Chiome Bioscience Inc.
4583 Mothers

14-Aug.-14

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Ready to commercialize a fully human ADLib® system, the company has strong growth prospects

Chiome Bioscience Inc. is a biotechnology company that discover s 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 challenging antigens for which it is difficult to produce antibodies by other methods. Among its main business accounts are Chugai Pharmaceutical Co. Ltd. (4519) and Fujirebio Inc., a subsidiary of Miraca Holdings Inc. (4544).

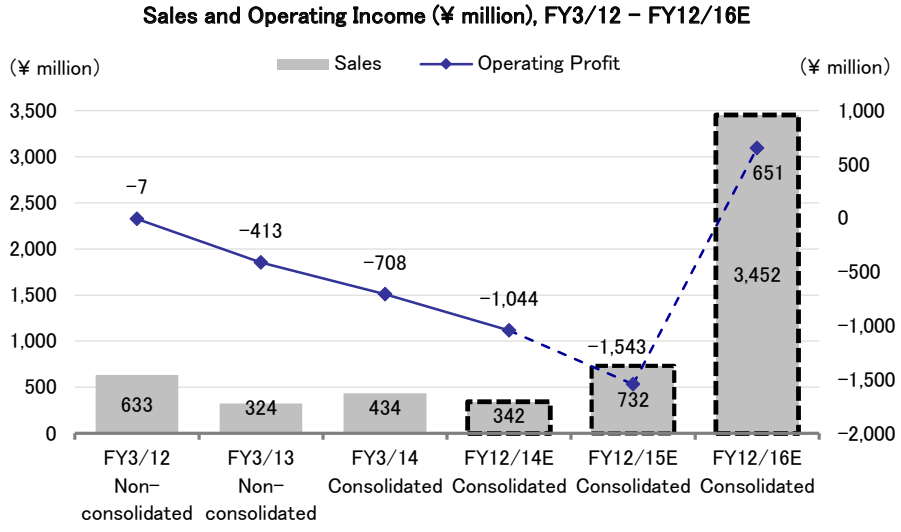
The fiscal year that ended in March 31, 2014, i.e., FY3/14, was the first fiscal year for which Chiome Bioscience reported consolidated results. In that year, the company reaped consolidated sales of ¥434 million, which was 34% year on year higher than its non-consolidated sales in FY3/13, of ¥324 million. This sales growth stemmed mainly from the renewal of the drug discovery alliance business with Chugai Pharmaceutical Co., Ltd. However, the company increased its R&D investment and other SGA expenses in FY3/14, resulting in a consolidated operating loss of ¥708 million, up from a non-consolidated operating loss of ¥413 million in FY3/13.

However, the company succeeded in developing a fully human ADLib® system, which it regards as the key to future growth—a system capable of directly generating human antibodies for the most intractable antigens, i.e. those for which it is difficult to obtain antibodies. Having completed the patent application process, the company is expected to benefit from an increase in drug discovery alliances and basic technology license agreements. Furthermore, a diagnostic kit that includes an antibody generated by the ADLib® system is expected to generate royalty income when sales of the kit begin following the launch of marketing in Europe by alliance partner Fujirebio Inc. This kit demonstrates the ability of the system to deal with intractable antigens, its key strength, and the commercial potential of the system .

In the three-year medium-term plan announced at the same time as the earnings update, Chiome Bioscience set itself a sales target of ¥3,452 million and an operating income target of ¥651 million for the final year of the plan ending December 2016—bringing operations out of the red for the first time. In the areas of drug discovery alliances and licensing out platform technology, the company will increase the number of fully human ADLib® system contracts signed, targeting pharmaceutical companies in Japan and overseas. Another aim is to generate earnings through the business of licensing out lead antibodies, creating multiple lead antibodies using the development know-how of LivTech, Inc., which became a subsidiary in December 2013. Now that the fully human ADLib® system has reached the point of commercialization, the company will probably grow strongly.

Main Points

- A biotechnology company specialized in basic technology for antibody drug discovery with a wide network of pharmaceutical partners in Japan and overseas
- About to commercialize a fully human ADLib® system
- The company strengthened its financial condition, raising its equity ratio to 89.8% at the end of March 2014



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

Company Description

A biotechnology company specialized in the platform technology for antibody drug discovery with a wide network of pharmaceutical partners in Japan and overseas

(1) Company History

Chiome Biotechnology is a biotechnology company specialized in a platform technology for antibody drug discovery. It was founded in 2005 by current president Masaaki Fujiwara to commercialize the ADLib® system, a technology platform developed by RIKEN for antibody discovery. After graduating with a master's degree, Mr. Fujiwara worked for Chugai Pharmaceutical Co., Ltd., the Japanese leading pharmaceutical company in the antibody medicines, from 1987 to 2000. From 2000 to 2003, he was in charge of clinical drug development project management and organization design for a leading non-Japanese consulting company. From 2003 to 2005, he served as a director of Quintiles Inc., the world's largest commissioned developer of clinical drugs. Thus, he has cultivated a wide network of contacts in the pharmaceutical industry, both in Japan and overseas.

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In April 2005, Chiome Bioscience entered an agreement with RIKEN for joint research to commercialize the ADLib® system and began this research. In July 2005, it obtained the exclusive right to sublicense the ADLib® system technology to third parties. In 2007, it concluded a joint research agreement with Chugai Pharmaceutical Co., Ltd. to produce antibodies using the ADLib® system, and in following years, it finalized similar contracts with many other companies, medical institutes, and universities, including Yokohama City University and the Japanese Foundation for Cancer Research. In 2010, Chiome Bioscience licensed the ADLib® system technology to Fujirebio Inc. on a non-exclusive basis. As of the end of April 2014, the company managed 11 main alliances, five with corporations in Japan and overseas and six with universities and medical institutes.

