Chiome Bioscience Inc.

4583 TSE Mothers

27-Oct.-14

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FISCO Ltd. Analyst
Yuzuru Sato

Focusing on improving technology to obtain antibodies using the fully human ADLib® system

Chiome Bioscience Inc. (4583) (subsequently, "the company") is a biotechnology company that discovers antibodies for medical applications using a proprietary technology discovered by RIKEN. It also supports the research and development of such antibodies by other entities. This technology, called the ADLib® (Autonomously Diversifying Library) system, has three distinct features: 1) it can generate antibodies for a wider range of antigens than most conventional methods, 2) it generates antibodies faster than other methods, and 3) it can be applied to tough antigens for which it is tough to produce antibodies by other methods.

In its consolidated financial results for the first quarter of the fiscal year ending December 2014 (9 months), i.e., Q1 FY12/14 (April to June) announced on August 14, 2014, the company recorded sales of ¥78 million and an operating loss of ¥285 million, which were roughly in line with company forecasts. In terms of the progress the company is making, after announcing in March 2014 that it had completed the fully human ADLib® system, it began receiving inquiries for this technology from potential customers both domestically and overseas. But within the current fiscal year it intends to focus on further finalizing this technology while using it for its own projects. Therefore, it will have no effect on results during this year's fiscal quarters and the company will only record sales from existing customers. Going forward, it will focus its resources into further improving its technology to obtain antibodies using the fully human ADLib® system and is looking to conclude trial contracts for the system with Japanese and overseas pharmaceutical companies around the beginning of next year at the earliest.

In its three-year medium-term management plan, R&D costs will keep down its results up to the end of FY12/15 and so it will continue to record an operating loss. But in the final year of the plan, FY12/16, it is targeting sales of ¥3,452 million and operating income of ¥651 million, bringing operations out of the red for the first time. Now that the fully human ADLib® system is ready for practical use, it expects to conclude platform technology licensing agreements with pharmaceutical companies, and also anticipates that it will license a number of lead antibodies. Among lead antibodies, the company is scheduled to license the evaluation of anti-semaphorin 3A antibody, which is the company's first lead antibody, in FY12/15. In the future, in addition to antibodies indicated for cancer and autoimmune diseases, which are the effective areas of antibodies, the company is also planning to develop antibodies indicated for pandemic contagious diseases.

Moreover, toward the generation of high value-added lead antibodies, the company is actively forming drug discovery alliances with companies with cutting edge technologies and is aiming to establish ADLib® system, its core technology, as a drug discovery platform. Going forward, it will be worth paying attention to the progress the company makes toward achieving its vision of providing the "ultimate made-to-order medicine".

Check Point

- The ADLib® system can generate broader antibody diversity than conventional antibody production systems
- From Q2 onwards, the company will be focusing on trial contracts for its fully human ADLib® system
- It is forecasting a dramatic improvement in results in FY12/16, driven by its licensing out platform technology business

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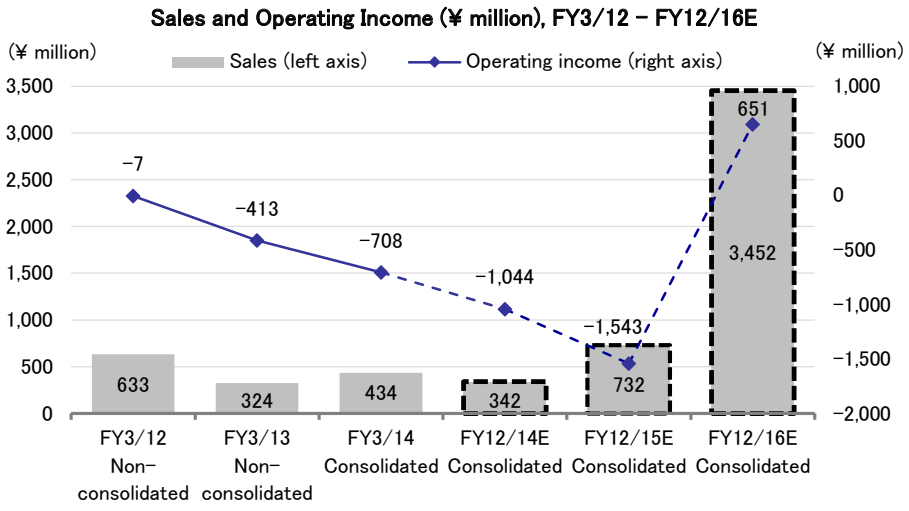


