Carna Biosciences, Inc.

4572 TSE JASDAQ

15-Apr.-16

Important disclosures and disclaimers appear at the end of this document.

FISCO Ltd. Analyst
Yuzuru Sato

Engaged in the production and sale of kinase protein and the discovery and development kinase inhibitor drugs

Carna Biosciences, Inc. <4572> is a bioventure company that provides drug discovery and support services, including the production, sale and outsourcing of kinase proteins, which are intracellular signaling substances, to pharmaceutical companies, other bioventures and public research institutes such as universities, and also engages itself in creating kinase inhibitor drugs aimed at diseases which have high, unmet medical needs.

In its FY12/15 results, the Company recorded its first profitable full-year since its establishment, with sales up 156.5% y-o-y to ¥1,569mn, and operating income of ¥472mn (compared with an operating loss of ¥634mn in the previous period). In addition to securing ¥614mn in revenues from a lump sum contractual payment in its Drug Discovery and Development business, through the derivation of immunological disease pipeline compounds for Janssen Pharmaceutical, Inc. of the US, in its Drug Discovery Support business also, the provision of a large scale contract screening service to Ono Pharmaceutical Co., Ltd. <4528>, and sales expansion mainly surrounding leading North American bioventures were factors behind the significant growth in revenues and earnings.

The Company has not disclosed its consolidated FY12/16 results outlook, however, it has adopted a conservative plan in the Drug Discovery Support business calling for a 10% y-o-y decline in sales to ¥858mn, and a 22% decline in operating income to ¥320mn. It is expected that, given that the Company anticipates ¥566mn in R&D expenses, if it doesn't record sales in its Drug Discovery and Development business, it will record a loss of around ¥400mn on a profit basis. However, apart from the possibility of a determination on the derivation of the CDC7ASK inhibitor drug for cancer diseases, as a candidate in FY12/16, it may obtain milestone revenues if clinical trials are commenced for the products derived for Janssen Biotech in June last year.

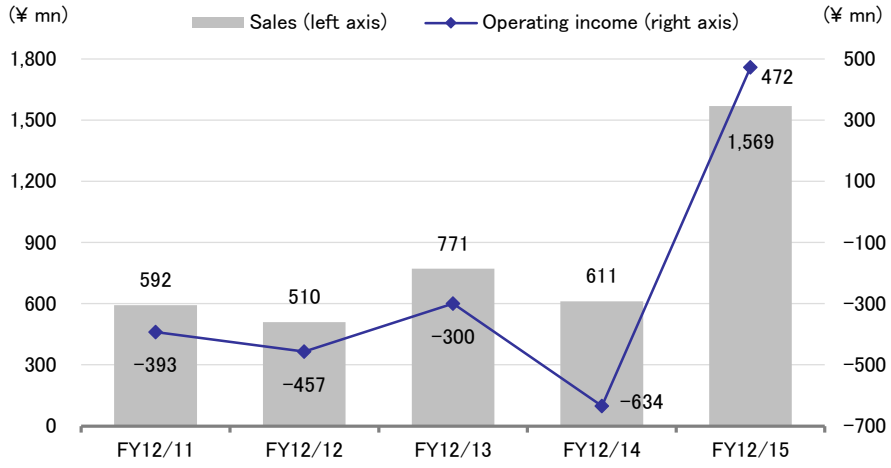
The Company's business strategy aims to secure stable revenues from core drug discovery support operations with world class kinase protein production technology and measurement technology that evaluates whether compounds are inhibiting kinase* functions. Further, through upfront investment of income secured it seeks to promote R&D in drug discovery. Also, it is a strategy where, by expanding its track record of deriving pharmaceutical pipeline compounds for pharmaceutical companies and others that have been created through the Company's R&D, it obtains high future returns. In FY12/15, by creating its initial track record for derivation, expectations are rising in respect of concluding further derivation agreements. In February 2016 it established a new research base in the US, CarnaBio C-Lab. As it is in an area where many bioventures and academia are gathered, not only is the acquisition of leading edge technology and its development expected from this base, just by being a base to establish a human network with local businesses and academics, in promoting future derivation activities, we feel that its establishment is significant, with future developments to be watched closely.

* Kinase is a kind of enzyme that exists inside cells, being a phosphoric acid enzyme that mainly fulfils the function of transmitting a range of signals within cells. In normal kinase signals (stimuli) are received from outside the cell, creating a state where phosphorus is added (active kinase), with adding phosphorus to separate kinase involved in the control of, amongst other things, cell proliferation, cell division and cell death. Further, the state where phosphorus is not added is called inactive kinase (dormant state). It is said that 518 varieties of kinase exist, with many of them used as drug discovery targets.

Check Point

- Kinase inhibitor drugs possess high therapeutic value and few side effects, and may be mass produced
- Securing stable income from the Drug Discovery Support business, and injecting funds into R&D into the Drug Discovery and Development business
- FY12/15 sales set a new, significantly higher record high, with profits in the black for the first time since establishment

Results trends



■ Company overview

Kinase inhibitor drugs possess high therapeutic value and few side effects, and may be mass produced

(1) Corporate history

The Company was established in Kobe, Hyogo Prefecture in April 2003, by way of spin-off of the pharmaceutical research facility of Dutch pharmaceutical major Organon's Japanese entity Nippon Organon K.K., aimed at developing a drug discovery businesses specializing in kinase.