In December 2011, Chiome Bioscience listed its shares on the Mothers market of the Tokyo Stock Exchange, and in December 2013, the company took a 52.9% equity stake in biotechnology company LivTech, Inc., making it a subsidiary.

Company History

Feb. 2005	Established in Bunkyo Ward, Tokyo to commercialize the ADLib® system developed jointly by the Genetic Dynamics Research Unit of RIKEN, a unit then headed by Kunihiro Ota (now one of the external board member of Chiome Bioscience) and by the Saitama Small and Medium Enterprises Development Corporation (now the Saitama Industrial Development Corporation).
Apr. 2005	Concluded a joint research contract with RIKEN to commercialize the ADLib® system and began research.
May 2005	The ADLib® system was published in Nature Biotechnology.
Jul. 2005	Obtained the exclusive right to sublicense the ADLib® system technology to third parties.from RIKEN and the Japanese Science and Technology Agency.
Jul. 2007	Concluded a joint research agreement with Chugai Pharmaceutical Co., Ltd. to produce antibodies using the ADLib® system.
May 2008	To expand its research facilities, the company transferred its research laboratory to the RIKEN WAKO Incubation Plaza.
Oct. 2008	Concluded a joint research agreement with Yokohama City University for antibody discovery using the ADLib® system.
Nov. 2008	Concluded an alliance agreement with Chugai Pharmaceutical Co., Ltd. to produce antibodies developed using the ADLib® system.
Oct. 2009	Moved the head office to Shinjuku Ward, Tokyo.
Apr. 2010	Concluded a joint research agreement with the Japanese Foundation for Cancer Research for antibody discovery using the ADLib® system.
Aug. 2010	Concluded a patent transfer agreement on the ADLib® system's basic technology with the Japanese Science and Technology Agency.
Sep. 2010	Concluded an agreement to license the ADLib® system to Fujirebio Inc. and to conduct research with that company.
Jan. 2011	Obtained a 50% patent right to the ADLib® system basic technology from RIKEN and concluded an agreement with the institute for joint discovery activities.
Nov. 2011	Concluded a joint research agreement with Five Prime Therapeutics, Inc. for antibody discovery using the ADLib® system.
Dec. 2011	Listed shares on the Mothers market of the Tokyo Stock Exchange.
Feb. 2012	Concluded a comprehensive joint research agreement with the Shizuoka Cancer Center for antibody discovery using the ADLib® system.
Apr. 2012	Concluded a joint research agreement with the Glaxo Group Limited for antibody discovery using the ADLib® system.
Jul. 2012	Concluded a joint research agreement with the National Cancer Center of Japan for antibody discovery using the ADLib® system.
Aug. 2012	Concluded a basic agreement on the procurement of research materials needed to conduct R&D on efficient antibody medicines for Chugai Pharmabody Research Pte., Ltd., a Singapore subsidiary of Chugai Pharmaceutical Co., Ltd.
Jan. 2013	Concluded an agreement with Biotecnol, Inc., of the U.S., for the joint development of antibody medicines using the ADLib® system and the technology of Biotecnol, Inc. The companies also signed an option agreement.
Dec. 2013	Took a 52.9% equity stake in biotechnology company LivTech, Inc. and made it a subsidiary.
Jan. 2014	Fujirebio's diagnostic kit, which contained specific antibodies developed using the ADLib® system, was launched in Europe.
Mar. 2014	Chiome Bioscience completed to establish a fully human ADLib® system for commercial use.

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*1 Antibody drugs are based on the antigen-antibody reactions that naturally protect the human body from disease. Pharmaceutical companies develop antibodies that target specific antigens.

Global market for antibody medicines is now ¥4 – 5 trillion per year

(2) Position of Antibody Drugs among Medical Agents

The quality of medical agents varies depending on their production method and raw materials. Among these, medical agents that target and control specific molecules that pose health hazards are called molecular targeted drugs. These are commonly used to treat diseases such as allergenic diseases, cancer and rheumatism. Molecular targeted drugs can be subdivided into two types depending on their molecular type: small-molecule drugs and biological drugs including antibody drugs. Chiome Bioscience develops antibody drugs*1.

Although small-molecule drugs currently account for more sales than antibody drugs, in many applications, antibody drugs are superior to small-molecule agents in terms of their treatment effects and persistency. In addition, antibody drugs generally cause fewer undesirable side effects than small-molecule agents. Consequently, leading pharmaceutical companies throughout the world are aggressively engaging in R&D into antibody medicines.

