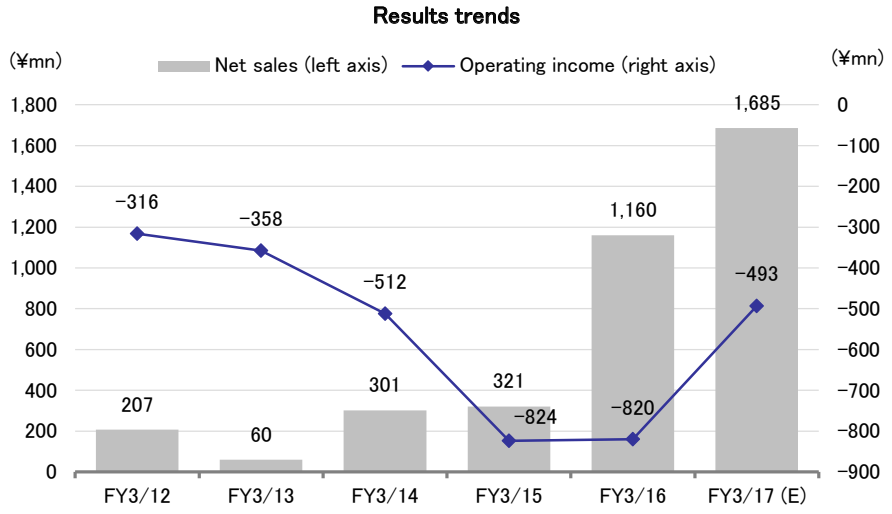
In FY3/16, in addition to the steady increase in the net sales of the filgrastim biosimilar, which increased by 3 times year-on-year (y-o-y), the Company also made steady progress in business partnerships for the development of biosimilars, announcing the basic agreements for joint development and sales with Mochida Pharmaceutical Co., Ltd. <4534> in the oncology field in August 2015, and with Senju Pharmaceutical Co., Ltd., in the ophthalmology field in November 2015. Also, in March 2016, the Company concluded a capital and business partnership agreement with Noritsu Koki Co., Ltd. <7744> to develop the biologics business, and implemented a ¥2bn capital increase through a third-party allocation in April. As the core company in the Noritsu Koki Group, the Company is likely to continue to develop and grow the biologics business, whilst also expanding into areas such as regenerative medicine.

In the FY3/16 results, net sales rose 260.9% y-o-y to ¥1,160mn and the operating loss was ¥820mn (compared to a loss of ¥824mn in the previous fiscal year). While gross profit rose from the increase in sales of the filgrastim biosimilar, higher R&D expenses meant that the operating loss was around the same level as the previous fiscal year. The forecasts for FY3/17 are for net sales to increase 45.1% to ¥1,685mn and an operating loss of ¥493mn. The double-digit growth in net sales is expected from the higher sales of the filgrastim biosimilar and also from the upfront payments and milestone payments from the joint development agreements for development pipelines. Despite the R&D expenses set to increase from ¥1,075mn to ¥1,283mn, the operating loss is still expected to shrink from ¥820mn to ¥493mn due to the effects of the higher sales.

In May 2016, the Company announced the business partnership agreement with Changchun Changsheng Life Sciences Ltd. (hereafter, Changsheng Life Sciences) of China toward the commercialization of biosimilars in China. Changsheng Life Sciences is among the top five vaccine pharmaceutical companies in China, with annual sales in the region of ¥20bn. Guidelines for biosimilars have also been established in China and a full-scale market expansion is expected, so we will be paying attention to the positive contribution that this partnership makes to the Company’s results in the medium-to-long term.

Check Point

- Specializes in biologics and has a track record of R&D over more than 10 years and launched biosimilars in the market
- Is actively conducting M&As with promising bio-related companies
- Is seeking for alliance with US or EU pharmaceutical companies and opening-up markets in newly emerging countries



■ Company outline and the biologics market

Actively pursuing business partnerships to strengthen the development pipeline

(1) Company history

The Company is a bioventure 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 in the Institute for Genetic Medicine. In terms of research and development of new biologics, anti-integrin alpha 9 antibody was licensed-out to Kaken Pharmaceutical Co., Ltd. <4521> in June 2007, and currently continues to advance the R&D activities. The Company began developing biosimilars in order to build a stable earnings foundation. In 2007, it entered into a joint-development agreement with Fuji Pharma Co., Ltd. <4554> for a filgrastim* biosimilar, and in November 2012, it was the first company to obtain approval for manufacturing and sales for the first biosimilar under Japan's biosimilar guidelines. This product has been marketed by Fuji Pharma and Mochida Pharmaceutical since May 2013.

Whilst strengthening its biosimilar development pipeline, the Company has been actively forming collaborations with other companies for joint developments. It entered into a capital and business partnership agreement with ITOCHU CHEMICAL FRONTIER Corporation in August 2013 and a joint-development agreement with Sanwa Kagaku Kenkyusho Co., Ltd., in January 2014. It concluded basic agreements for joint development and sales with Mochida Pharmaceutical in the oncology 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 business partnership with Senju Pharmaceutical, 138,000 of Company's share were acquired (3.08%, as of May 2016), and then, the companies concluded a joint commercialization agreement toward acquiring manufacturing and sales approval for biosimilars in the domestic ophthalmology field in May 2016.

