



Bridge Report EIKEN CHEMICAL (4549)

 President Morifumi Wada	Company	EIKEN CHEMICAL CO., LTD.	 EIKEN CHEMICAL CO., LTD.
	Code No.	4549	
	Exchange	Tokyo Stock Exchange, First Section	
	Industry	Pharmaceuticals (manufacturing)	
	President	Morifumi Wada	
	HQ Address	Yamaguchi building 7, 4-19-9, Taito, Taito-ku, Tokyo 〒110-8408	
	Business Description	Major manufacturer of clinical diagnostics. Its immunochemical fecal occult blood test reagents occupies over 50% share of the domestic market. It is strengthening its molecular genetics. It is proactive in forming alliances.	
	Year-end	End of March	
	URL	http://www.eiken.co.jp/en/	

— Stock Information —

Share price	Number of shares issued (excluding treasury shares)		Total market cap	ROE (Actual)	Trading unit
1,910 Yen	18,256,169 Shares		34,869 million yen	8.3%	100 shares
DPS (Est.)	Dividend yield (Est.)	EPS (Est.)	PER (Est.)	BPS (Actual)	PBR (Actual)
35.00 Yen	1.8%	102.43 Yen	18.6times	1,323.98 Yen	1.4 times

*Share price is as of the end of October 30. The number of shares issued is from the latest financial settlement report (excluding treasury shares from the number of shares issued). ROE and BPS are based on actual results at the end of the first term.

— Business Performance Trends —

(Unit: Million yen, Yen)

Fiscal Year	Net Sales	Operating Income	Ordinary Income	Net Income	EPS	DPS
March 2010 (actual)	26,841	1,902	2,011	1,214	66.87	25.00
March 2011 (actual)	27,562	2,709	2,775	1,672	92.06	30.00
March 2012 (actual)	27,702	2,363	2,543	1,460	80.38	30.00
March 2013 (actual)	28,645	2,548	2,812	2,453	134.98	35.00
March 2014 (actual)	30,027	3,008	3,095	1,984	109.13	35.00
March 2015 (estimate)	31,320	2,900	2,930	1,870	102.79	35.00

*The figures for the fiscal year ending March 2015 are based on the estimates made by EIKEN CHEMICAL.

This Bridge Report presents EIKEN CHEMICAL's earnings results for the first half of fiscal year March 2015.

—Table of Contents —

- [1. Company Overview](#)
- [2. Characteristics and Strengths](#)
- [3. First Half of Fiscal Year March 2015 Earnings Results](#)
- [4. Fiscal Year March 2015 Earnings Estimates](#)
- [5. Interview with President Morifumi Wada](#)
- [6. Conclusions](#)

Reference: New Management Plans "EIKEN WAY" and "EIKEN ROAD MAP 2009"

Key Points

- EIKEN CHEMICAL is a general manufacturer of clinical diagnostics. It offers many products that occupy high market share including fecal occult blood test reagents with about 57% of the domestic share. Its unique gene amplification technology, “LAMP,” is highly recognized world-wide. With the fecal occult blood tests and LAMP, EIKEN aims to grow into a global corporation.
- Net sales for first half of fiscal year (FY) 2015 were 15,800 million yen, up 5.0% year-on-year. Domestic sales were affected by a rebound from increased demand before the consumption tax increase, but recovered from June onwards. Recovery of the American market and other factors led to overseas sales increasing 45.7% year-on-year. With research and development costs shifting into Q3, operating income and ordinary income both had double-digit increases. Sales did not quite reach planned amounts, but income surpassed planned amounts.
- There is no change in the estimates for FY 2015. Sales are planned to increase 4.3% compared to the previous year. The domestic increase will be minor, but overseas sales are expected to expand mainly in Europe and China, as well as recovery in America. However, significant increase in investment in research and development and facilities will cause profit to decrease. Dividends of 35 yen/share are planned, the same as the previous year.
- With the closing of the FDA's warning letter, the American market has begun to recover. As mentioned in President Wada's comment, hopefully this will prove a valuable lesson and further improve the quality of products. In the short term, there is the possibility that the recovery of the American marketplace for fecal occult blood test reagents and devices and their adoption in France may increase overseas sales for the fiscal year. In the mid-term it will be interesting to see how much the expansion speed of the FIND business will be increased, including acquisition of a WHO recommendation for tuberculosis, which will take time.