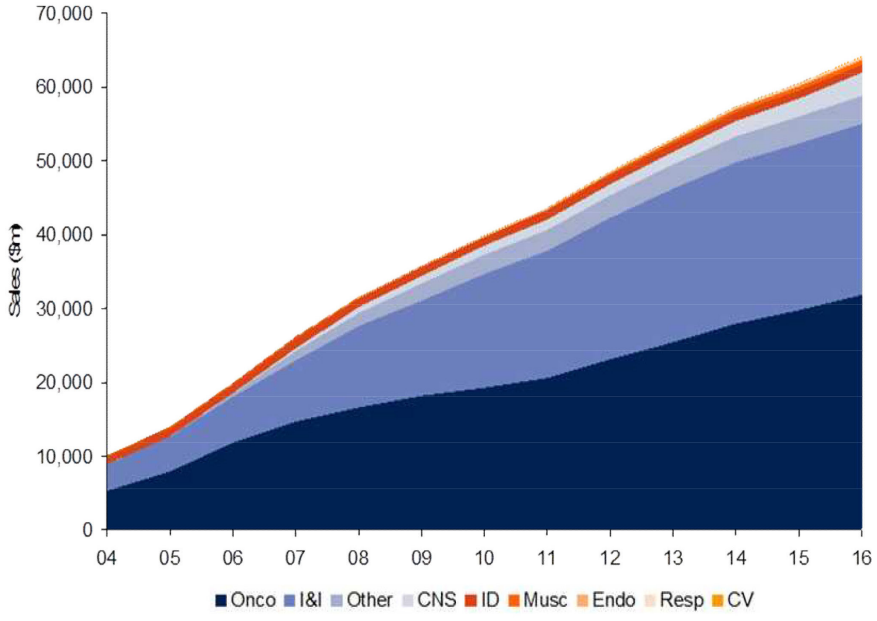
Comparison of Antibody Drugs and Small-Molecule Agents

	Antibody drugs	Small-molecule agents
Side effects	Because of their high target specificity, they do not harm normal cells and have fewer side effects.	Those with low target specificity might cause side effects.
Therapeutic effects	Attack therapeutic targets directly with greater and durable effects on diseases such as cancer, allergies and inflammatory diseases by harnessing immunological mechanism.	Generally used for treatment of infectious diseases or chronic therapy for diseases such as circulatory diseases. Sometimes used for symptomatic treatment.
Administration method	Mainly intravascular administration	Intravascular, oral or subcutaneous administration
Persistency	Long half-life in the blood	Relatively short
Target specificity	High	Relatively low
Production method	Animal cell protein production or microbial production	Chemical synthesis or microbial production

Source: Chiome Bioscience

The global market for monoclonal antibodies has grown rapidly since the mid-2000s, and the market size is estimated at ¥4 – 5 trillion per year. Market research companies forecast that it will grow by 10 – 20% per year to about ¥6 trillion by 2016. Only 30 – 40 antibody drugs are now officially permitted. Each of the top five drugs, used to treat cancer, rheumatism and other diseases, generates annual sales of ¥600 billion or more independently, which is quite large in the industry. Including drugs under development, there are 300 – 400 antibody drugs.

Forecast of Global Market (US$mn) for Antibody Medicines



Source: Monoclonal Antibodies Market Analysis Update 2011 by Datamonitor, a division of Informa plc.

Another reason that pharmaceutical companies are undertaking R&D into antibody drugs aggressively is that they are more commercially viable than small-molecule agents. Of all antibody drugs that reach clinical trials, 22% are successfully marketed. For small-molecule agents, this rate is only 5%. Furthermore, from the time a target is specified for an antibody drug, the drug can enter clinical trials in as little as three years, which is much shorter than the development period for small-molecule agents. Thus, antibody drugs cost less to develop than small-molecule agents.

In the development of most drugs, the developer ties up with a pharmaceutical company in Phase II*2 of clinical trials of the drug. However, for about 80% of antibody drugs, the developer ties up with a pharmaceutical company before the drug enters clinical trials. This allows the developer to reduce its R&D cost and recoup its investment quickly.

*2 The normal schedule for drug commercialization is as follows: development → clinical trials (Phases I - III) → application for production and sales → regulatory approval → marketing. Phase I trials test the safety of a drug on sick and healthy people. Phase II trials test the effectiveness, safety and mechanism of a drug on a limited number of sick people. Phase III trials test the effectiveness and safety of a drug on a large number of sick people.

Superiority of ADLib® system over other antibody production systems

(3) ADLib® System

The ADLib® system was developed by RIKEN as a method for antibody discovery in 2002. Most of therapeutic monoclonal antibodies now on the market were discovered by one of two methods: the mouse hybridoma method, which was established about 38 years ago, or the phage display method, which was established about 22 years ago. These two methods have a number of problems: only a limited number of antibody candidates (with unique gene sequences) can be discovered, antibodies take a long time to produce, and there are many antigens for which it is difficult to discover antibodies. The ADLib® system was developed to resolve these problems. Its merits are its diversity of antibodies, its speed of antibody production, and its ability to deal with difficult antibodies. One disadvantage, until recently, was an inability to produce fully human antibodies. However, generation of fully human antibodies became possible in March 2014, meaning that the ADLib® system is now ready for full-scale practical use.

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

	ADLib® system	Hybridoma method	Phage display method
Applicability to difficult antigens	**Applicable**	Partially applicable	Partially applicable
Antibody production time	**Approx. 10 days**	Approx. 6 months	2.5 – 3.5 months
Amount of antigen needed	**10 – 100 μg**	mg level	approximately 500 μg
Automation	**Yes**	No	**Yes**
Ability to produce fully human antibodies	**Most human antibodies**	**Yes**	**Yes**

Note: Characteristics highlighted in bold letters are advantages of ADLib® system

Simply stated, in the ADLib® system, the diversification of antibody genes in DT40 cell line established from chicken lymphocyte is activated to generate the antibody library. Antigen-specific DT40 cells are isolated by magnetic beads coated with the target antigen. Antigen-specific antibodies can be harvested by culturing those cells for about a week.

By utilizing the intrinsic gene diversification mechanism in DT40 cells or manipulating the antibody genome in these cells, the ADLib® system can generate broader antibody diversity than other antibody production systems, and indeed is theoretically capable of limitless diversity.