Other than the above, the Company has started initiatives for the healthcare-related field. In November 2014, it entered into a capital and business partnership with bioventure, ORTHOREBIRTH Co., Ltd., which is conducting research and development on synthetic bones, and, started collaborating with DyDo Drinco, Inc. <2590> in the healthcare field in July 2015.

* Filgrastim: a granulocyte growth factor drug product (G-CSF). Following chemotherapy (dosages of anti-cancer agents), white blood cells decrease and immunity is weakened (called neutropenia), causing various symptoms, and filgrastim is used to treat this. The innovator drug is Gran by Kyowa Hakko Kirin Co., Ltd. <4151>.

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Company history

Date	Main events in the Company's history
March 2001	Established in Sapporo with the objective of developing diagnostic and therapeutic agents based on the research of the Division of Molecular Interaction, Institute for Genetic Medicine, Hokkaido University
June 2002	As a bioventure 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 a 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	Moved its research facility 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
June 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 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 a capital and business partnership with Senju Pharmaceutical Co., Ltd. toward the joint development and sales of a biosimilar in the ophthalmology field
March 2016	Entered into a capital and business partnership agreement with Noritsu Koki Co., Ltd.
May 2016	Entered into a basic agreement for the commercialization of biosimilars in China with Changsheng Life Sciences
May 2016	Entered into a joint-commercialization agreement with Senju Pharmaceutical Co. Ltd. toward the development and sale of biosimilars in Japan in the ophthalmology field

Specializes in biologics and has an R&D track record of more than 10 years

(2) Biologics and biosimilars

The biologics developed by the Company means pharmaceuticals manufactured utilizing the ability of microorganisms or cells to create specific proteins (hormones, enzymes, antibodies, etc.) that are useful for pharmaceuticals. As it involves creating pharmaceuticals using the proteins that are originally present in the human body, biologics are kinder to the human body, and antibody pharmaceuticals, one type of biologics, have a lower risk of side effects as they act directly on the diseased or affected area. Well-known biologics include insulin (a diabetes therapeutic agent) and interferon (a hepatitis C therapeutic agent).

General pharmaceuticals (small molecule drugs) are mass-produced by chemosynthesis on a molecular level. But the manufacturing process of biologics is very different, as it utilizes gene recombination technology and cell culture techniques to synthesize microorganisms and cells in large volume. In the case of biologics, major costs must be undertaken for their development and the manufacturing facilities for their mass production. Biologics also tend to have shorter expiry than small molecule drugs, leading to higher product prices.

In the same way general pharmaceuticals have innovator drugs, which are the drugs that were developed first and then followed by generic pharmaceuticals that use the same molecules as these innovator drugs, biosimilars are the follow-on products of biologics. In case of biosimilars, the drug efficacy and safety do not change compared to the innovator drug because the type of protein is the same as that in the innovator drug. However, the sugar chain attached to the protein is slightly different, so biosimilars are not identical to the innovator drugs. In order to demonstrate the similarity between the innovator drugs and the biosimilars, it is necessary to establish an independent manufacturing process and to accumulate physicochemical data to prove the similarity. It is also necessary to conduct clinical trials to prove the safety and efficacy. Approvals are given based on these requirements, and therefore the R&D costs of biosimilars are much higher than those of generic pharmaceuticals.

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As the drug prices of biosimilars are set at around 70% of the prices of the innovator drugs, high productivity in the development and manufacturing process are important for the 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 levels of the developed biosimilars. The Company specializes in biologics and biosimilars and has accumulated a track record in this field from conducting research and development for more than 10 years, establishing its position as the leading expert for the development of biologics and biosimilars in Japan.

When comparing new biologics and biosimilars, we see that it takes around 15 to 17 years from the start of the research to the launch of a new biologics, where as it takes from 4 to 7 years to develop and launch a biosimilar. In case of a new biologics, it takes 2 to 3 years to search for genes (functional analysis) and a further 2 to 4 years to screen the candidate compounds. After that, a long period of time is required from the start of the non-clinical trials through to the completion of the clinical trials. The R&D costs for new biologics will therefore be in the range of ¥20bn to ¥30bn. In contrast, the cost for a biosimilar will be from ¥2.5bn to ¥6bn, and it also has a higher probability of success 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 means pharmaceuticals manufactured through the application of gene recombination technology and cell culture techniques, utilizing the ability of microorganisms and cells to create in large quantities specific proteins (hormones, enzymes, antibodies, etc.) that are useful for pharmaceuticals.
- The 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

Explanation of biosimilars

- Biosimilars are pharmaceutical products that have demonstrated the equivalent efficacy and safety compared to previously approved biologics through clinical trials.