*Reflecting a change of fiscal year, FY12/14 contains nine months

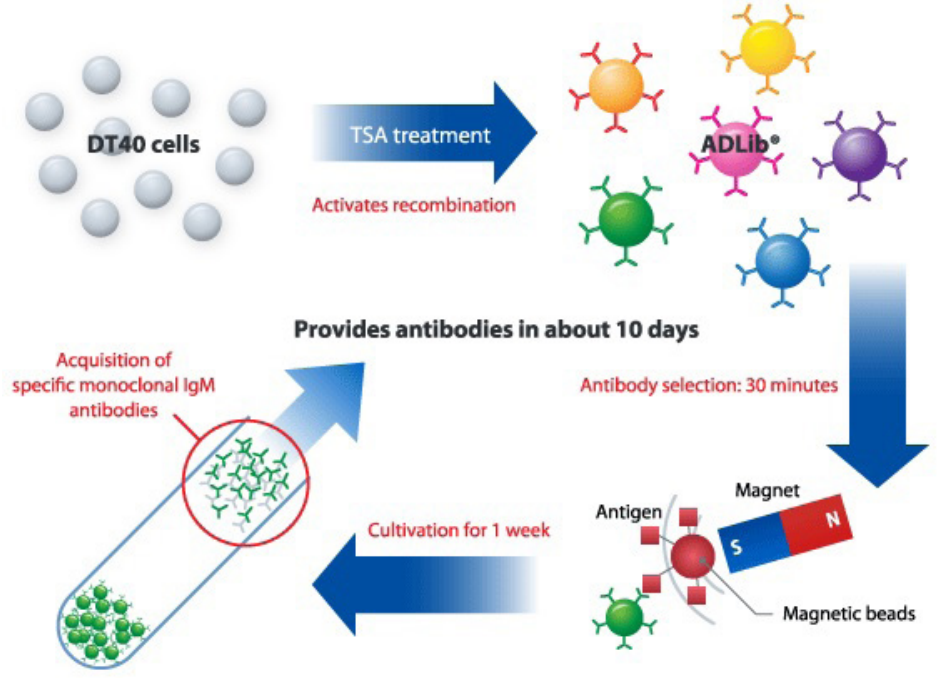
■ Company Description

The ADLib® system can generate broader antibody diversity than conventional antibody production systems

(1) ADLib® System

The ADLib® system, the company's core technology, was developed by RIKEN as a method for antibody discovery in 2002. Today, the patent rights to it are shared equally by the company and RIKEN (50% each). Simply stated, the ADLib® system promotes DNA recombination (gene conversion) in the antibody locus of DT40 cells, a cultured cell line derived from chickens, to generate the antibody protein library. Then with magnetic beads the system collects only the cells that bind to the target antigen. Antigen-specific antibodies can be harvested by culturing those cells for about a week.

Diagram Showing How the ADLib® System Produces Antibodies



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Most of the therapeutic monoclonal antibodies now on the market were discovered by one of two conventional methods; the mouse hybridoma method or the phage display method. The table below shows the differences between these existing technologies and the ADLib® system.

Comparison of the ADLib® System with the Mouse Hybridoma Method and the Phage Display Method

Built a strong competitive advantage through the establishment of the fully human ADLib® system

	ADLib® system	Hybridoma	Phage display
Tough antigens*	Applicable	Applicable to some	Applicable to some
Antibody generation time	About 10 days	About 6 months	2.5 to 3.5 months
Amount of antigen required	10μg~100μg	~mg	~500μg
Automation	Yes	No	Yes
Fully human antibody	Practical ⇒ Fully workable	Fully workable	Fully workable

: a competitive advantage to other methods

* Tough antigen: an antigen for which antibodies are difficult to obtain

Source: from the company's briefing materials

As for above "Application to tough antigens", the ADLib® system can also be used to generate antibodies for those for which access by conventional antibody production methods is tough, such as pathogenic toxins or proteins that are conserved across species by evolutionary mechanisms. Among those tough antigens, GPCR or G protein-coupled receptors is now the main focus of antibody development. It is a group of antigens with complicated structure for which it was tough to produce antibodies. However, several small-molecule medicines against diseases caused by these molecular group are now on the market (among these are Gaster to treat peptic ulcers and the antihistamine Claritin). There are several hundred such antigens for which it is tough to produce an antibody. The production of therapeutic antibodies for them would expand the market for antibody drugs substantially. The ADLib® system has the greatest advantages for this production, compared to conventional methods.

In addition, by utilizing the intrinsic gene diversification mechanism in DT40 cells or introducing the artificial arrangement of genes, the ADLib® system can generate broader antibody diversity than conventional antibody production systems, and indeed is theoretically capable of limitless diversity.

A short development time before a pharmaceutical is brought to market not only provides patients with a new drug faster, it will also contribute more to sales. Because patents expire after 20 years, a shorter period to generate the antibody makes it possible to reduce the time from discovery to market launch, which is another benefit of the ADLib® system.