Shortening the time required to develop an antibody drug contributes to its sales growth. As shown in the table above, the ADLib® system produces antibodies in about 10 days, which is much faster than the production times for the other two methods (6 months for hybridoma and 2.5 to 3.5 months for phage display). Rapid antibody discovery is one of the advantages of the ADLib® system in antibody drug development. The shorter the development time before antibody pharmaceuticals be brought to market, the greater the contribution to sales, it is said. Because patents covering antigens expire after 20 years, speed is another benefit of the ADLib® system.

The ADLib® system can also be used to discover antibodies for "difficult" antigens, those for which access by other antibody generation methods is difficult, such as pathogenic toxins or proteins that are conserved across species by evolutionary mechanisms. Furthermore, the ADLib® system can be applied to G protein-coupled receptors, a group of antigens for which it is difficult to produce antibodies and which is now the target of antibody development. Several small-molecule agents against diseases caused by these antigens are 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 difficult to produce an antibody. The generation of therapeutic antibodies for them would expand the market for antibody drugs substantially. The ADLib® system has the greatest advantage for this generation, compared to other methods.

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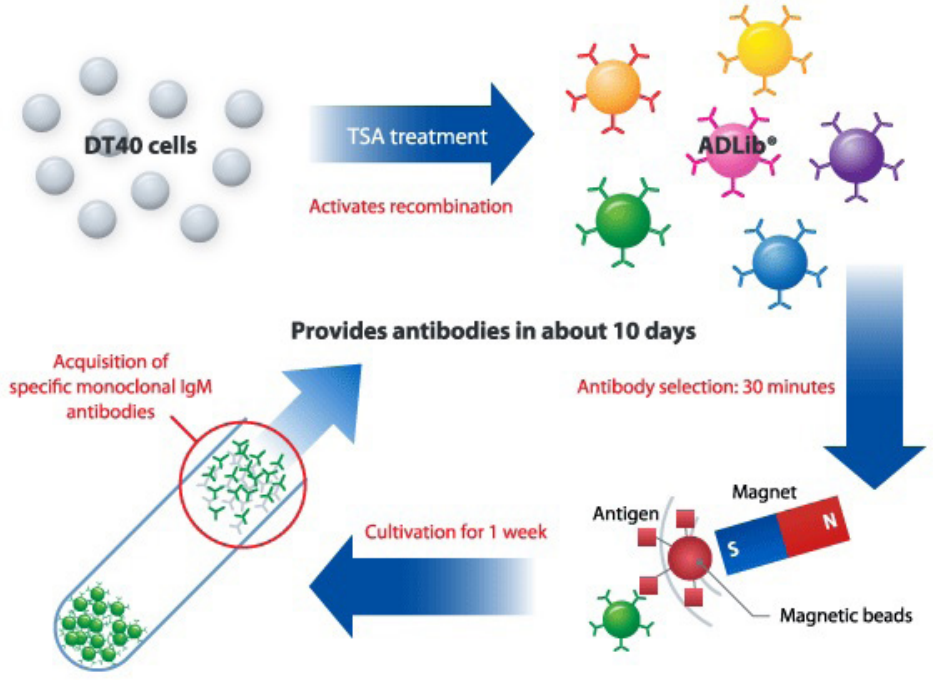
Diagram Showing How the ADLib® System Produces Antibodies

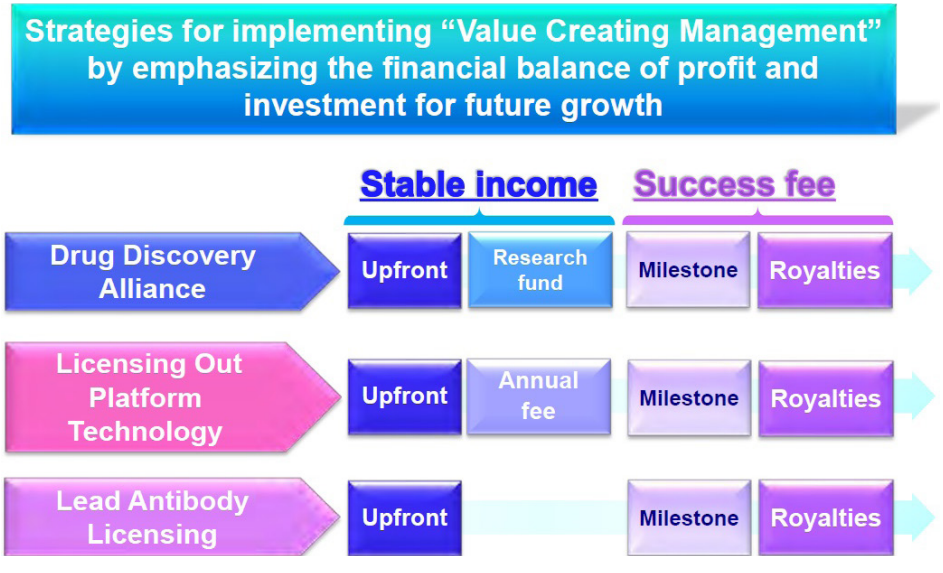


Three business pillars based on ADLib® system

(4) Overview of Business Structure

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

Revenue Source by Business



The drug discovery alliance business generates 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. Revenue consists of upfront income when a joint R&D contract is concluded, milestone income reflecting R&D expenses and progress, and royalty income after a drug is marketed. In this business, Chiome Bioscience retains at least a 50% share of the right to a developed antibody, so it provides greater added value than traditional 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 non-clinical development, → 3.5 – 5 years for clinical studies → 1 – 2 years for review → approval and marketing.