Difference between biosimilars and other generic pharmaceuticals

	Biosimilars	Other generic pharmaceuticals
Molecular structure	Large and complex	Small and simple
Efficacy and safety	Substantially the same as innovator drug (Amino acid sequence is the same, but aspects such as the molecular structure and manufacture process differ)	Same as innovator drug (Same molecular array, same structure)
Development cost and manufacturing equipment cost	High (¥20-30 billion) *Innovator drug: ¥100 billion	Low (around ¥0.1 billion) *Innovator drug: ¥30 – ¥100 billion
Price difference against innovator drug	70% of innovator drug price *60% for oral drugs when more than 10 biosimilars of a specific innovator drug are launched	60% of innovator drug price *50% for oral drug when more than 10 generic products of a specific innovator drug are launched
Official number of items listed in the NHI price list (As of June 30, 2014)	27 (5 components)	9,478

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

The outlook is for the market to grow to approaching $300 billion by 2020

(3) The biologics market environment

The biologics market is continuing to expand year by year. In 2014, the global pharmaceutical market was worth approximately $800bn, within which, the biologics market was estimated to be worth around $180bn, or 23% of the total market, and it is expected to grow to be worth approaching $300bn by 2020. Another characteristic of biologics is the high percentage with large-scale sales, and among the top 10 pharmaceutical products in 2014 according to sales, 7 were biologics.

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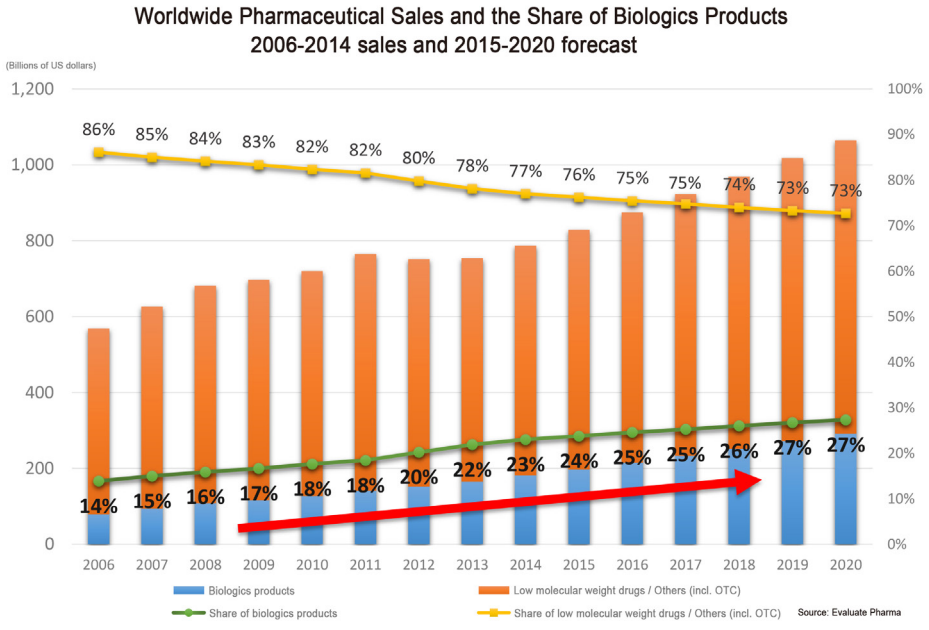
Overview of the worldwide pharmaceutical market



The biologic market is expanding year after year

Source: Company materials

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

Sales of the top twenty products and the biologics market scale

	2008	2014	2020 (F)
Sales of the top twenty product ($100mn)	1,110	1,315	1,350
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 ($100mn)	362	737	854
Within which, net sales of biologics whose patents are expiring ($100mn)	0	0	622

Source: Company materials

In the biosimilar market, a human growth hormone pharmaceutical was first launched in the European Union (EU) in 2006, and it is currently sold in Europe and Japan. In 2015, the United States published the biosimilar guidelines and opened-up the biosimilar market. In March 2015, Sandoz Inc. was the first company to receive manufacturing and sales approval for a biosimilar product (a filgrastim biosimilar) in the US market, the world's largest market for pharmaceuticals, and it is now at the stage of launching sales. This event set 2015 as "year one" of the biosimilar market in the US, and it is expected to expand and enter a fully-fledged growth stage. In the emerging market countries other than Japan, the US, and EU, it is likely that approval can be obtained if the biosimilar product was already approved in at least one or two counties out of Japan, the US, or EU.

The increased use of biosimilars can be described as one key to keep medical costs down. Due to their efficacy, demand for biologics is increasing year by year to the extent that biologics occupy most of the top positions in the sales ranking. As their drug prices are expensive, they are putting pressure on the national healthcare expenditures. The drug prices of biosimilars are around 70% of the prices of innovator drugs, so the difference is smaller compared to the prices of generic pharmaceuticals, which are around 60% of the prices of their innovator drugs. As the drug prices of biologics themselves are high, the increased use of biosimilars will have a significant effect in reducing medical costs.