It established its corporate headquarters and laboratory in April 2003 in the Kobe International Business Center (KIBC) in Kobe City. In 2004 it set up a laboratory for animal testing in the Kobe Business Support Center for Biomedical Research Activities and commenced animal testing. In March 2008 it listed its shares on the JASDAQ NEO exchange, and the following month established a sales subsidiary, CarnaBio USA, as its first overseas base. From 2010 it has focused in earnest on drug discovery research, and in June 2015, in a first for the Company, concluded a pipeline compound licensing agreement with Janssen Biotech, one of US Johnson & Johnson's pharmaceutical divisions.

Corporate history

Date	Major events
April 2003	Established in Kobe, Hyogo Prefecture, with the spin-off of Nippon Organon K.K., aimed at developing a drug discovery businesses specializing in kinase
October 2003	Commenced operations in the Kobe International Business Center
August 2004	Established a new facility at the Kobe Business Support Center for Biomedical Research Activities and commenced animal testing
October 2007	Established a new chemical testing facility at the Kobe Healthcare Industry Development Center
March 2008	Listed on the JASDAQ NEO exchange (currently JASDAQ)
April 2008	Established CarnaBio USA, Inc. in the US
December 2008	Integrated its headquarters and research facility, shifting to the Kobe Business Support Center for Biomedical Research Activities
October 2013	Made Probex K.K. a fully-owned subsidiary by way of simplified share swap
June 2015	Concluded an exclusive global licensing agreement with Janssen Biotech of the US in relation to the development and commercialization of pipeline compounds created by the Company

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* Molecular targeting drugs are drugs that respond to certain molecules that form the cause of a disease, and inhibit the function of those molecules.

(2) Special characteristics of kinase inhibitor drugs

Anti-cancer and other medications to date have produced serious side effects, placing a considerable physical and mental burden on the patient compared to the therapeutic benefits. In 2001, following the approval by the US FDA of Gleevec as having application for chronic myelogenous leukemia, there has been a succession of kinase inhibitors that have come into general circulation. Special characteristics cited for these kinase inhibitor drugs include that they may be taken in oral form, and compared with previous drugs have high therapeutic benefits with few side effects. As a result, R&D for kinase inhibitor drugs is being promoted by major global pharmaceutical companies and research institutes as representative of molecular targeting drugs*. R&D is also undertaken actively on antibody drugs (high polymers) as molecular targeting drugs, however, examining the differences between low molecular weight drugs and antibody drugs, given that antibody drugs are biopharmaceuticals and require large scale cell culturing facilities in their production, medication costs are extremely high, with treatment at a hospital also required as they are injections, they arguably place a considerable burden on the patient. On the other hand, given that kinase inhibitor drugs are low molecular weight drugs, apart from being able to keep medication costs low by allowing mass production through chemosynthesis, because they are oral medicines that may be prescribed for home usage, the low burden placed on the patient forms another special characteristic.

(3) Kinase inhibitor drug discovery research process

In drug discovery research for kinase inhibitors, one first determines the specific target kinase for the disease in question on which drug discovery research will be undertaken. Then, one makes a selection by way of a screening process for hit compounds that have the potential to inhibit this specific kinase's function. Then one selects several types of compounds that are likely drug candidates from amongst the hit compounds and, based on this, further synthesizes similar compounds to undertake optimization of the molecular structure to promote enhanced selectivity and reduction in side effects. For example, if there is a target kinase A, a compound that inhibits only A is important in developing a drug which has few side effects. Testing to determine which kinase functions a compound inhibits and which it does not is called "profiling". After this sort of research process is completed, drug candidate compounds to proceed to preclinical trials are identified from the compounds that have been optimized.

In the research process for a series of kinase inhibitor drugs, what is important is the evaluation system for drugs used in screening and profiling (called "assay systems"). This is because if the quality of the kinase used in the assay system, the precision of the measuring systems, or the ability to duplicate results is not high, it is difficult to select good drugs, and it also lowers the research efficiency. For the Company, its know-how in screening and profiling and production technology for high quality kinase are its strengths. As of March 2016 the Company possessed 347 varieties of kinase and 422 products, making it a world leader in terms of number of kinases produced, with its possession of technological capabilities to produce high quality kinase also one of its strengths. By way of reference, it is said that 518 varieties of kinase exist in human cells and thus less than 70% are covered. Competitors that undertake kinase production and screening services include US Thermo Fisher Scientific Inc. and German Merck Millipore.