1. Company Overview

EIKEN CHEMICAL is a general manufacturer of clinical diagnostics, including immunological and serological, microbiological, clinical chemistry, urine analysis and molecular genetics. It also develops and sells medical devices. It offers many products that occupy high market share including fecal occult blood test reagents that occupy about 57% of the domestic share. Its unique gene amplification technology, “LAMP”, is highly recognized in the world. With the fecal occult blood tests and LAMP, EIKEN is aiming to become a global corporation.

【History】

1939	Establishment of Koa Kagakukogyo Co., Ltd. Initiation of the manufacturing and sales of nourishing food article. (founder, Tsuyoshi Kurozumi)
1949	Powdered agar for the detection of bacteria, the first product of the field, was successfully commercialized in Japan.
1961	Establishment of Clinical Laboratory Division. Initiation of R&D of clinical diagnostics.
1969	Company name was changed to EIKEN CHEMICAL CO., LTD. in recognition of its 30th anniversary.
1972	Commencement of the sales of “Uropaper EIKEN”, a urinalysis test strip.
1987	Commencement of the sales of “OC-hemodia”, the immunochemical fecal occult blood test reagent.
1989	Commencement of the sales of “OC SENSOR”, the automated fecal occult blood analyzer.
1990	Stocks listed in the second section of the Tokyo Stock Exchange.
1998	Development of novel DNA amplification LAMP method and filing of its patent applications.

Mar.	2002	Stocks listed on the first section of the Tokyo Stock Exchange.
Mar.	2002	Establishment of patent for LAMP in U.S.A.
Mar.	2002	Commencement of the sales of novel “Loopamp Bovine Embryo Sexing Kit” and “Loopamp End Point Turbidimeter”, using LAMP.
May	2002	Establishment of patent for LAMP in Japan.
Nov.	2004	Acquired FDA approval for fecal occult blood test reagent and analyzer and commencement of their sales in the U.S.A.
Jul.	2005	Conclusion of agreement with Foundation for Innovative New Diagnostics (FIND) for development of rapid diagnostic test for tuberculosis using LAMP.
Aug.	2006	Completion of construction of plant and company building of EIKEN SHANGHAI CO., LTD.
Oct.	2008	Expansion of collaborative development with FIND to include malaria and African trypanosomiasis. Conclusion of agreement with FIND for development regarding malaria, human African trypanosomiasis and HIV.
Mar.	2009	Establishment of new management plans, ‘EIKEN WAY’ and ‘EIKEN ROAD MAP 2009’.
Jul.	2010	Commencement of the sales of various in vitro diagnostic products using LAMP including “Loopamp Mycoplasma P Detection Kit,” “Loopamp Legionella Detection kit C.”
Jun.	2011	Commencement of the sales of “Loopamp MTBC Detection Kit”.
Dec.	2011	Conclusion of agreement with FIND for development of diagnostics for Leishmaniasis.
Aug.	2012	Commencement of the sales of ultrasensitive fully automated biochemiluminescent immunoassay analyzer, “BLEIA-1200” and “BL-NV EIKEN” to detect Norovirus.
Nov.	2012	Commencement of the sales of “Immuno Catch Noro” using the immunochromatographic analysis method.
2013		Commencement of the sales of BLEIA-1200 specific reagents, called “BLEIA EIKEN HCV antibody”, “BLEIA EIKEN HCV antigen”, and “BLEIA EIKEN HBs antibody”.
Jan.	2014	Conclusion of agreement with FIND for development against Chagas disease.
Mar.	2014	Commencement of the sales of an analyzer for drug sensitivity ‘DPS192iX’ and three types of Dry plate ‘EIKEN’ (192 plates)

*For LAMP and FIND, please refer to “2. Characteristics and Strengths (4) Competitive Advantages of LAMP”.