The Chugai Pharmaceutical group of companies remains a key account for this segment. In fact, business with this group accounted for 88.9% of Chiome Bioscience's total sales in FY3/14.

The licensing out platform technology business is the second pillar, in which Chiome Bioscience licenses the ADLib® system to other companies, which use this technology to produce antibodies. From this business Chiome Bioscience obtains upfront income when a licensing contract is concluded, annual license fees, milestone income reflecting the progress in antibody development, 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 (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 Inc. commenced sales in Europe of a diagnostic kit that includes an antibody generated 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 Chiome Bioscience in the discovery or pre-clinical stage. These antibodies are generated 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.[*3] In the future, this business model will generate upfront income from a licensing agreement, 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, Chiome Bioscience is collaborating with several organizations, including Yokohama City University, University of Tokyo, the National Cancer Center, and Biotecnol, Inc.

The ADLib® system is patented in Japan, the U.S., Europe and China. The patent rights are shared equally by Chiome Bioscience and RIKEN. Chiome Bioscience pays a royalty to RIKEN. This patent will expire in Japan, Europe and China in 2023, and those in the U.S. will expire in 2025, but Chiome Bioscience has been taking measures to strengthen and extend its commercial life, including the patenting of the fully human ADLib system. Thus, Chiome Bioscience should retain a strong patent position even after the existing patent expires.

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

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
Chugai Pharmaceutical Co., Ltd.	7/2011 - 12/2014	Service agreement to support R&D using the ADLib® system
Chugai Pharmabody Research Pte., Ltd.	8/2012 - undisclosed	Service agreement on the procurement of research materials necessary for R&D using the ADLib® system
Licensing out platform technology business		
Fujirebio Inc.	For life of patent	Produce and sell in-vitro diagnostic agents, including antibody produced 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 to produce antibodies
Lead antibody licensing business		
Yokohama City University	10/2008 - 3/2014	Develop a specific antibody for the semaphorin molecule
Biotecnol, Inc.	2/2013 -	Jointly discover and develop novel and high value-added therapeutic antibodies that cannot be expected from conventional technology

Source: Company materials and Japanese Securities Report

Applying LivTech's technology to develop new antibodies

(5) New Subsidiary LivTech, Inc.

In December 2013, Chiome Bioscience invested about ¥90 million for a 52.9% stake in LivTech, Inc., making the company a subsidiary. LivTech is a biotechnology company founded in 2004 with experience in developing antibodies for cancer stem cell antigens. The company has developed two antibodies. In 2011, it licensed one of these lead antibodies to Yakult Honsha Co., Ltd. (2267) for joint R&D toward the production of a cancer medicine. 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.

Chiome Bioscience acquired LivTech to obtain LivTech's expertise in the early stage development of antibodies and its knowledge of commercializing an antibody. Chiome Bioscience also gained access to LivTech's animal facility. By combining LivTech's know-how with its ADLib® system, Chiome Bioscience will be able to accelerate its development of antibodies to counter the antigens causing cancer, autoimmune diseases, and contagious diseases.

Chiome Bioscience posted its first consolidated financial results in FY3/14 to reflect the acquisition of LivTech.

Business Trends

Sales grew but increased investment expanded losses

(1) FY3/14 Results

On May 15, 2014, Chiome Bioscience announced its business results for FY3/14, reporting consolidated sales of ¥434 million and a consolidated operating loss of ¥708 million. Non-consolidated sales grew 27.3% year on year to ¥412 million, but the non-consolidated operating loss increased to ¥690 million, from ¥413 million in FY3/13 because of increased investment in R&D and personnel and the costs of moving the head office. Most of the increase in R&D expenses stemmed from the development of the fully human ADLib® system and the consolidation of R&D facilities. The company expanded its work force from 31 employees at the end of March 2013 to 67 employees at the end of March 2014.

Business Results in FY3/13 - FY3/14

(¥ million)

	FY3/13		FY3/14				
	Non-consolidated		Non-consolidated		Consolidated		
	result	vs. sales	result	y-o-y	forecast	result	vs. sales
Sales	324	-	412	27.3%	435	434	-
Drug discovery alliance business	318	98.4%	-	-	-	417	95.9%
Lead antibody licensing business	-	-	-	-	-	-	-
Licensing out platform technology business	5	1.6%	-	-	-	18	4.2%
Cost of sales	119	36.8%	-	-	-	173	40.0%
SGA expenses	617	190.6%	-	-	-	969	223.0%
R&D expenses	309	95.5%	-	-	-	442	101.8%
Operating loss	-413	-	-690	-	-687	-708	-
Ordinary loss	-424	-	-692	-	-689	-706	-
Extraordinary loss	-	-	-37	-	-	-37	-
Net loss	-426	-	-748	-	-739	-757	-

Note: Company forecasts are as of May 15, 2014

In the drug discovery alliance business, sales grew from ¥318 million on a non-consolidated basis in FY3/13 to ¥417 million on a consolidated basis in FY3/14. Most of this growth came from the renewal of a joint R&D contract with Chugai Pharmaceutical Co., Ltd. The business received milestone income from the Glaxo Group, but its contract with this group expired in September 2013. The business also recorded some sales generated by LivTech, Inc. from non-clinical trials on its LIV-2008 antibody medicine against cancer being developed with Yakult Honsha Co., Ltd.