Broadly categorized, there are low molecular weight drugs and antibody drugs. Antibody drugs inhibit the binding of proteins such as ligand, mainly in the receptors on the surface of cells. Because they are cultured and produced within the cell the production cost is high. Further, as they are biopharmaceuticals it is difficult to produce the identical drug and it is hard to create generics. While they contribute to pharmaceutical company sales, on the other hand they are a cause of financial pressure in broader healthcare economics. Additionally, given that they are injected treatments, they are required to be administered at a hospital. In comparison, low molecular weight drugs penetrate into the cell and control the function of a range of molecules within the cell. Accordingly, it is possible to control them precisely against the kinase that is responsible for signal transmission within cells, and as well as being able to expect significant therapeutic benefits if inhibiting a particular kinase function is possible, these drugs have few side effects. Also, as they may be prescribed as tablets or capsules, may be taken at home, and can be produced inexpensively by chemosynthesis, a special characteristic is the potential to curb medication costs. When their products are replaced by generic drugs, sales at pharmaceutical companies decline dramatically; however, the dissemination of innovative drugs at low cost means they may be used in developing countries, which has enormous social significance.

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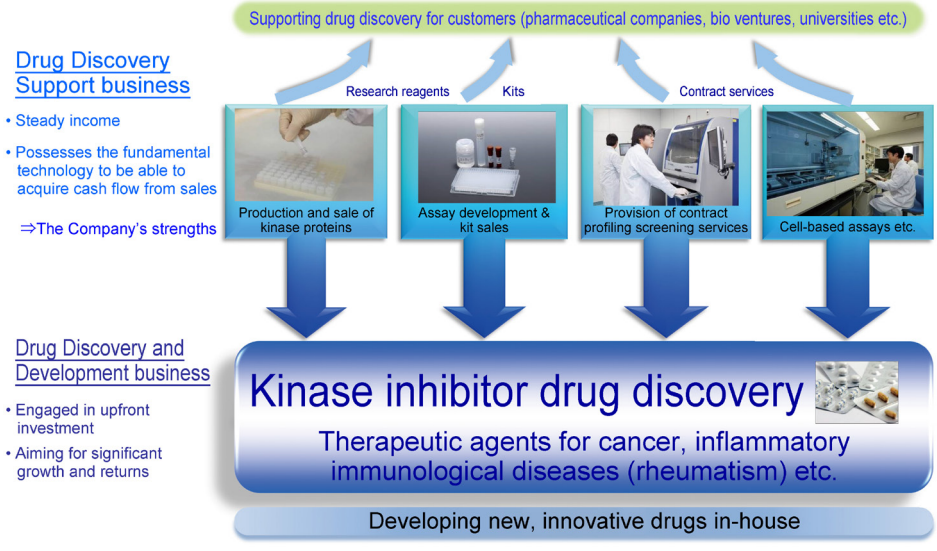
Securing stable income from the Drug Discovery Support business, and injecting funds into R&D in the Drug Discovery and Development business

(4) Business model

As well as the parent, the Group comprises two consolidated subsidiaries (CarnaBio USA, Inc. and ProbeX K.K.), and is divided into two business segments: the “Drug Discovery Support business” and the “Drug Discovery and Development business.” Know-how on kinase production technology as well as profiling, screening and other technology required in kinase inhibitor research forms the Company’s fundamental technology. At the Company, the business model aims to achieve high growth and returns by utilizing these fundamental drug discovery technologies, obtaining stable income from the Drug Discovery Support business, deploying funds into drug discovery research development, and licensing out drugs discovered. The core of the Company’s operations is drug discovery, and it aims to have the pharmaceuticals created from its proprietary drug discovery activities delivered to patients around the globe.

The Company’s business model



Source: Results briefing materials

○ **Drug Discovery Support business**

The Drug Discovery Support business involves the sale and provision of products and services to pharmaceutical companies, universities and other research facilities to support drug discovery research they are engaged in. Kinase proteins used in kinase inhibitor drug discovery research and assay kits*1 are the products sold. Contract services include carrying out screening and profiling of the compounds that form the foundation of drugs produced by pharmaceutical companies and others, assay development in respect of kinases specifically requested by customers, as well as the provision of cell-based assay services developed by the Company or companies it is collaborating with. Amidst the development of kinase inhibitor research, cell-based assay services respond to customer needs for lower costs and faster evaluation of compounds at a cellular level. Further, at its subsidiary ProbeX, it undertakes research development and provides stable cell lines based on complementary split luciferase assay technology*2. The majority of the Group’s sales are represented by kinase protein sales and screening and profiling contract services. The main customers for these services are domestically Ono Pharmaceutical and Gilead Sciences Inc., of the US.

*1 Assay is the term for measurement testing, referring to checking how much a test compound inhibits or doesn’t inhibit a target kinase function, with the kinase required for testing, buffering solutions etc. being sold as a kit.

*2 Complementary split luciferase assay technology refers to a technique utilizing a phenomenon whereby the luciferase (an enzyme present in the body of the light-emitting organisms, such as fireflies) DNA sequence is divided into two at an appropriate juncture, and each of these pieces is introduced into a cell to produce luciferase protein fragments within the cell that do not exist in the natural world. When these protein fragments become physically close within the cell, even though they are divided, light emission is restored.

○ **Drug Discovery and Development business**

The Company's drug discovery business fully employs its fundamental drug discovery technology in relation to the kinases it possesses, with its unique fundamental drug discovery technology and research team capable of creating it being points of differentiation with other companies.