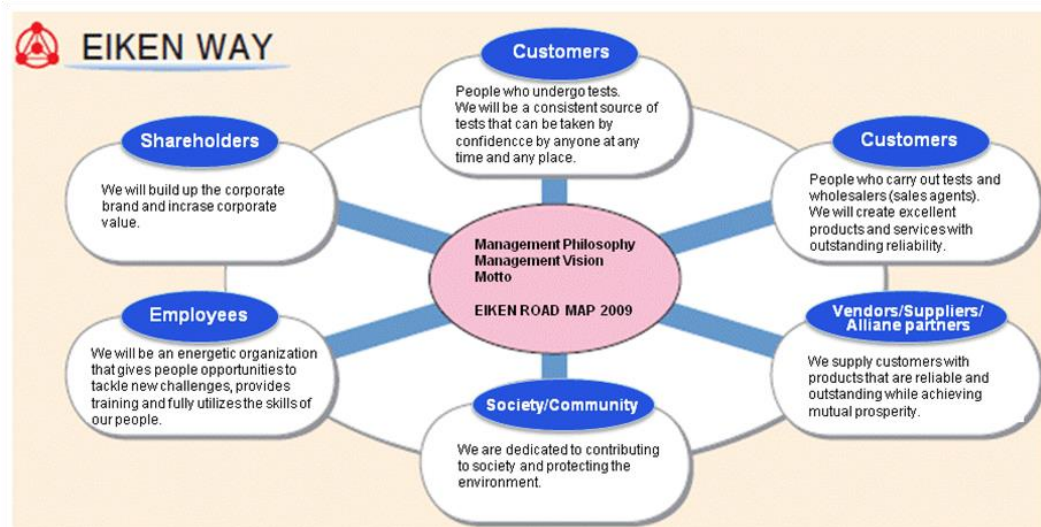
【Management Philosophy】

“Management Philosophy”: Protect the health of the public through health care services.

“Management Vision”: EIKEN group is dedicated to leveraging expertise as a medical testing pioneer in order to increase corporate value by protecting the health of the public with products and services that customers can trust.

“Motto”: We EIKEN provide trustworthy quality, and develop with technology.

EIKEN group formulates “EIKEN WAY” as its attitude toward each stakeholder, centering these philosophy, vision and motto.



(Source: EIKEN CHEMICAL)

【Market Environment】

<Domestic Market>

The market scale of clinical reagents (including diagnostics devices) is about 338 billion yen as of 2013 (survey by the Japan Association of Clinical Reagents Industries, or JACRI). In order to control medical cost, the Japanese government is focusing on preventive medicine such as special health check-up (check of metabolic syndrome) and cancer screening. Thus, it is expected that the number of sample (number of specimen) for testing will increase as the population ages. Some negative factors include impact of population decline as a result of decreasing birth rates and revision of medical treatment fees (reduction). However, the trends of laboratory test fees which had been subject to revision of medical treatment fees show that, even though they were cut by some 40% from 1997 to 2006, the fees have been stable or only slightly reduced after 2007. This is a result of advocacy on the importance of prevention and test by the entire industry including EIKEN. Thus, in the medium to long term, the domestic market is expected to slightly grow by approximately 3% per year.

According to the “Prospect of Clinical Laboratory Test Market, 2009” conducted by Yano Research Institute, EIKEN CHEMICAL ranked **the fifth** largest sales, occupying **5.8% market share**, after Sysmex (6869, first section of Tokyo Stock Exchange), Roche Diagnostics (Japanese corporation of the Roche Group in Germany), FUJIREBIO (now known as Miraca Holdings, 4544, first section of Tokyo Stock Exchange), and Abbott Japan (Japanese corporation of the Abbott Group in the USA).