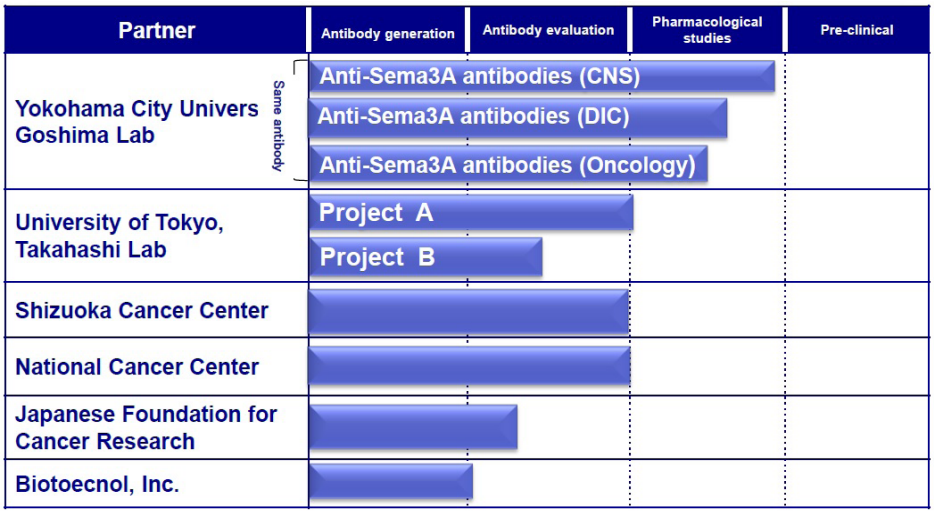
In the licensing out platform technology business, sales grew from ¥5 million on a non-consolidated basis in FY3/13 to ¥18 million on a consolidated basis in FY3/14, due mainly to an extension of the contract with Fujirebio Inc., which launched European sales in December 2013 of an in-vitro diagnostic kit that includes an antibody produced with the ADLib® system for detecting vitamin D. This diagnostic kit is the first commercial application of an antibody produced with the ADLib® system.

The lead antibody licensing business continued to generate no sales in FY3/14. Anti-semaphorin 3A antibody was studied in collaboration with Yokohama City University. Anti-semaphorin 3A antibody showed significant effect in the treatment of sepsis in a mouse model, but the antibody has not yet been licensed for this indication. Chiome Bioscience is expanding potential indications to the treatment of cancer and disseminated intravascular coagulation (DIC*4). Data suggests that this antibody may be effective in controlling the migration of cancer cells from tumors of the pancreas, lung and brain, indicating that it could combat cancer metastasis. In February 2014, it filed for international patents on the application of this antibody against cancer, and it plans to further develop the antibody for this purpose.

Chiome Bioscience is executing other joint research projects to develop antibodies with partners. Chiome Bioscience and Biotecnol, Inc., a U.S. biotechnology company that is developing the TribodyTM technology, a multispecific antibody technology, have been collaborating in study to generate innovative lead antibodies, through a fusion with the ADLib® system. Chiome Bioscience and the Clayton Medical Research Foundation, of the U.S., have signed an agreement for collaborative research on therapeutic antibodies against cancer.

Illustration title: Progress on Joint R&D Projects Conducted by the Lead Antibody Licensing Business.

Progress on Joint R&D Projects Conducted by the Lead Antibody Leasing Business



L ivTech Inc. has completed efficacy, toxicity and other animal tests on its LIV-1205 anti-cancer therapeutic antibody and is seeking a pharmaceutical company partner to further develop the antibody.

Brought fully human ADLib® system close to commercialization

(2) Major Accomplishments in FY3/14

Despite the ongoing losses booked in FY3/14, Chiome Bioscience achieved some notable accomplishments during the fiscal year that should contribute to future growth. Most notable was the establishment of the fully human ADLib® system and successful generation of human antibodies. The lack of a human library in the ADLib® system was one reason that Chiome Bioscience could not get as many contracts with pharmaceutical companies as expected, since other technologies to generate human antibody are available. Now that the company has a fully human system in hand, the number of its deals is likely to grow.

*4 DIC, disseminated intravascular coagulation, is a condition in which there is continuous blood coagulation throughout the body. Small platelets form in blood vessels and cause organ failure and hemorrhage. This condition is usually triggered by septicemia, acute leukemia and similar problems. In Japan, about 73,000 people a year are afflicted by DIC, and 42.4 – 56% of these people die of this syndrome.

As mentioned previously, in December 2013, Fujirebio Inc. commenced marketing in Europe an in-vitro diagnostic kit containing an antibody generated by the ADLib® system. This demonstrated the ADLib® system's ability to generate an antibody for a challenging antigen for which conventional methods are not applicable, and should heighten the reputation of the system. Furthermore, indications that the anti-semaphorin 3A antibody could be applied in oncology raise the probability of licensing this antibody.

Equity ratio rose to 89.8% at the end of March 2014

(3) Financial Condition

At the end of March 2014, cash and deposits grew by ¥3,361 million compared with the end of March 2013, mainly because of the ¥4,271 million proceeds of stock issuance accompanying the exercise of equity warrants issued in March 2013. Property and equipment increased by ¥256 million, reflecting the relocation of the head office and the R&D laboratory. Consequently, total assets expanded by ¥3,716 million to ¥5,012 million. Interest-bearing debt declined by ¥111 million, but advances received, accounts payable, other, and other liabilities increased. Therefore, total liabilities grew by ¥194 million. Due to the exercise of equity warrants, shareholders' equity increased by ¥4,271 million, but the net loss suffered in FY3/14 raised cumulative losses to ¥2,184 million.