In respect of derivations for Janssen Biotech also, this was from results generated by the Company's fundamental drug discovery technologies, with the Company's drug discovery pipeline created entirely in-house or in collaboration with, for example, academia, and not from themes introduced from other companies. In its own facilities, the Company has fully fledged chemical laboratories synthesizing compounds, with facilities to evaluating in vitro (in test tube), in vivo (intracellular) and via animal model trials. The Company has completed investment in the major items of laboratory equipment.

Also, in current derivation negotiations for drug candidate compounds, the accuracy of results data for each of the trials carried out by the Company was assessed by J&J, and the high evaluation received also appears to be a major factor behind being allowed to conduct the derivation.

In drug discovery, the Company's basic policy is to carry out R&D to the Phase IIa stage in clinical trials and license out at one of the stages to that point, with the business model being to receive compensation for that derivation by lump sum payment, milestone income as developmental stages are reached, or royalty income after the drug has come to market. Currently it is planning derivation at the preclinical trial stage; however, in the mid-term management plan referred to below, the Company plans to carry out clinical trials itself and hopes to increase derivation remuneration of drug candidate compounds by advancing them to the clinical trial stage.

Further, post-derivation, the research resources invested in the derived theme may be invested into other latent themes held by the Company. Arguably, its ability to continually create new drug discovery pipelines from its fundamental drug discovery technology is one of the Company's strengths.

The Company has selected unmet medical needs (where innovative treatment methods haven't been established) as the core of its drug discovery research themes, undertaking research into cancer, and inflammatory immunological diseases as key disorder areas. Drugs with sales over ¥100bn are referred to as blockbusters, with research and development being undertaken on its drug discovery pipeline, towards the goal of producing drugs that can become the Company's blockbusters.

■ Results trends

FY12/15 sales set a new, significantly higher record high, with a profits in the black recorded for the first time since establishment

(1) FY12/15 consolidated results

The FY12/15 consolidated results saw sales up 156.5% y-o-y to ¥1,569mn, operating income of ¥472mn (versus a loss of ¥634mn in the previous period), ordinary income of ¥492mn (versus a loss of ¥607mn in the previous period), and net income of ¥456mn (versus a loss of ¥846mn in the previous period). Sales set a significantly higher record high, and from a profit perspective, the Company achieved its first profit for the first time since establishment.

In addition to securing ¥614mn in revenues from a lump sum contractual payment in the Drug Discovery and Development business through its first license-out agreement, in the Drug Discovery Support business also, the provision of a large scale contract screening service to Ono Pharmaceutical causing sales to expand significantly and perform well was a factor behind the significant growth in the Company's sales and income. Also, while sales and income were ahead of the Company's plans, this was also due to sound performance in domestic and North American sales and improved productivity in its contract services in the Drug Discovery Support business.

Consolidated FY12/15 results

(Unit: ¥mn)

	FY12/14		FY12/15				
	Actual results	% of sales	Company plan	Actual results	% of sales	y-o-y	Vs Plan
Sales	611	-	1,532	1,569	-	156.5%	102.4%
Gross profit	378	61.9%	-	1,299	82.8%	243.1%	-
SG&A	1,013	165.7%	-	826	52.7%	-18.4%	-
(R&D expenses)	561	91.8%	-	417	26.6%	-25.7%	-
Operating income	-634	-103.8%	372	472	30.1%	-	127.1%
Ordinary income	-607	-99.3%	395	492	31.4%	-	124.6%
Extraordinary income (loss)	-237	-	-	-6	-	-	-
Net income	-846	-138.4%	364	456	29.1%	-	125.4%