Out of the 124 member companies (as of July 2014) of JACRI mentioned above, about 80 are manufactures, and there are about 10 companies with over 10 billion yen sales. Most of them are small to medium sized companies. Because the test items of diagnostics tests range widely, each company has its own strong field, and business segregation is already established in the industry. As a result, collaboration, such as supplying the products from other companies and selling them, is often observed. In addition, the market is modestly growing. Therefore, there is currently no obvious trend of weeding out uncompetitive corporations.

<Overseas Market>

According to the “Prospect of Global Clinical Laboratory Test Market, 2009” conducted by Yano Research Institute, the global clinical laboratory test reagent/device market is US\$ 44.5 billion or 4.45 trillion yen (1 USD=100 yen), and, by region, the market is occupied by the USA at 41.2%, followed by Europe at 36.9% and Asia/Pacific at 12.0%.

The overseas market is over ten times larger than the domestic market. In developed countries, the number of tests is

increasing as aging of population progresses. Furthermore, in emerging countries, the needs for medical services are expanding because of economic and income growth. As a result, the annual growth rate of overseas market is expected to be 7 to 8%, which is much higher than that of the domestic market. Therefore, the Japanese companies in the industry are vigorously undertaking globalization of their businesses.

In the global market, the global large companies such as Roche, Abbott, SIEMENS, and Beckman, whose sales are 200,000 to 900,000 million yen, are leading the market, and in order for Japanese companies to survive the competition, they must strengthen their competitiveness by, for example, developing unique products or systems.

【Business Description】

1. What are clinical tests?

One type of clinical tests is “biological tests” that directly examine body using medical equipment such as X-ray, CT, MRI, electrocardiogram, and ultrasound. Another type of clinical test is “**medical laboratory tests**” that examine biological sample (specimen) obtained from people such as blood, urine/feces, and cells.

The clinical test reagents made by EIKEN CHEMICAL are the ones used for medical laboratory tests. For example, they are used to test infectious diseases or to measure small amount of blood contained in stool. They are made to support diagnosis.

Most of these reagents are called in vitro diagnostics (IVD). Reagent manufactures usually file applications for the approval of the Ministry of Health, Labor and Welfare.

The users of these reagents include hospitals, clinics, medical test centers that carry out tests based on request from medical institutions, health check-up centers, public health departments, institutions for health research, etc.

2. Major products

EIKEN CHEMICAL mainly manufactures and sells the following reagents and medical devices.

As it deals with a wide range of reagents and medical devices, it not only sells their in-house products but also purchases and sells the products of other companies.

Their major in-house products include fecal occult blood test reagents, microbiological reagents, general test reagents (e.g. test strip for urinal test), and molecular genetics.

The sales composition ratio of their in-house products and other companies' products are about 50%-50%. The gross profit margin rate is about 55% by the in-house products, about 35% by other companies' products.

Name of product	Sales	Sales composition ratio
Fecal occult blood test reagents	6,791	22.6%
Immunological and serological reagents (excluding fecal occult blood tests)	9,636	32.1%
Microbiological reagents	4,745	15.8%
General test reagents (e.g. test strip for urinal test)	2,132	7.1%
Clinical chemistry reagents	686	2.3%
Equipments/ culture medium related to food and environment	2,350	7.8%
Medical devices (excluding devices related to molecular genetics)	2,570	8.6%
Molecular (LAMP method) genetics (including devices)	1,113	3.7%
Total sales	30,027	100.0%

*Results for fiscal year ending March 2014. Unit: Million yen

Fecal occult blood test reagents

The reagents and sampling bottles for immunochemical fecal occult blood tests to specifically detect and measure human hemoglobin in feces as a screening test for colon cancer are the major products of EIKEN CHEMICAL. They are sold globally.

Immunological and serological reagents (excluding fecal occult blood tests)

EIKEN CHEMICAL develops, manufactures and sells various reagents to diagnose and measure infectious disease, rheumatism, inflammation, atrophic gastritis, and prostate-specific antigen. Such reagents include reagents for automated analyzer called “LZ test EIKEN.” EIKEN also purchases medical devices from TOSOH Corporation and sells them.