The equity ratio at the end of March 2014 rose by 12.5 ppts to 89.8%, indicating a strong financial position.

Summary Balance Sheet at the end of March 2013 and March 2014

(¥ million)

	FY3/13	FY3/14	Absolute change	Reasons for change
Current assets	1,084	4,514	3,429	
Cash and deposits	988	4,349	3,361	Increase in proceeds of stock issuance accompanying the exercise of equity warrants
Property and equipment	117	373	256	Relocation of head office and R&D lab
Intangible assets	9	51	42	Goodwill accompanying investment in LivTech
Investments and other assets	85	72	(12)	
Total assets	1,296	5,012	3,716	
Current liabilities	238	347	109	Advances received grew by ¥68 million; accounts payable, other rose by ¥75 million
Non-current liabilities	20	106	85	Asset retirement obligations grew by ¥47 million
Interest-bearing debt	132	20	(111)	
Total liabilities	258	453	194	
Shareholders' equity	988	4,502	3,513	Increase in proceeds of stock issuance accompanying the exercise of equity warrants
Cumulative losses	(1,427)	(2,184)	(757)	
Ratios of financial stability				
Current ratio (current assets ÷ current liabilities)	455.8%	1300.8%		
Equity ratio (Equity capital ÷ total assets)	76.3%	89.8%		
Interest-bearing debt to asset ratio (interest-bearing debt ÷ total assets)	10.2%	0.4%		

■ Medium-term Plan

Targets consolidated sales of ¥3,452 million and operating income of ¥651 million for FY12/16

(1) Outline of new medium-term plan

In May 2013, the company announced a plan for FY3/14 – FY3/16 with non-consolidated targets calling for initial profitability in FY3/15. The new plan for FY12/14 – FY12/16, with consolidated targets, postpones profitability until the final year, when the company foresees a surge in sales to ¥3,452 million and an operating income of ¥651 million. The company postponed its forecast of profitability because it plans to further finalize its fully human ADLib® system in FY12/14 to boost the company's enterprise value and increase the likelihood of greater contracts, revenue and profits from this system. In addition, the company will invest aggressively in R&D to expand the pipeline of antibodies under development in the lead antibody licensing business and to strengthen development before the clinical testing stage.

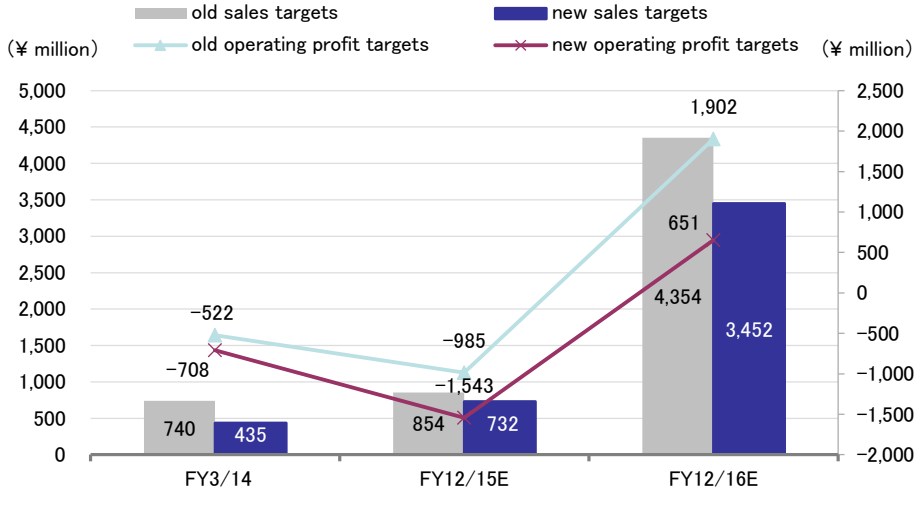
Consolidated Business Results Targeted in the Medium-term Plan

(¥ million)

	FY12/14 (9 mos)		FY12/15		FY12/16	
	forecast	vs. sales	forecast	vs. sales	forecast	vs. sales
Sales	342	–	732	–	3,452	–
Drug discovery alliance business	312	91.2%	366	50.0%	614	17.8%
Lead antibody licensing business	0	0.0%	300	41.0%	460	13.3%
Licensing out platform technology business	30	8.8%	66	9.0%	2,378	68.9%
Cost of sales & SGA expenses	1,386	405.3%	2,275	310.8%	2,801	81.1%
R&D expenses	636	186.0%	1,224	167.2%	1,490	43.2%
Other costs	750	219.3%	1,051	143.6%	1,311	38.0%
Operating income (loss)	-1,044	–	-1,543	–	651	18.9%
Ordinary income (loss)	-1,042	–	-1,541	–	655	19.0%
Net income (loss)	-1,044	–	-1,503	–	670	19.4%
No. of employees	81	–	87	–	90	–

Note: Old targets were set in May 2013, non-consolidated, and for FY3/14 – FY3/16
Reflecting a change of fiscal year, the term to 12/14 contains nine months

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



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

Increases in technology licenses and licenses of lead antibodies to lead sales growth

(2) Forecasts of Sales by Business

Even though FY12/14 will contain only nine months of operations, the company forecasts that consolidated sales for this irregular period will total ¥342 million or ¥7 million more than consolidated sales in the same 9-month period in FY3/14. In the drug discovery alliance business, the company projects a ¥13 million year-on-year drop in sales to ¥312 million. It expects continued strong business with Chugai Pharmaceutical Co., Ltd. and also some additional plans for new businesses. On the other hand, the company forecasts a ¥20 million year-on-year rise in sales to ¥30 million in the licensing out platform technology business, mainly reflecting royalty payments from Fujirebio Inc. on sales of its in-vitro diagnostic kit.