Generation of fully human antibodies has been a big challenge in the past. However, on March 2014, the company announced that it had completed its technology for producing fully human antibodies and that opened the way for full-scale commercialized use of human ADLib® system. The fully human ADLib® system is able to generate human antibodies as drug candidates by humanizing chicken antibodies by replacing antibody genes in a DT40 cell line established from chicken lymphocyte with artificial human genes.

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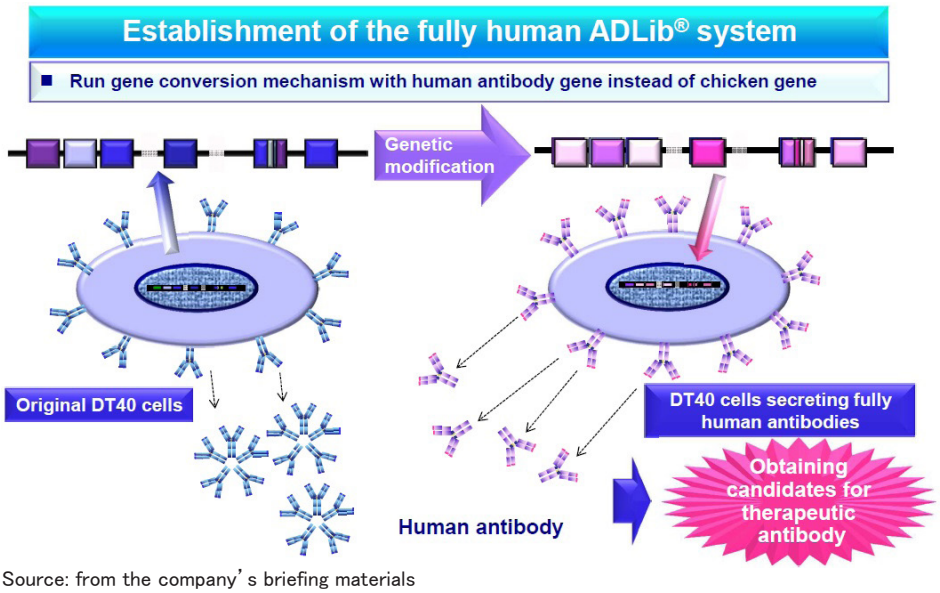
Structure of the Fully Human ADLib® System (outline)



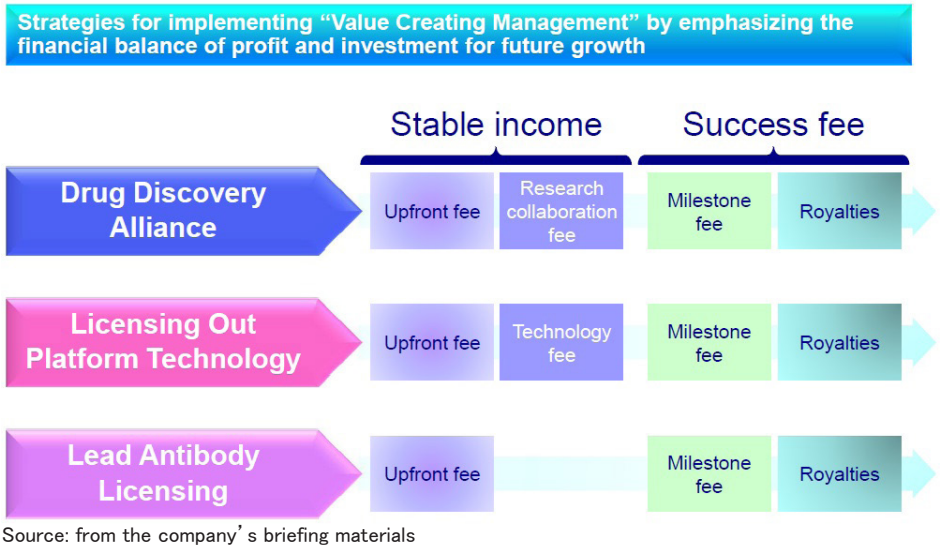
Source: from the company's briefing materials

The drug discovery alliance business currently accounts for the majority of the company's revenues

(2) Overview of Business Structure

With the ADLib® system as its core technology, the company manages three types of business.

Revenue Source by Business



Source: from the company's briefing materials

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■ Company Description

The drug discovery alliance business produces new antibodies using the ADLib® system, mainly for therapeutic drugs, in collaboration with pharmaceutical companies around the world. This business currently accounts for a majority of the company's revenue, which consists of upfront income when a joint R&D contract is concluded, milestone income reflecting R&D expenses (including personnel expenses) and progress, and royalty income after a drug is marketed. In this business, in principle the company retains at least a 50% share of the right to a developed antibody, so it provides greater added value than conventional consigned or commissioned drug development. The standard time frame for antibody drug development is 6.5 – 10 years. This could be broken down into about 1 year of basic research and discovery → 1 – 2 years for non-clinical development, → 3.5 – 5 years for clinical trials → 1 – 2 years for review → approval and marketing.