Microbiological reagents

Since its establishment, EIKEN CHEMICAL has been developing reagents for microbiological tests in order to prevent infectious diseases and food poisoning. Currently, it develops, manufactures and sells various reagents that are effective for diagnosis and treatment of microorganism infection, such as medium, powder medium, drug sensitivity test reagents, and rapid test reagents.

General test reagents (e.g. test strip for urinal analysis)

EIKEN CHEMICAL develops, manufactures and sells “URO PAPER III EIKEN” series for testing various items such as occult blood, protein and glucose in urine as well as “URO PAPER α III EIKEN”, a dedicated test strip for fully automated urine analyzer.

Clinical chemistry reagents

EIKEN CHEMICAL develops, manufactures and sells reagents for biochemical tests including “EXDIA XL EIKEN” series that assist to measure and analyze biological components in blood serum and urine, specifically for the test items that are related to life-style related diseases.

Equipments/ culture medium related to food and environment

EIKEN CHEMICAL sells reagents for food microorganism tests to detect food-poisoning bacteria as well as reagents for environmental microorganism tests and equipment/devices to measure contamination of work environment.

Medical devices (excluding molecular genetics)

EIKEN CHEMICAL sells various types of automated analyzers. Since its commencement of sales in 1989, it has been working on technical innovation and quality enhancement of its automated fecal occult blood analyzers, “OC SENSOR” series.

It also offers the “US,” automated urine analysis devices using EIKEN’s proprietary color CCD sensor, as well as fully automated biochemiluminescent immunoassay, “BLEIA-1200,” which is the world’s first fully automated device in the clinical test field.

Molecular genetics (including devices)

In 1998, EIKEN CHEMICAL developed an innovative gene amplification technology, called “LAMP” (Loop-mediated Isothermal Amplification), and applied for patent. LAMP is “simple, rapid, and accurate” and is a critical tool for EIKEN’s future global expansion of its business. (The details are described later.)

2. Sales structure

EIKEN CHEMICAL has 11 sales offices and 2 sales divisions in Japan. Its academic department supports sales promotion.

Out of 620 employees (non-consolidated) during FY 2014, about 280 belong to the sales department.

As for the sales channels for medical institutions such as hospitals, the Company’s direct sales partners are medical wholesale companies, and it has businesses with almost all of the wholesale companies in the medical industry.

For overseas sales, EIKEN CHEMICAL has basically 1 agency per country, and the sales and maintenance are commissioned to the agencies.

EIKEN’s products are exported to 43 countries (FY 2014). The high proportion of overseas sales is occupied by the sales in the USA, Italy, South Korea, and Taiwan.

In addition to the Europe Office in Amsterdam (the Netherlands), the Company is strengthening its manufacturing and sales structure through its consolidated subsidiary, “EIKEN CHINA CO., LTD.,” as well as aiming to expand its businesses by setting a business office in China. In the future, it will explore the possibility of making the office as a local corporation, as the size expands.

The overseas sales for FY 2014 are 20.17 billion yen, out of which 16.67 billion yen, 82.6%, is from the sales of fecal occult blood test reagents.

<ROE Analysis>

	FY3/11	FY3/12	FY3/13	FY3/14
ROE (%)	8.5	7.0	10.9	8.3
Net Profit Margin (%)	6.07	5.27	8.56	6.61
Asset Turnover Ratio (x)	0.89	0.84	0.84	0.84
Leverage (x)	1.57	1.58	1.52	1.50

<Reference: TSE First Section ROE by Industry>

Units: %	FY2012 (FY3/13)	FY2013 (FY3/14)
All Industries (Exc. Financial)	5.01	8.71
Manufacturing	4.55	8.62
Non Manufacturing	5.69	8.85
Pharmaceuticals	7.94	7.16

The ROE for FY 2014 was 8.3%. Although slightly lower than the ROE of 8.71% announced by the Tokyo Stock Exchange summary of financial statements for all industries in the First Section, it is above the 7.16% for the pharmaceutical industry, making it an acceptable level.

(The reason for the high ROE in FY 2013 was the net profit to sales for the year increased due to extraordinary income from property sales.)