Note: Figures in the Company plan announced July 2015

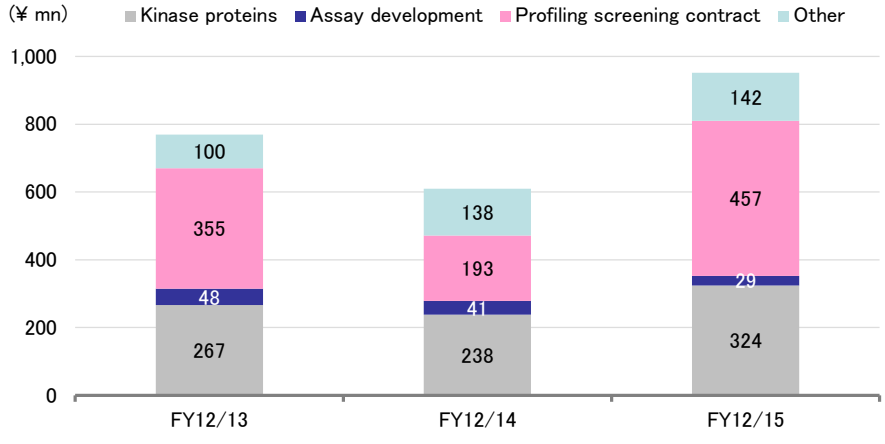
(2) Trends by business segment

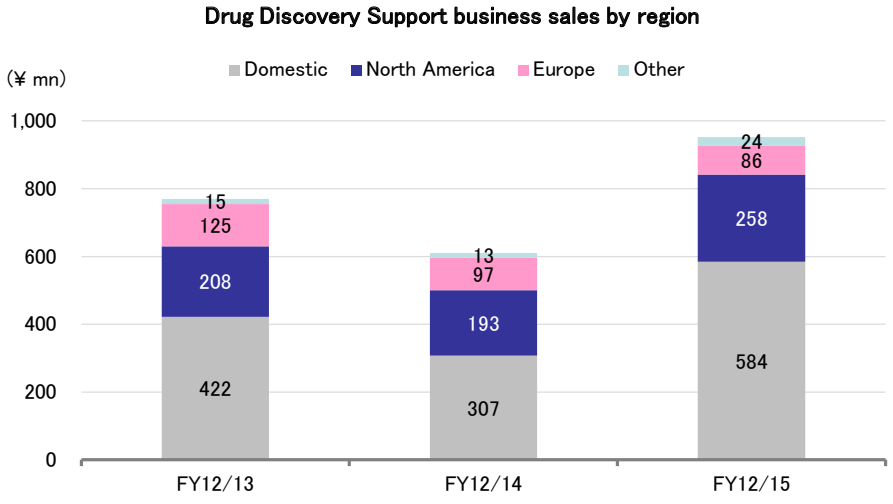
○ **Drug Discovery Support business**

There was significant expansion in both sales and income, with sales in the Drug Discovery Support business rising 56.0% y-o-y to ¥954mn, and operating income up 720.4% y-o-y to ¥412mn. Looking at a breakdown of sales, contract services for screening profiling grew significantly by 136.5% y-o-y to ¥457mn. Through the conclusion of a large scale contract agreement with Ono Pharmaceutical in February 2015, sales for Ono Pharmaceutical rose dramatically from ¥180mn in the previous period to ¥317mn, which was also a major factor behind sales growth. Kinase proteins also performed well, rising 36.3% y-o-y to ¥324mn. The quality of the Company's kinase is highly regarded, a factor behind the sound trend in inquiries from North American bioventures and other customers. In addition to increased revenues, significant improvement in productivity at contract services was a factor behind increased operating profit.

Looking at sales trends by region, domestic sales rose 90.3% y-o-y to ¥584mn, North American sales by 33.8% y-o-y to ¥258mn and European sales declined by 11.2% y-o-y to ¥86mn, while other rose 76.4% y-o-y to ¥24mn. A factor behind growth in domestic sales was the increased screening profiling sale for Ono Pharmaceutical referred to above. Also, in North America the growth in sales reflected increased kinase protein sales and solid performance in profiling screening services. Inquiries for profiling screening services increased, especially at Gilead Sciences, US.

Drug Discovery Support business sales breakdown



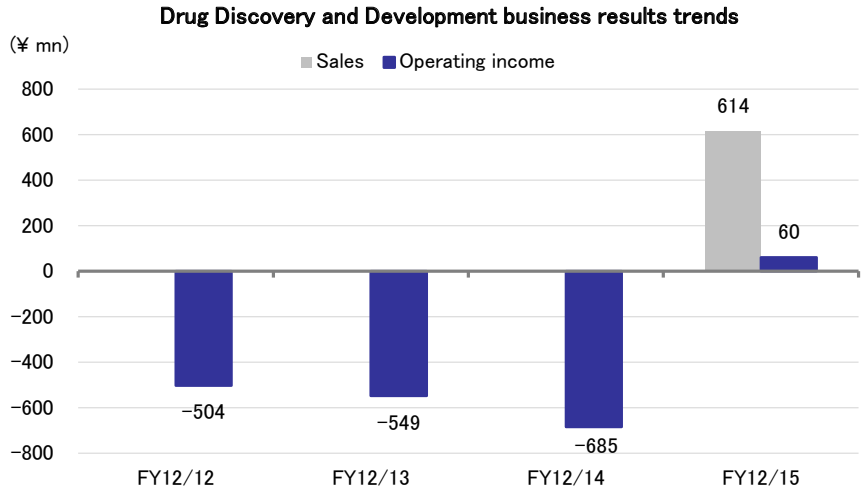


(2) Drug Discovery and Development business

Sales in the Drug Discovery and Development business were ¥614mn (being nil in the previous period), and operating income was ¥60mn (versus a loss of ¥685mn in the previous period), being the first time a profit has been recorded. In June 2015, the Company succeeded in deriving drug candidate compounds targeting rheumatoid disorders for Janssen Biotech and received a lump sum contractual payment. That agreement grants exclusive global development and commercialization rights, and in the future, apart from milestone payments as each step in the development process is made, it also includes royalty income in line with product sales after the drug comes to market. As it generally takes 5-10 years from commencing clinical trials to coming to market, we feel that even at the earliest it will be 2020 or later before the company receives steady royalty income.