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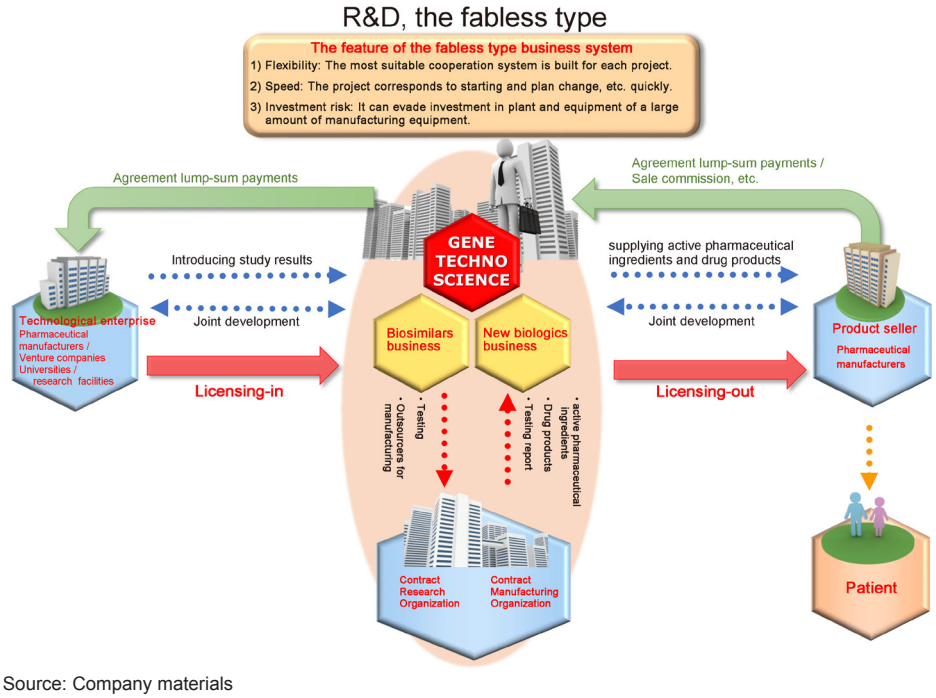
In order to reduce government spending on healthcare in Japan, institutional reforms are being implemented to increase the use of generic pharmaceuticals, but so far biosimilars have not been the subjects of these reforms. In March 2015, the Parliamentary Association for Promoting Biosimilars, which 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. Domestically, the Company's biosimilar competitors include JCR Pharmaceuticals Co., Ltd. <4552> and Kyowa Kirin Fujifilm Biologics Co., Ltd., which is a subsidiary of Kyowa Hakko Kirin Co., Ltd. <4151>.

A hybrid business structure comprised of biosimilars business and new biologics business

(4) Business model

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

R&D system



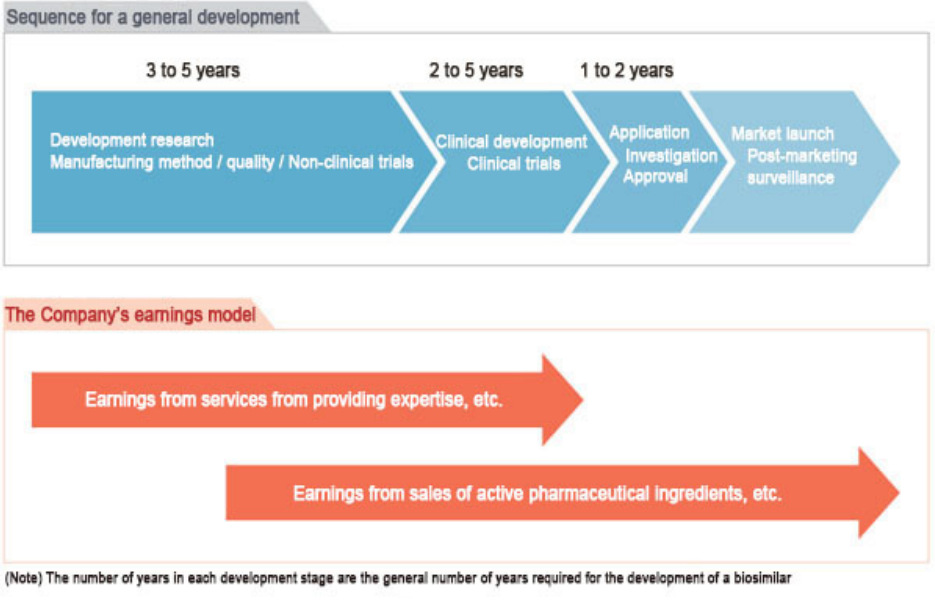
Source: Company materials

○**Biosimilars business**

The earnings model in the biosimilar business is comprised of sales from earnings at the research-and-development stage and the post-market-launch stage from supplying the drug substance that will be the main raw material for the drug product developed by the collaborating pharmaceutical company with the Company. Earnings are also from payments for development expertise and other such services provided to the collaborating company after the joint research and development agreement is entered. The Company adopts a fabless system and outsources to a CRO, contract research organization or a CMO, contract manufacturing organization, all of the tasks of manufacturing, analysis, evaluation, and testing of the drug substance.