However, with the pharmaceutical sector's net profit to sales for the year 8.27% for FY 2014, it will be necessary to further strengthen productivity and profitability with the company's stated goal of developing products with high added value, creating new businesses and markets and lowering cost rate and SG&A expenses rate in order to further increase the ROE.

2. Characteristics and Strengths

(1) Products that occupy high share in the market

The share of EIKEN's fecal occult blood test reagents is top ranked (about 57%) in the domestic market. Furthermore, its in-house products occupy high share in the market, as its test strips for urinal analysis occupies about 23% (second rank) in the market and its microbiological reagents occupy about 18% (second rank) in the market.

The distribution of fecal occult blood test reagents rapidly expanded after 1992 when fecal occult blood test became available at public expense as a colon cancer screening method as a result of an amendment of the Health and Medical Service Act for the Aged.

The reasons why EIKEN could obtain a high share are that 1) it launched fecal occult blood test reagents called “OC-Hemodia” in 1987, 2) it kept improving sanitation aspect and handling of feces sampling bottle, 3) it developed automated analyzers using latex photometric immunoassay method for the first time in the world, and 4) the performance of its reagents is excellent.

Especially combination of sampling container and device was favorably accepted by the users, which became a big factor for the expansion of its distribution.

Fecal immunochemical test (FIT)

When there is cancerous tissue or polyps in the colon, due to friction they withstand as stool comes out, there may be blood on the stool. Fecal occult blood test can detect even the smallest quantities of blood attached to stool that normally go unseen by the naked eye.



(Source: EIKEN CHEMICAL)

As for fecal occult blood test, EIKEN will globally expand its business based on the above characteristics.

The immunochemical method in Japan applies reagents that react only to human hemoglobin, and also it is possible to process a large volume at the same time.

Meanwhile, in other countries, reagents for chemical method (Guaiac method) based on old measuring principles are still used, which presents accuracy challenges. In recent years, the test guidelines in Europe finally begin recommending automated analyzers using immunochemical method. As a result, the market is beginning to go through a dramatic change.

Furthermore, although the chemical method is still common in the USA as well, which has the largest potential market, there is a gradual shift of trend towards the immunochemical method. This means that, in both developed and emerging countries in Europe, North America, Asia and Oceania, there is a large yet-to-be-developed market.

(2) Focusing on research and development

EIKEN CHEMICAL is focusing on research and development of unique technologies as a research and development corporation, and the development of original products that respond to customers' needs, using the unique technologies. The number of staff assigned for research and development is about 100.

The demand from the customers is higher quality of medicine. Specifically, they demand for higher differential diagnosis accuracy with high sensitivity and high quality and improved detection rate. In addition, easier usage will lead to reduction in the work of medical staff. Responding to such needs is critical.

Since its establishment in 1939, EIKEN CHEMICAL has accumulated unique technologies for manufacturing reagents. Their unique technologies are applied to the measuring principles of their devices such as fecal occult blood test analyzer, automated urine analyzer, and biochemiluminescent immunoassay analyzer "BLEIA" that are designed to optimize the performance of the reagents.

(3) Development of various types of products in various fields through alliance strategy

Because clinical test reagents have wide range of subjects and items, it is not possible for one company to develop, manufacture and sell all types of reagents. The other companies in the industry are focusing on the technologies and products that they are specialized in. However, as an integrated manufacturer of clinical test reagents, EIKEN CHEMICAL aims at stabilizing profit structure, expanding their own strengths through alliance strategy, and pursuing synergy effects such as complementing functions and acquiring new technologies, while dealing with a wide range of products and responding to the needs of customers and users such as medical institutions.

Another reason why they cover various types of products in various fields is that they believe that covering wide range of clinical tests is their social responsibility to protect the health of the public, as is stated in their management philosophy: "protect the health of the public through health care services".

(4) Competitive advantages of "LAMP"

Currently, the mainstream technology for amplifying genes as a process of gene test is called "PCR method." Against this, EIKEN CHEMICAL developed a unique technology called "LAMP" in 1998.