The market size for anti-rheumatic drugs is approximately ¥2 trillion for antibody drugs. For kinase inhibitor drugs, US Eli Lilly is engaged in Phase III clinical trials, with annual sales of at least ¥300bn expected. In respect of kinase inhibitors successfully derived by the Company also, good data results have been obtained from animal model trials, and if sales approvals can be obtained then sales in the order of several hundred billion yen may be expected. If they have the same level of efficacy as antibody drugs, given that they have the merits of being cheaper, having fewer side effects, and being orally administered with a lower burden of hospital visits, we feel there is a strong possibility they will replace antibody drugs.

Moreover, in this business R&D into multiple drug candidate compounds focusing on kinase inhibitors is being promoted either independently or in cooperation with academia, with multiple pipeline products currently at the development stage referred to as preclinical trials. As such, if there are no licensing agreements or milestone payments, losses will be recorded in the amount of operating costs, based mainly on R&D expenses. This a characteristic feature of bioventures undertaking upfront investment in R&D. Going forward results will continue to close in the red or black depending on the presence or absence of income, and only at the stage when the Company's compounds come to market and it receives royalty income from the pharmaceutical companies it has derived for, will it gain stable revenues. Also FY12/15 R&D expenses were ¥417mn (compared with ¥561mn the previous period).



Shareholders' equity ratio rose as a result of increased retained earnings due to profitability

(3) Financial status

Looking at the financial status at the end of FY12/15, total assets grew ¥1,116mn year-on-year to ¥2,337mn. Major factors behind the growth were increases of ¥998mn in cash and deposits, ¥96mn in accounts receivable, and ¥45mn in investment securities.

On the other hand, total liabilities rose by ¥75mn from the previous period end to ¥467mn. Major factors behind the rise included increases of ¥52mn in interest bearing liabilities and ¥31mn in accrued tax payable. Net assets rose ¥1,040mn to ¥1,870mn. This rise reflected increases in paid-in capital and capital reserves of ¥547mn in line with the issue of new share warrants, as well as an increase in retained earnings as a result of recording a net income of ¥456mn. Due to profitability this period the Company's financial position improved, with the shareholders' equity ratio rising from 67.2% to 79.7% and the interest bearing debt ratio declining from 13.2% to 9.1%.

Going forward, while it depends on the state of progress in drug candidate compound development and negotiation for licensing-out agreements in the Drug Discovery and Development business, the Company has strengthened the revenue platform in the Drug Discovery Support business, and is developing a structure whereby the majority of R&D expenses in the Drug Discovery and Development business are covered by revenues from the Drug Discovery Support business. As a result, the Company is expected to become more stable from a financial perspective also.

Consolidated balance sheets

(Unit: ¥mn)

	FY12/12	FY12/13	FY12/14	FY12/15	Amount changed
Current assets	913	1,361	907	1,995	1,088
(Cash and deposits)	654	1,067	626	1,624	998
Noncurrent assets	203	527	313	341	27
Total assets	1,116	1,888	1,221	2,337	1,116
Total liabilities	236	291	391	467	75
(Interest bearing debt)	134	140	160	213	52
Total net assets	880	1,597	830	1,870	1,040
(Safety indicators)					
Shareholders' equity ratio	78.9%	84.1%	67.2%	79.7%	
Debt/equity ratio	12.0%	7.4%	13.2%	9.1%	

■ Future outlook

Outlook for solid performance in kinase protein sales to be maintained

(1) FY12/16 Outlook

The Company's FY12/16 results outlook is not disclosed. This is because the public announcement of plan targets would be disadvantageous in derivation negotiations in its drug discovery business, and the earnings outlook is fluid as it is highly dependent on contract trends and hard to ascertain at this point. However, disclosure is made in respect of the Drug Discovery Support business, where lower revenues and earnings are expected, with sales down 10.0% y-o-y to ¥858mn and operating income down 22.4% y-o-y to ¥320mn. The main reason is a projected ¥91mn y-o-y decline in screening and profiling contract services. However, given that orders from its main customer Ono Pharmaceutical are somewhat fluid this is arguably a conservative figure. Also, the outlook does not include a certain scale of screening services the Company is focusing on mainly domestically and in North America. Moreover, it does not anticipate any revenue from its RPPA business. That is because this business is a service that investigates whether kinase is activated within cells, and due to the bankruptcy of the South Korean company that was the supplier of glass slides used in the process, supply of glass slides has been halted. Currently the Company is seeking an alternate manufacturer of glass slides. On the other hand, the outlook for kinase protein sales is for continued sound performance with sales up ¥41mn over the previous period. A factor behind this is the expanding demand for the Company's high quality products, amidst greater kinase inhibitor development activity by North American bioventures.

Drug Discovery Support business sales outlook

(Unit: ¥mn)

	FY12/14	FY12/15	FY12/16 (E)	Amount changed
Total	611	954	858	-95
Kinase proteins	238	324	366	+41
Assay development	41	29	30	+0
Contract screening profiling	193	457	366	-91
RPPA	23	14	-	-14
ProbeX	0	6	15	+8
Crelux (purchased products)	24	-	5	+5
ACD (purchased products)	65	50	34	-16
NTRC (purchased products)	16	58	28	-30
Other	8	13	13	+0

In R&D expenses, the Company plans a ¥149mn y-o-y increase to ¥566mn, based mainly on strengthening its R&D structure in its Drug Discovery and Development business. Apart from adding three new research staff, including new graduates, in April 2016, it also includes the costs of establishing its US research facility CarnaBio C-Lab in February 2016. R&D costs are also expected to increase going forward.