For FY12/15, the company projects that its consolidated sales for the full year will be ¥732 million, more than twice as much as that of the previous fiscal year (irregular 9-month period). In the drug discovery alliance business, the main factor is likely to be an increase in contracts for tests using the fully human ADLib® system. Likewise in the lead antibody licensing business, it is expected that a sales contribution will come through license-out of anti-semaforin 3A antibodies.

For FY12/16, the company anticipates a surge in sales to ¥3,452 million, led by a massive jump in sales by the licensing out platform technology business, reflecting the evolution of the fully human ADLib® system. An increase in the lead antibody licensing is also seen raising sales in that business.

Aiming to be an efficient organization with a small, elite workforce effectively using external resources

(3) Operating Expenses

R&D expenses comprise a large proportion of the company's total operating expenses. Over the next three fiscal years, the company intends to allocate its R&D expenses to improve the fully human ADLib® system, to expand its pipeline of antibodies under development, and to undertake non-clinical tests of antibodies in joint R&D with other companies.

Chiome Bioscience intends to increase its workforce from 67 employees at the end of March 2014 to 90 employees at the end of December 2016. Basically, it aims to operate efficiently with a small, highly qualified staff and to rely on external personnel to handle non-core business. In FY12/15, it plans to open an office in the U.S. and to increase the number of contracts with non-Japanese companies. In FY12/16, it aims to open an R&D center in the U.S.

Because the company had cash and deposits of more than ¥4,300 million at the end of March 2014, it should not need to raise additional funds for operations in FY12/14 - FY12/16.

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Chiome Bioscience Inc.
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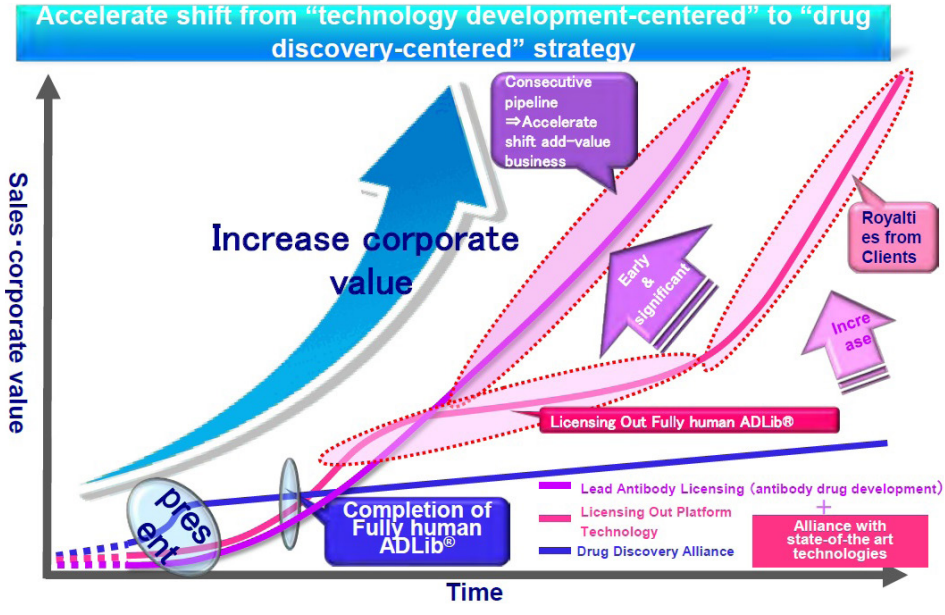
*5 Unmet medical needs are diseases for which an effective therapy has not been developed, even though it is greatly desired. Cancer and Alzheimer's Disease are typical examples of such diseases.

By shifting emphasis from technology development to drug discovery, aims to build a business model offering greater added value

(4) Long-term Business Strategy

As shown in the diagram below, over the long term, the company aims to build a business model offering greater added value by shifting emphasis from technology development to drug discovery. Reflecting its ability to generate many kinds of antibodies, including those for antigens that are difficult to match, the ADLib® system has infinite possibilities to address unmet medical needs*5. This system is the optimal tool needed for the company to realize its vision of personalized medicine.

Long-term Business Strategy



Development of antibody medicines with large market potential could propel growth

(5) Recent Examples of Agreements to License Basic Technology for Antibody Medicines

As explained previously, the market for each antibody medicine is large. The fees to license basic 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 Chiome Bioscience 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: Chiome Bioscience

■ Risks and Return to Shareholders

Adverse changes in relationships with a business partner could depress sales and profit growth

(1) Risks

We see the following three potential risks to the business of Chiome Bioscience.

○The growth potential of antibody medicines could decrease

The market for antibody medicines may not grow as much as currently projected, for several reasons. If the mechanisms and pathologies of diseases were clarified, small-molecule agents that target specific antigens or molecules could be developed for specific diseases. Systems could be developed for the delivery of small-molecule agents to specific sites of disease, thereby reducing the adverse side effects of these medicines. Finally, the number of small-molecule agents that compete with antibody drugs could increase.

○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 Chiome Bioscience's total sales in FY3/14. If the relationship with the group deteriorated for some reason, Chiome Bioscience's business would be severely threatened.

Creation of a stable earnings base, with dividends to be paid as 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, it would pay dividends reflecting its improved financial condition and business performance.

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