As an example, for the market-launched 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, developed the drug substance and the manufacturing process for its commercial production, and it sells the developed drug substance to its partner, Fuji Pharma. Fuji Pharma manufactures and sells the drug product, and also supplies the drug product to Mochida Pharmaceutical. Filgrastim biosimilar developed by the Company accounts for approximately 30% of filgrastim sales in Japan since the sales started in 2013, and this ratio is expected to rise even further. Filgrastim biosimilars are sold by a number of pharmaceutical companies other than Fuji Pharma and Mochida Pharmaceutical, including Nippon Kayaku Co., Ltd. <4272>, and Teva Pharma Japan Inc. and Sawai Pharmaceutical Co., Ltd. <4555>. Since Fuji Pharma and Mochida Pharmaceutical started the sales promotion in advance of their competitors, together they hold a considerable share of the market for filgrastim biosimilar in Japan.

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 institutes. Manufacturing, quality testing, and non-clinical trials for the discovery of drug candidates are outsourced to CROs 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 the candidate to a pharmaceutical company at this stage.

For its earnings model, the Company enters into joint research and development agreements or license agreements and obtains earnings from agreement upfront payments, milestone payments according to the progress made in the research and development, and then from royalties after the product is launched.

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

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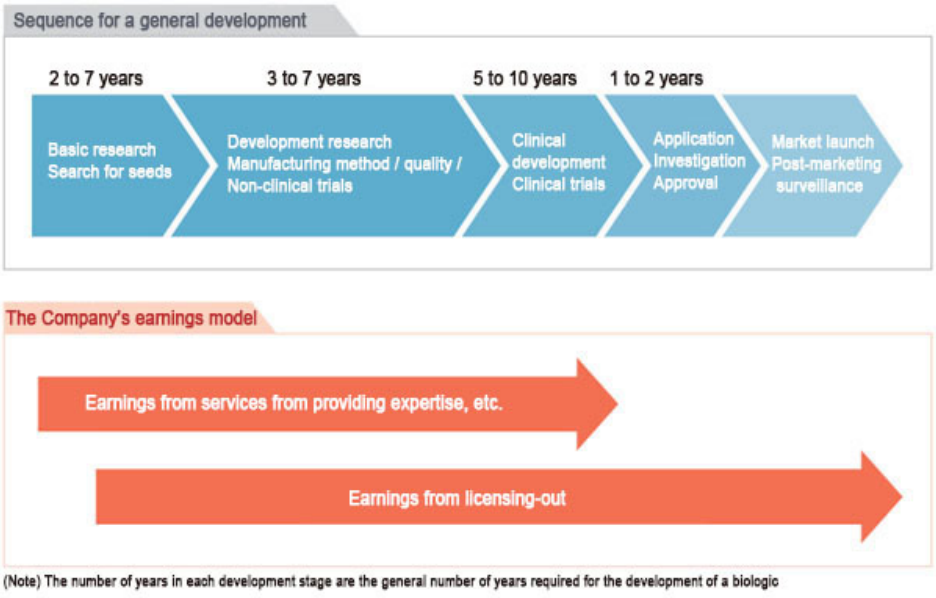
New biologics development schedule and earnings model



(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 biosimilars' development pipeline

The Company is currently developing 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 have been launched in the market or that are currently under development. The potential markets for the main 6 products have been provisionally calculated to be ¥1.2 trillion globally and even ¥90bn for Japan alone (innovator sales × 60% as biosimilar volume penetration rate × 70% of the innovator drug price). Among these 6 products, the filgrastim biosimilar has already been launched in the domestic market. The Company also plans to launch it overseas and it is currently at the stage of searching for business partners.

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, oncology, and ophthalmology for the 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 oncology field with Mochida Pharmaceutical in August 2015, and in the ophthalmology field with Senju Pharmaceutical in November 2015, and each of these agreements are accelerating the development of their respective biosimilars.

Also, the non-clinical trials have been completed and the production process is to be established towards commercialization of PEG-filgrastim that has superior longevity than filgrastim, which reduces the burden on the patient. PEG-filgrastim is manufactured using filgrastim as the raw material, so the companies that have already commercialized filgrastim biosimilar are likely to have an advantage to enter this market. The Company is targeting a market launch of 2023 domestically, and 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 for the treatment of age-related macular degeneration, which is the largest market in the ophthalmology field. Eylea and Lucentis are antibody medicine-related innovator drugs for the same therapeutic agent, and the Company plans to proceed with development by focusing on a biosimilar for either one, and it is aiming to enter clinical trials at an early stage aiming the domestic market launch around the first half of the 2020s.