Based on the above, results for FY12/16 in the event that no sales are recorded in the Drug Discovery and Development business are conservatively estimated as sales of ¥858mn and around ¥400mn in operating losses. However, in the Drug Discovery and Development business, apart from milestone income if Phase I clinical trials are started in 2016 under the contract concluded in June 2015 with Janssen Biotech, in respect of the CDC7/ASK inhibitor in the development pipeline, because there is the possibility it may be derived within 2016, if either of these developments progresses, they will be factors adding to revenue and earnings.

(2) Significance of CarnaBio C-Lab's establishment

The company considers it extremely significant that it was able to establish CarnaBio C-Lab as its North American research base. This base is within J&J's incubation laboratory, JLABS. The location is a cradle for biotech research, with many bioventures located within the laboratory, as well as research bases for companies that have grown into megapharma players, including Amgen and Genentech. Through their research activities at this base, research staff will be able to form mutual networks, and will be able to share the latest intelligence from the bioindustry. Further, not only will it promote drug discovery technology research, it will allow networks to be created that will be crucial in undertaking future derivation activities. This laboratory's occupancy rate appeared high at about 20x; however, it is felt that the Company's track record in derivation for J&J Group company Janssen Biotech and its fundamental drug discovery technology in relation to kinase inhibitors were highly regarded, making the Company's entry possible. At present only one researcher is undertaking research activities full-time; however, as staff capacity is up to four it is thought there will be successive staff increases.

Two projects have progressed to preclinical trials in the drug discovery development pipeline

(3) Trends in the development pipeline

Currently, there are two themes in projects that have progressed to preclinical trials in the drug discovery development pipeline, with both of them kinase inhibitors targeting cancer diseases. The status of major engagements in the pipeline is as set out below.

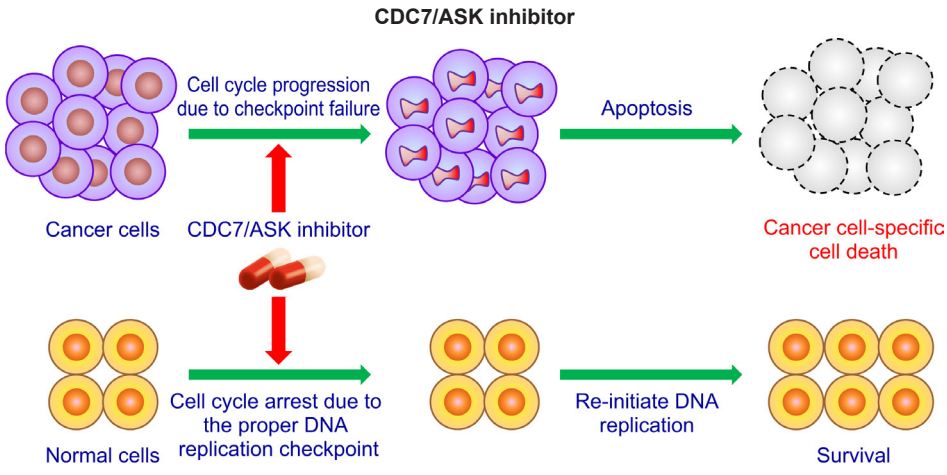
Development pipeline status

Compound	Target kinase	Target disease	Lead Generation	Lead Optimization	Candidate Selection	Preclinical trials	Clinical trials	Application for approval – going to market
Small molecules	Kinase	Immunological diseases	Out-licensed to Janssen Biotech US in June 2015					
AS-141	CDC7/ASK	Cancer						
Back-up compound								
NCB-0846	Wnt-signal (TNIK)							
NCB-0594								
Small molecules	kinase	Leukemic stem cells						
		Autoimmune diseases						
	N/A	Malaria						
	Kinase	Neurodegenerative diseases						
		Anemia						

○ **CDC7/ASK inhibitor drugs**

Regarding the kinase inhibitor CDC7/ASK, which targets cancer diseases, in its independent research, the Company is using external contractors to undertake preclinical trials. Trials are scheduled to be completed at the end of H1 2016 at the earliest. If it were not to proceed to clinical trials, it appears that a back-up compound would be used and proceed again to preclinical trials. Currently, it is at the stage of negotiations for derivation with multiple companies, and if contractual terms can be agreed upon it is possible derivation work will start in 2016. Developments going forward will be keenly watched.

It has been made clear that CDC7/ASK kinase plays a crucial role in inhibiting cell cycle activity (gene duplication during cell division), and by inhibiting activation of that kinase, cancer cells may be eradicated. Because it is not targeting a specific gene, it is possible it may be applicable for a range of carcinomas, and is being closely watched as an innovative cancer treatment drug with few side effects. The basic policy at the Company is to tackle unmet medical needs, and it is initially progressing development of triple-negative breast cancer treatment.