The Chugai Pharmaceutical Group (4519) is the main collaborative research partner for this segment (business with this group accounted for 88.9% of the company's total sales in FY3/14).

The licensing out platform technology business is the second pillar, in which the company licenses the ADLib® system to other companies, which use this technology to generate antibodies. From this business, it obtains upfront income when a licensing contract is concluded, annual license fees, milestone income reflecting the progress in the development of antibodies discovered using the ADLib® system, and royalty income after a drug is marketed. This business is highly profitable since the only costs, apart from the royalties paid to RIKEN, are for technology transfer work (for about one month).

Currently, Fujirebio Inc. is the only licensee of the ADLib® system for the discovery of antibodies for in-vitro diagnostic agents. In December 2013, Fujirebio commenced sales in Europe of an in-vitro diagnostic kit that includes an antibody produced by the ADLib® system. This was the first commercialization of an antibody made with this system.

The third pillar, the lead antibody licensing business, is the licensing of antibodies that have been developed by the company in the discovery or pre-clinical stage. These antibodies are produced using the ADLib® system for target antigens obtained through joint R&D or business agreements with universities, public medical institutes and companies with proprietary technology, such as Biotecnol, Inc.* In the future, this business model will generate upfront income from licensing agreements, milestone income reflecting progress in antibody development, and royalty income after a drug is marketed, supplementing the company's revenue from the other two businesses. In this business, the company is collaborating with several organizations, including Yokohama City University, The University of Tokyo, National Cancer Center, and Biotecnol, although at the current stage it does not record sales in it.

The ADLib® system is patented in Japan, the U.S., Europe, and China. The patent rights are shared equally by the company and RIKEN and it pays royalties to RIKEN. This patent will expire in Japan, Europe and China in 2023, and in the U.S. in 2025. But the company has been applying for relevant patents, including the patenting of the fully human ADLib® system. Thus, it should retain competitive advantage for the ADLib® system even after the existing patent expires.

* The company and Biotecnol concluded a joint research agreement in February 2013 and they are conducting R&D into the development and production of high value-added antibody medicines using Biotecnol's TribodyTM technology and the ADLib® System. Their target medicines could not be produced using other current technologies.

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The table below shows the main partners in each business and the purposes of the agreements.

Main Partners of Each Business

Partner	Agreement term	Purpose of agreement
○ Drug discovery alliance business		
Chugai Pharmaceutical Co., Ltd.	11/2008 - 12/2014	Joint R&D using the ADLib® system to generate antibody.
Chugai Pharmaceutical Co., Ltd.	7/2011 - 12/2014	Service agreement to support R&D using the ADLib® system to generate antibody.
Chugai Pharmabody Research Pte. Ltd.	8/2012 - undisclosed	Service agreement on the procurement of research materials necessary for efficient antibody drug development.
○ Licensing out platform technology business		
Fujirebio Inc.	For life of patent	Produce and sell in-vitro diagnostic agents, including antibody generated using the ADLib® system to measure vitamin D.
Fujirebio Inc.	For life of patent	Joint R&D and the non-exclusive right to use the ADLib® system.
○ Lead antibody licensing business		
Yokohama City University	10/2008 - 3/2014	Develop a specific antibody to recognize the semaphorin molecule.
Biotecnol, Inc.	2/2013 -	Research and develop novel and high value-added therapeutic antibodies that cannot be generated from conventional technologies.

Source: Company materials and Japanese Securities Report

Utilizing LivTech's animal research facility

(3) Subsidiary LivTech, Inc.

In December 2013, the company invested about ¥90 million for a 52.9% stake in LivTech, Inc., making the company a subsidiary. LivTech has been developing antibodies for cancer stem cell antigens and has two development pipelines. For one pipeline, it licensed one of these lead antibodies to Yakult Honsha Co., Ltd. (2267) in 2011 for joint R&D toward the production of a cancer medicine. For another, LivTech is now seeking a pharmaceutical company as a partner for the development of a medicine based on its other lead antibody. It owns a facility for animal research and is particularly strong in developing antibodies up to the clinical trial stage. LivTech generates annual sales of about ¥100 million but suffers an annual operating loss of several tens of millions of yen.

The company acquired LivTech to obtain its expertise in the pre-clinical stage development of antibodies and in actual licensing record of antibodies, and it also gained access to LivTech's animal facility. By combining LivTech's expertise with its ADLib® system, the company will be able to accelerate its development of antibodies to counter the antigens causing cancer, autoimmune diseases, and contagious diseases.