The Company is also currently developing a biosimilar of Humira (a biologics for rheumatoid arthritis; generic name, adalimumab), which has the largest sales of all pharmaceuticals. Global sales of Humira are on the scale of approximately ¥1.3 trillion, and the potential market for a Humira biosimilar has been provisionally calculated to be around ¥520bn. As the market scale is so large, many competitors are also developing Humira biosimilars, and it seems that the Company places importance in high levels of quality and productivity. It is currently progressing non-clinical trials and is aiming to enter into agreements at the earliest with pharmaceutical companies during 2016, and then to enter into clinical trials toward a market launch in Japan around 2020.

Main biosimilars in the pipeline

Pipeline (generic name)	Innovator drug, product name	Biosimilars' potential market scale		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 to commercialize 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 technologies 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 for partner companies for joint development. Scheduled to start clinical trials from 2016.
(ophthalmic biologics)	Ophthalmic biologics age-related macular degeneration, etc.	¥25.2bn	¥307bn	First half of 2020s	-	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, including for cancer, immune disorders, and circulatory diseases						

Note: the potential market scale is calculated as approximately 40% of that 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

(1) Overview of the FY3/16 results

In the FY3/16 results announced on May 12th, net sales increased 260.9% y-o-y to ¥1,160mn, the operating loss was ¥820mn (compared to a loss of ¥824mn in the previous fiscal year), the ordinary loss was ¥785mn (a loss of ¥790mn), and the net loss was ¥787mn (a loss of ¥792mn). The positive net sales were achieved as in the biosimilars business, sales of the filgrastim biosimilar increased by 3 times, to ¥1,100mn as expected, while the upfront payment 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 biologics of antibody, 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 application with the National Cancer Center. In July, it began a business collaboration in the healthcare-related field with DyDo Drinco.

In terms of profits, although expenses increased, including that R&D expenses rose ¥385mn y-o-y to ¥1,075mn and that other SG&A expenses climbed ¥96mn, the loss was basically the same as in the previous fiscal year due to the effects of the higher sales of the filgrastim biosimilar. The operating loss shrunk by ¥225mn compared to the Company target, which was mainly due to the reduced development expenses by improving the development process.

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FY3/16 results

(¥mn)

	FY3/15	FY3/16			FY3/17 (F)	
	Result	Company target	Result	y-o-y	vs. target	Company target	y-o-y
Net sales	321	1,132	1,160	839	28	1,685	525
Gross profit	174	-	660	486	-	-	-
SG&A expenses	998	-	1,480	482	-	-	-
(R&D expenses)	689	1,296	1,075	385	-221	1,283	208
Operating income	-824	-1,045	-820	3	225	-493	327
Ordinary income	-790	-1,019	-785	4	234	-494	291
Net income	-792	-1,021	-787	4	234	-497	290

Note: the FY3/16 Company targets are as of November 2015

(2) FY3/17 outlook

For FY3/17, the outlook is for net sales to increase 45.1% y-o-y to ¥1,685mn, an operating loss of ¥493mn, an ordinary loss of ¥494mn, and a net loss of ¥497mn.

An increase in net sales is forecast in the biosimilar business, as sales of the filgrastim biosimilar and revenue from upfront payment and milestone payments from business partners for GTS's pipeline are set to increase. It is highly likely that progress will be made toward concluding an agreement with Mochida Pharmaceutical, with which the Company entered into a basic agreement in the previous fiscal year toward developing biosimilar for the oncology field. It also appears that progress is being in the partnership negotiations for the adalimumab biosimilar, so revenue from upfront payment and milestone payments is expected during this fiscal period. For the project with Senju Pharmaceutical in the ophthalmology field, the aim is to complete the non-clinical trials during this fiscal year and to start the clinical trials around 2017. The agreement with Senju Pharmaceutical is in the form of a capital partnership, not in the form of development milestone payments, and it already holds shares in the Company and is contributing to its strengthened financial foundations.

R&D expenses are expected to increase ¥208mn y-o-y to ¥1,283mn, including the establishment of production process for the development projects and implementation of non-clinical trials. However, the R&D expenses for the on-going projects are forecast to peak in this fiscal period and then decline from FY3/18 onwards.

In May 2016, the Company entered into a basic agreement with Changsheng Life Sciences toward the commercialization of biosimilars in China. Changsheng Life Sciences is among the top five vaccine pharmaceutical companies in China, and it is a highly profitable company with annual sales of ¥20bn and profits of ¥4bn in vaccine business in China. Guidelines for biosimilars have already been established in China and the situation is that various companies are competing fiercely to develop biosimilars for this market. In order to enter into this market, Changsheng Life Sciences entered into a basic business partnership agreement with the Company, which has a track record of market launches in this field. At the present time, there is the only one product in development, but this may increase to multiple products if the development proceeds steadily. This is the Company's first business partner in the overseas market, and it is expected to acquire even more partners in the future.