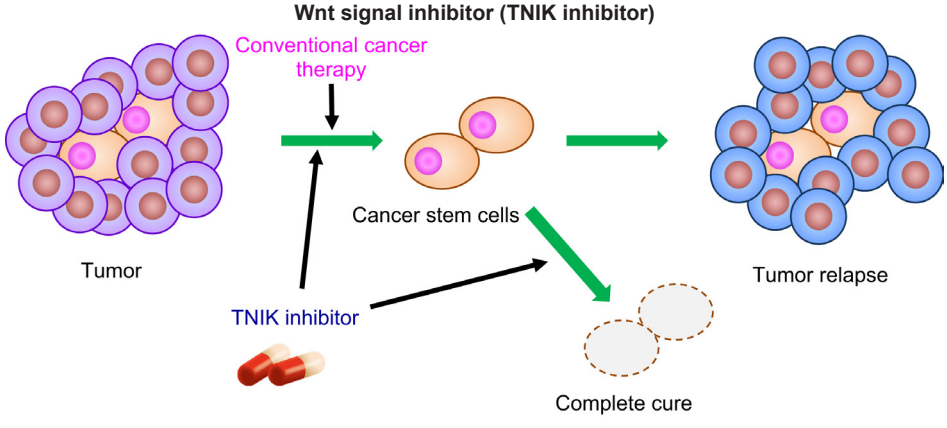


Source: Results briefing materials

○ **Wnt signal (TNIK) inhibitor**

The Wnt signal inhibitor drug that targets cancer diseases is a joint research theme undertaken in collaboration with the National Research and Development Agency's National Cancer Center, with preclinical trials being carried out based primarily at that Research Center.

It is understood that the Wnt signal is activated in cancer stem cells in colon and other cancers, supporting these stem cells, and it has also become clear that the TNIK kinase is deeply involved in inhibiting Wnt signals. By administering TNIK inhibitors targeting cancer stem cells, the Wnt signals within cancer stems cells are forcibly inhibited, and the cancer stems cells may be eradicated. In existing cancer agents, because they only eradicate cancer cells the risk of the cancer recurring remains; however, if a TNIK inhibitor is used, as it is possible to eradicate the cancer stem cell, it is hoped that it will become a definitive treatment without the risk of cancer recurrence. Research is currently underway to step up to the next stage, including combined treatment with animal models.



Source: Results briefing materials

○ **Other**

Amongst other items in the pipeline being closely watched, in respect of the kinase inhibitor targeting leukemia stem cells, where joint research is being promoted with Hiroshima University, currently compounds are being optimized, and it is felt it will proceed to the next step—selecting candidate compounds—by 2017. Leukemia treatments include chemotherapies employing anti-cancer agents and hematopoietic stem cell transplantation; however, in either case there are powerful side effects. Kinase inhibitors Imatinib (product name Glivec®) and ibrutinib (product name Imbruvica®) exist, with both of them having sales in the range of several hundred billion yen. However, both are drugs to inhibit leukemia cell proliferation, being palliative treatments that do not eradicate leukemia stem cells. The kinase inhibitor drug being developed by the Company aims to be a definitive therapy that eradicates leukemia stem cells. If R&D proceeds, the market value is expected to be significant. Accordingly, the Company has indicated its R&D policy for this treatment method is to undertake up to Phase II Clinical trial itself, which confirm efficacy and patient safety, and after raising its market value undertake derivation. Moreover, the outlook for R&D expenses up to Phase II clinical trials is in the order of ¥2bn.

Further, in kinase inhibitors targeting neurodegenerative diseases, the Company is optimizing compounds for use as treatment drugs for Parkinson's disease. Parkinson's disease is brought on by reduction in dopamine, which is a neurotransmitter within the brain responsible for body movement, caused by necrosis of the substantia nigra, which produces dopamine. Currently, the typical treatment method is to take multiple drugs that supplement dopamine, inhibit dopamine degradation, and so forth. The kinase inhibitor that the Company is promoting development of is a drug that inhibits the necrosis of the substantia nigra itself.

Promoting a multitude of joint projects with fundamental drug discovery technologies involving kinase

(4) Mid-term management plan basic policy

The basic policy of the Company's mid-term management plan (2016-2018) references the following three points.

- Based on its derivation track record to megapharma, realize the derivation of multiple drug discovery pipelines
- Commence its own preclinical trials aimed at expanding its Drug Discovery and Development business
- Secure stable income in its drug discovery support business

In the Drug Discovery Support business, the strategy is to make sales and operating income key management indicators, while seeking continuous business growth and expansion of the earnings base. In the Drug Discovery and Development business, the Company will focus on R&D and promote mid- to long-term strengthening of the overall earnings base. As it possesses world class fundamental drug discovery technology involving kinase, the Company is promoting multiple joint research projects with academia, and with CarnaBio C-Lab, established in Southern San Francisco in the US in 2016 as a base, by developing new drug discovery technology in North America and networks with local bioventures and research institutions. The Company aims to promote further growth towards building an operational platform, and thus anticipates further growth in the future.

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