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Business Trends

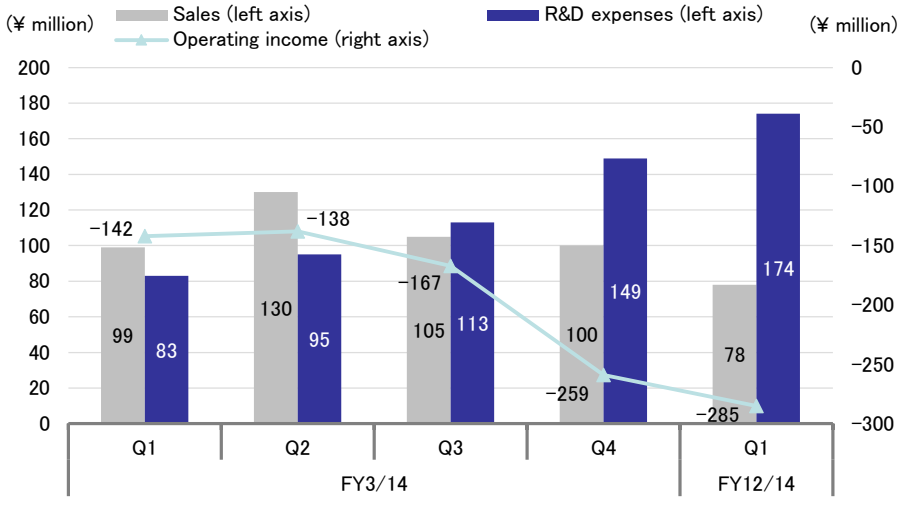
The lower sales and higher operating loss in Q1 are roughly in line with forecasts

(1) Q1 FY12/14 Results

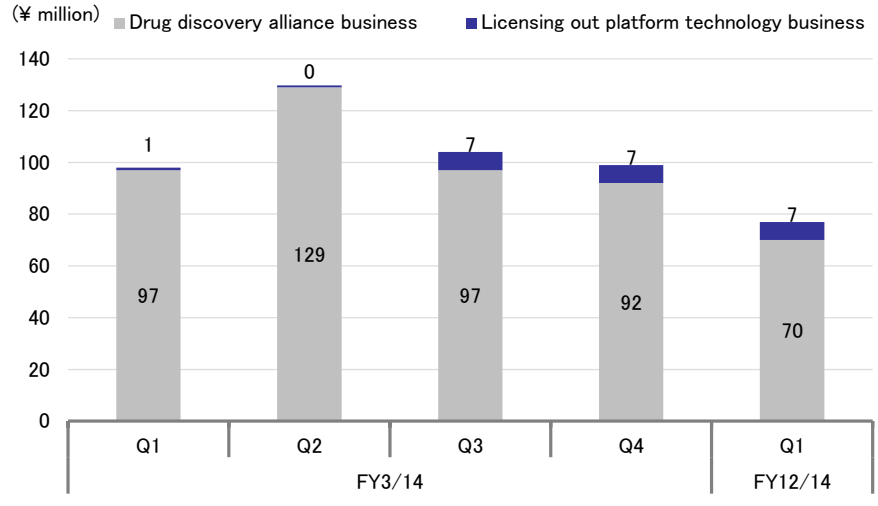
On August 14, 2014, the company announced its consolidated business results for Q1 FY12/14 (April to June), reporting sales of ¥78 million, an operating loss of ¥285 million, an ordinary loss of ¥285 million, and a net loss of ¥267 million. Sales declined year-on-year (y-o-y) and in addition, the operating loss increased slightly, but these results were roughly in line with the company's forecasts. The main factor behind the decline in sales was a fall in sales from the drug discovery alliance business, while an increase in R&D expenses was the primary reason for the operating loss. The company's main R&D costs are all to widen its pipeline and to create strategic antibodies, including the costs to improve the diversification of the fully human ADLib® system, to expand its library, and to generate specific antibodies for tough antigens.

Trends according to business segment were as follows.

Quarterly Results (¥ million), Q1 FY3/14 - Q1 FY12/14



Sales by Business Segment (¥ million), Q1 FY3/14 - Q1 FY12/14



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○ Drug discovery alliance business

In Q1, the drug discovery alliance business recorded sales of ¥70 million (compared to ¥92 million in Q4 FY3/14) and segment income of ¥42 million (¥35 million). While sales to the Chugai Pharmaceutical group were down, R&D operations progressed smoothly and as planned. Also, the subsidiary LivTech, Inc. continued with various types of non-clinical trials for its LIV-2008 antibody medicine indicated for cancer that it is developing with Yakult Honsha Co., Ltd.

○ Lead antibody licensing business

Anti-semaphorin 3A is the company's first lead antibody candidate and it is currently studying it in collaboration with Yokohama City University. They have started drug efficacy tests using an animal model for human diseases toward an inflammatory diseases model (sepsis and DIC model) and indications in the area of oncology. Also Biotecnol, which is a technology alliance partner, is making steady progress in a R&D project to develop an antibody indicated for cancer. In addition, the company is strengthening its alliances with a number of universities and public research facilities and is continuing to discover antibodies for new indications. It is currently receiving an increasing number of requests for joint research and is selecting and narrowing down those development projects that are best suited to its ADLib® system. Therefore at the current stage, this business does not record sales.