Actively conducting M&As for promising bio-related companies

(3) The capital and business partnership with Noritsu Koki

In March 2016, the Company concluded a capital and business partnership agreement with Noritsu Koki, and in the future it will likely continue to expand its biologics business, including regenerative medicine, as a core member of the Noritsu Koki Group. In April 2016, the Company implemented a capital increase through a third-party allocation for the limited liability company (LLC) Launchpad12 that was established by NK Relations Co., Ltd., which is a wholly-owned subsidiary of Noritsu Koki. Launchpad12 conducted a tender offer for the Company's common stock by the end of May. The Company's previous leading shareholder, Whiz Partners Inc., also submitted its Company shares in this tender offer, and the shareholding ratio of Launchpad12 as of the end of May was 58.15%, making the Company a consolidated subsidiary of Noritsu Koki.

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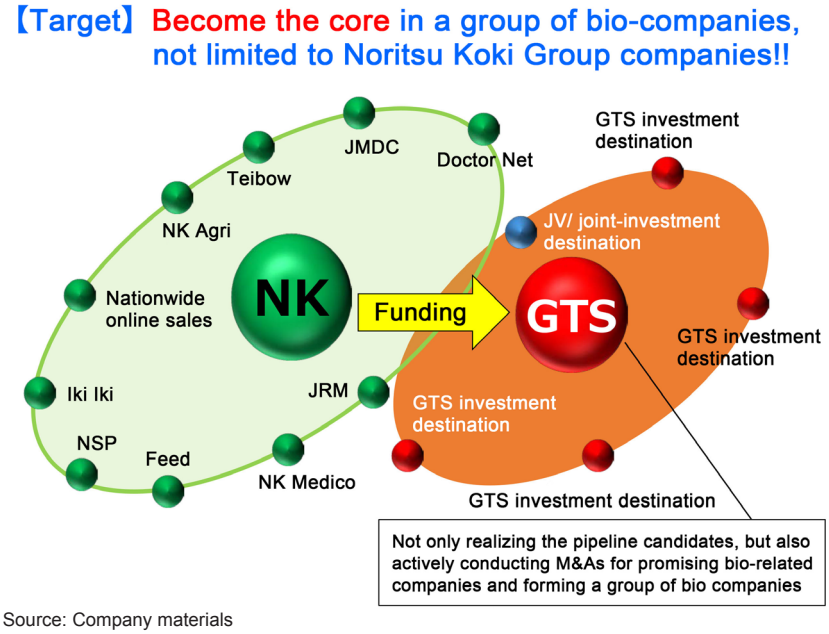
The Company raised funds of ¥2,000mn from a capital increase through a third-party allocation. In addition, it newly raised ¥1,119mn as a result of the exercise of stock acquisition rights by Whiz Partners in April, with total fund raising of ¥3,119mn. Conversely, the number of shares outstanding increased by 55%, from 2,885,000 shares at the end of the previous fiscal year to 4,503,000 shares, so shareholder value per share has been diluted.

In terms of an overview of the business partnership with Noritsu Koki, it will include cooperation toward the commercialization of the Company's biologics business, a capital and business partnership with the subsidiary NK Relations and also with other affiliates, considering investment in bio-related companies, cooperating to search and to commercialize business seeds that apply bio-technologies, and utilizing the medical information databases and big data analytical capabilities of the subsidiary NK Relations and the affiliates toward the commercialization of biologics.

Noritsu Koki plans to actively invest in three growth fields; the digital field, the bio field (regenerative medicine, genetic testing, and biologics), and the medical information field. Its Group companies undertaking the biologics business will include Japan Regenerative Medicine Co., Ltd, which is involved in the regenerative medicine business; GeneTech Co., Ltd, which has an 80% share of the prenatal genetic testing market, and NK Medico Co., Ltd, which possesses biomarkers for arteriosclerosis. It is thought that the Company will obtain synergy effects in the future through sharing the development resources with these companies. The plan is to actively invest in venture companies, as well as to progress the capital and business partnerships between the Group companies, and the Company is expected to grow to become the core company in Noritsu Koki's biologics business.

The position of Gene Techno Science



Source: Company materials

(4) Financial position

Looking at the Company's financial position at the end of March 2016, total assets increased ¥547mn compared to the end of the previous fiscal year to ¥1,694mn. The main reasons for this were that in current assets, cash and deposits rose ¥217mn, and in addition, advance payments for the development of biosimilars increased ¥200mn.

Liabilities increased ¥414mn compared to the end of the previous fiscal year to ¥1,290mn, within this amount, interest-bearing debt rose ¥35mn. Convertible corporate bonds with subscription rights to shares decreased ¥425mn following the execution of subscription rights for shares, but conversely short-term debt increased ¥460mn. Elsewhere, accounts payable and advances received increased ¥127mn and ¥145mn respectively. The increase in advances received was mainly from the receipt of advanced payments for sales of the drug substance of biosimilars. At the end of March, the balance of convertible corporate bonds with subscription rights to shares was ¥350mn, all of which were converted to common shares by Whiz Partners in April 2016 and then submitted to the Noritsu Koki Group in the recent tender offer.