○ Licensing out platform technology business

Sales in Q1 were ¥7 million and segment income was also ¥7 million, which were roughly in line with company forecasts. In December 2013, the European subsidiary of Fujirebio Inc., which is the company's original ADLib® system licensee, launched a diagnostic kit that included an antibody from the ADLib® system for measuring vitamin D (used for diagnosing rachitic patients), and the company is recording royalty income based on its sales and also the annual license fees for the ADLib® system. In addition, it is conducting technology assessment tests and negotiating technology license schemes with companies from Japan and overseas that have expressed an interest in licensing its technology.

Focusing on contracts for tests for the fully human ADLib® system from Q2 onwards

(2) Results Forecasts for FY12/14

For its consolidated results in FY12/14 (9 months), the company is forecasting sales of ¥342 million, an operating loss of ¥1,043 million, an ordinary loss of ¥1,041 million, and a net loss of ¥1,043 million.

A key point from Q2 onwards will be what kind of progress the company makes in concluding contracts for tests with Japanese and overseas pharmaceutical companies for the fully human ADLib® system. Interest in the fully human ADLib® system has been rising since March 2014 when the company announced it had succeeded in developing a system that was ready for practical use, and it has received a number of requests for trial contracts from major pharmaceutical companies in Japan and overseas. The company is working to further improve the fully human ADLib® system, such as by continuously increasing diversification. In parallel with this, is intends to actively conduct marketing activities from Q2 onwards and expects to conclude trial contracts for around the beginning of 2015 at the earliest. If this plan goes smoothly, it is targeting technology licenses in FY12/16, and so it will be worth paying attention to the progress it makes in achieving this target in the next few years.

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Currently, the licensing out platform technology business is still only at the initial marketing stage, so while it is dependent on the sales performance of Fujirebio's diagnostic kit in Europe, a major increase in sales is not expected in the current period. However, this diagnostic kit is able to detect vitamin D with a level of sensitivity 100 times greater than that of conventional methods and represents a significant step-up in performance, so there remains room for it to acquire market share. The market scale in Europe for this diagnostic kit is estimated to be around ¥30,000 million, so if it can capture share of around 30% of this market, it would realize sales on the scale of ¥10,000 million. The company would receive a fixed rate of these sales as royalty income and as the product's sales increase in the next few years, it can be expected to increasingly contribute to the company's earnings.

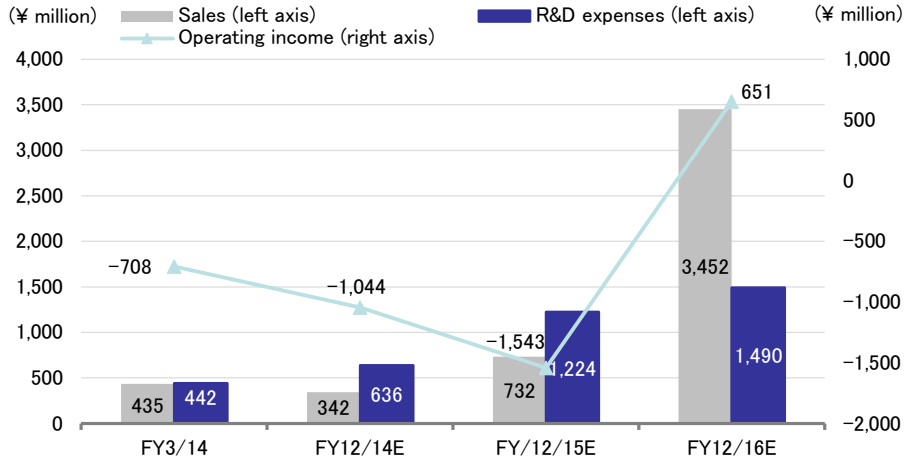
■ Medium-Term Plan

The company anticipates a surge in sales FY12/16, driven by the licensing out platform technology business

(1) Outline of the medium-term plan

In May 2014, the company announced its three-year plan ending in FY12/16 with targets calling for a dramatic improvement in performance in FY12/16, as is shown in the graph.

Consolidated Business Results Targeted in the Medium-term Plan (¥ million)



*Reflecting a change of fiscal year, FY12/14 contains nine months

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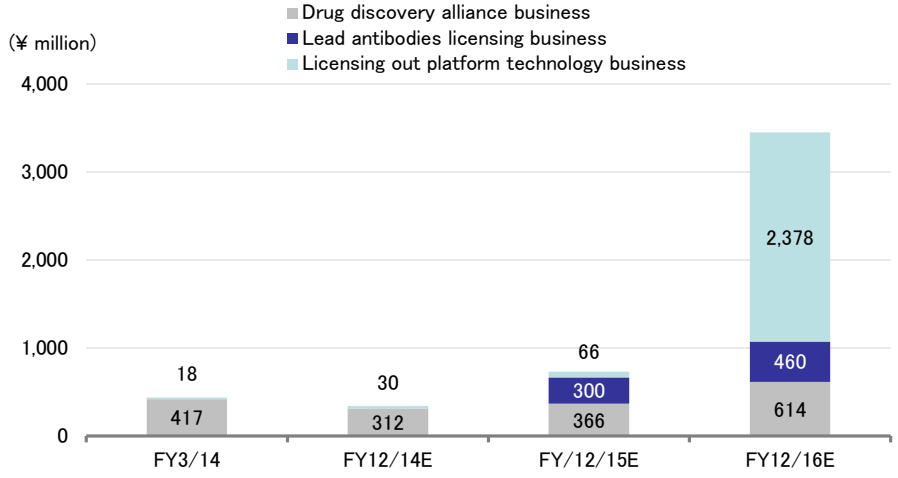
Sales Targets by Consolidated Business Segment (¥ million)

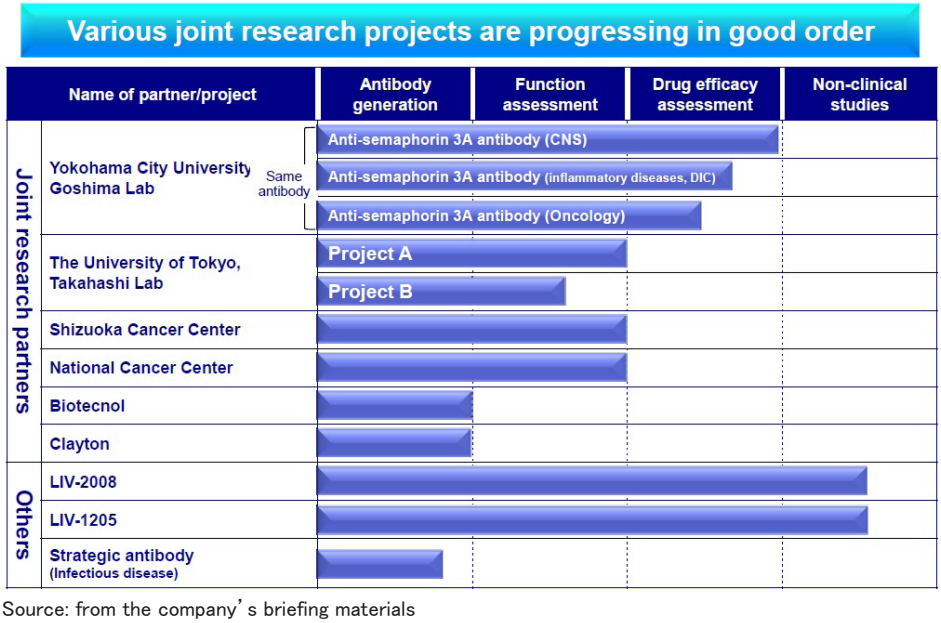


*Reflecting a change of fiscal year, FY12/14 contains nine months

For FY12/15, the company projects that its consolidated sales for the full year will be ¥732 million. In the drug discovery alliance business, it expects an increase in trial contracts for using the fully human ADLib® system to contribute to sales, while in the lead antibody licensing business, it plans to license its anti-semaphorin 3A antibody. In addition, in the licensing out platform technology business, it anticipates an increase in royalty income from Fujirebio Inc.

In FY12/16, the company anticipates a surge in sales to ¥3,452 million, which will be driven by the licensing out platform technology business. It expects a massive jump in sales from licensing out its platform technology to a number of Japanese and overseas companies, reflecting the higher maturity of the fully human ADLib® system. It is thought that the company will limit the number of companies it concludes licensing agreements with. This is because the company itself is aiming to primarily be a drug discovery company that targets the development of lead antibodies. Currently, its main R&D pipeline for the licensing of lead antibodies is progressing as planned. It is mainly targeting the field of oncology, but going forward it also intends to focus on developing lead antibodies for pandemic contagious diseases.

The status of its R&D for lead antibody licensing (extract)



Source: from the company's briefing materials

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In the future, the company is aiming to establish its fully human ADLib® system as a drug discovery platform that will enable the discovery of high value-added lead antibodies, while also collaborating with companies with cutting edge technologies. Going forward, it will be worth paying attention to how successful the company is in realizing its vision of "ultimate made-to-order medicine".