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Net assets rose ¥132mn compared to the end of the previous fiscal year to ¥403mn. This was primarily because although a net loss of ¥787mn was recorded, capital and the capital reserve increased ¥921mn on the execution of subscription rights to shares. For cash and deposits, as the previously mentioned, the capital increase through a third-party allocation to Noritu Koki and the execution of subscription rights to shares by Whiz Partners attributed to the Company's fund raising of ¥3,119mn. The Company's financial position has greatly improved recently as the equity ratio has risen to as high as approximately 80%.

Balance sheet

(¥mn)

	FY3/13	FY3/14	FY3/15	FY3/16	Change
Current assets	919	1,881	1,092	1,520	427
(cash and deposits)	887	1,610	599	817	217
Fixed assets	3	4	54	173	119
Total assets	922	1,886	1,146	1,694	547
Current liabilities	24	50	92	1,279	1,187
Fixed liabilities	9	783	783	11	-772
(interest-bearing debt)	-	775	775	810	35
Total liabilities	34	833	876	1,290	414
Total net assets	888	1,052	270	403	132
Management indicators (stability)					
Equity ratio	96.3%	54.7%	21.7%	22.6%	
Interest-bearing debt ratio	-	-	-	-	

■ Medium- to long-term vision

Collaborating with pharmaceutical companies in the United States and Europe and opening-up markets in newly emerging countries

The Company's future strategy is to supplement and accelerate its development in the biosimilar business through swiftly building collaborations with pharmaceutical manufacturers, and also to develop its business globally (through collaborations with pharmaceutical companies in the US and EU, and opening-up markets in newly emerging countries).

In the new biologics business, the Company is targeting fields of rare diseases and oncology agents, and it is aiming to rapidly build alliances with pharmaceutical companies as well as conducting its own R&D. It is also continuously progressing joint research with academia to strengthen its fundamental technologies. As a supplementary business for national projects, it is implementing various initiatives including developing the technological foundations for the discovery of next generation drugs for personalized medicine, and the trial production of cell lines and drug substance for antibody drugs. Furthermore, it may progress the launch and development of a new biologics business through the capital and business partnership with Noritsu Koki, and it can be said that its growth potential, including relating to regenerative medicine and healthcare, has risen to an even higher level.

The Company's medium- to long-term target are to use the filgrastim biosimilar as a stable source of earnings and from 2019 onwards, steadily launching biosimilars for PEG-filgrastim and adalimumab, and also biosimilars in the ophthalmology field, achieving net sales of several billions of yen by around 2021, and then in the next decade, achieve sales of several billions of yen from biosimilars alone. If the biologics and the new biologics businesses start contributing to earnings, growth can be expected to accelerate to an even greater extent.

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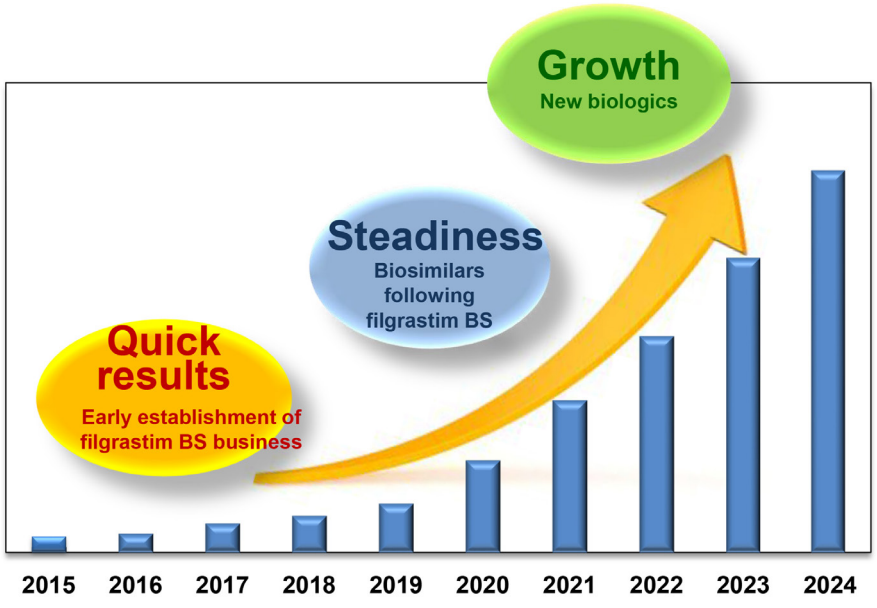
Medium- to long-term sales vision



Sales of biosimilar drug product / drug substance and upfront and milestone revenue of new biologics

Source: Company materials

The biosimilar market is expected to rapidly expand following the previously mentioned opening the world largest biosimilar market in the US in 2015, and the expiry of a number of patents covering biologics with large sales by 2020. An important point for whether or not the Company can achieve its targets is the extent to which it can acquire business partners in the next one to two years, while profits will also be dependent on the progress made in the development pipeline. Looking solely at the biosimilar business, it is possible that it will become profitable around FY19.

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