The large market potential could significantly propel growth

(2) Recent Examples of Agreements to License Platform Technology for Antibody Medicines

As the market for each antibody medicine is large, so the fees to license platform technology for the development of an antibody also tend to be large. The table below of recent, large licensing agreements indicates that the total amount of these agreements is worth several tens of billions of yen. The ability to negotiate such large licensing agreements depends in part on the number of antibodies in the development pipeline. However, if the company were to develop one antibody with large market potential, its sales and profits could grow rapidly.

Examples of Large Technology Licensing Agreements

Licensing company	Licensee (partner)	Approx. amount	Contract date
Seattle Genetics	Genentech	US$900 million	Jan. 2011
Regeneron	Astellas	US$295 million	Jan. 2011
Theraclone Sciences	Pfizer	US$632 million	Jan. 2011
Aveo Pharma	Johnson & Johnson	US$555 million	May 2011
Micromet	Amgen	US$888 million	Jul. 2011
F Star	Merck Serono	US$708 million	Sep. 2011
Five Prime Therapeutics	GlaxoSmithKline	US$1,191 million	Apr. 2012
Ablynx	Merck & Co.	US$587 million	Oct. 2012
Ambrx	Astellas	US$300 million	Apr. 2013
Seattle Genetics	Bayer HealthCare	US$520 million	Jun. 2013
CytomX	Pfizer	US$635 million	Jun. 2013
Ablynx	AbbVie	US$815 million	Sep. 2013

Source: Company materials

Management indicators of financial stability are at acceptable levels

(3) Financial Condition

The balance of total assets at the end of June 2014 was down ¥205 million compared to the end of the previous fiscal year, to ¥4,806 million. There were no major changes in assets, other than a decrease in cash and deposits on hand and in banks of ¥206 million due to a rise in operating expenses. Liabilities declined ¥54 million compared to the end of the previous fiscal year, to ¥399 million, primarily because interest-bearing debt fell ¥16 million and accounts payable, other decreased ¥25 million. Net assets declined ¥151 million, to ¥4,407 million, mainly due to a fall in retained earnings. As of the end of June, the company's total cumulative loss was ¥2,452 million.

While the company continues to record a loss, it is aiming to strengthen its financial structure and in the last fiscal year carried out equity financing that increased its cash and deposits in excess of ¥4,000 million. Management indicators of financial stability, such as equity ratio and interest-bearing debt to asset ratio, are at acceptable levels, and there seems little cause for concern for its funding up to FY12/16.

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Summary of the balance sheet

(¥ million)

	FY3/12	FY3/13	FY3/14 (cons.)	Q1 FY12/14 (cons.)	Absolute change
Current assets	1,096	1,084	4,514	4,297	-216
(cash and deposits)	1,013	988	4,349	4,143	-206
Property and equipment	169	211	498	508	10
Total assets	1,265	1,296	5,012	4,806	-205
Current liabilities	211	238	347	292	-54
Non-current liabilities	8	20	106	106	0
(interest-bearing debt)	84	132	20	4	-16
Total liabilities	220	258	453	399	-54
Shareholders' equity	1,045	988	4,502	4,380	-122
Capital stock	1,027	1,213	3,348	3,421	72
Capital reserves	1,017	1,203	3,338	3,411	72
Retained earnings	-1,000	-1,427	-2,184	-2,452	-267
Total net assets	1,045	1,037	4,559	4,407	-151
(Ratios of financial stability)					
Current ratio (current assets ÷ current liabilities)	517.7%	455.8%	1300.8%	1469.9%	
Equity ratio (equity capital ÷ total assets)	82.6%	76.3%	89.8%	91.1%	
Interest-bearing debt to asset ratio (interest-bearing debt ÷ total assets)	6.6%	10.2%	0.4%	0.1%	

■ Risks and Return to Shareholders

Delays in licensing agreement negotiations and R&D could depress sales and profit growth

(1) Risks

We see the following three potential risks to the business of the company.

○ Risk of delays in licensing agreement negotiations and R&D

Should there be a delay in licensing agreement negotiations with client candidates or should rupture of the agreement occur, or should the licensing of lead antibodies not progress as expected due to delays in R&D, or should the development be abandoned because of the results of assessments of efficacy or safety tests during the course of the drug development, which may arise at any time, there is the risk that these events could impact on the company's performance in the future.

○ Superior technologies could be developed

If a technology far superior to the ADLib® system for producing antibodies is developed, this system may not be able to maintain its competitiveness in the market.

○ High dependence on a single partner is potentially dangerous

The Chugai Pharmaceutical group accounted for 88.9% of the company's total sales in FY3/14. If the business relationship with the group deteriorated for some reason, the company's performance would be severely threatened.

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A policy of building a stable earnings base and investigating paying dividends as its financial condition and business performance improve

(2) Return to Shareholders

As the company still carries cumulative losses, it will not pay a dividend in the near future. However, after it establishes a basis for stable profits, its policy is that it will pay dividends that reflect its improved financial condition and business performance.

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