As compared with the PCR method, LAMP offers the following excellent characteristics and allows the users to carry out simple, rapid and accurate gene tests.

Simple	Amplification response occurs at a fixed temperature. (With the PCR method, temperature needs to be changed for amplification.)
Rapid	Amplification efficiency is high, and gene can be detected within 30 to 60 minutes. (With the PCR method, it takes 2 to 3 hours.)
Accurate	Specificity is extremely high.

Currently, in the medical field, LAMP is used to diagnose infectious diseases such as tuberculosis, mycoplasma and influenza.

EIKEN CHEMICAL is making focused efforts on infectious disease diagnostic tests in order to establish the status of LAMP. At the same time, it is promoting the use of LAMP in the other fields such as food production and processing, environment, agriculture/veterinary in order to spread and enhance recognition of LAMP. In fact, the products based on LAMP have been commercialized one after another since 2002.

Furthermore, for the same purpose, EIKEN CHEMICAL is giving license to external companies in order to build the LAMP camp.

One of the major actions to spread LAMP in the world is the alliance with “[Foundation for Innovative New Diagnostics \(FIND\)](#)”.

FIND is a non-profit organization, recognized by the Swiss government. It was launched at a meeting of the United Nations World Health Assembly in May 2003. In the initial five years, it received grant from the Bill & Melinda Gates Foundation for their activities.

The goal is to develop and introduce affordable, simple, and advanced diagnostic tests in order to mitigate infectious diseases in developing countries.

FIND’s scope of activities includes tuberculosis, malaria and human African trypanosomiasis. For tuberculosis, collaborative research between EIKEN CHEMICAL and FIND for tuberculosis test using LAMP began in July 2005. The purpose of the research was to improve the accuracy of tests to make it better than the one by microscopy test (sputum smear test) that is currently common in developing countries.

As a result of the collaboration, improvements such as simplified pretreatment, improved reagents storage and simplified devices were made to enable the developing countries to operate the procedure. These improvements were not possible with the conventional PCR method.

This product with LAMP was already launched in Japan in 2011.

Currently, FIND is carrying out on-going clinical trials in various developing countries in order to obtain recommendation from World Health Organization (WHO) for the products.

Furthermore, in addition to tuberculosis and other diseases mentioned above, FIND and EIKEN CHEMICAL conduct collaborative research for reagents of Leishmaniasis and Chagas disease.

EIKEN CHEMICAL expects that the results of these collaborative studies will accelerate the spread of LAMP as well as establish its status as a global standard, which will lead to their expansion in the gene test market.

* Gene amplification technology

Since the amount of genes found in a genetic test sample is extremely small, in order to detect genes, the targeted gene must be amplified first of all. Gene amplification technology, therefore, is crucially important for genetic testing.

* African trypanosomiasis

An endemic found in tropical Africa, African trypanosomiasis is a serious tropical disease transmitted to humans by a protozoa called *Trypanosoma brucei*. The disease is transmitted by a tsetse fly. *Trypanosoma* in human blood sucked by a tsetse fly develops and propagates inside the human body in 2 to 5 weeks, before turning itself into a terminal *Trypanosoma*-type, which becomes a source of next round of infection. The disease causes fever, headache, and vomiting, and the patient falls into constant sleep. Since the patient cannot take meals, he or she becomes thin and complain of generalized weakness and, in many cases, leads to a complication and dies.

* Leishmaniasis

Leishmaniasis is a disease transmitted by a protozoa called leishmania, and has various types such as visceral leishmaniasis (also known as black fever), Brazilian leishmaniasis that affects skin and mucous membranes, and skin tropical leishmaniasis which affects skin. All of these types are transmitted by blood-sucking insects, especially sandflies. Visceral leishmaniasis, after about three months incubation period, causes fever, sweating, diarrhea, etc. and, in about one month, causes a swollen liver and spleen, the patient becomes weak if untreated and may die in half a year to two years.

* Chagas disease

Found in southern U.S. as well as Central and South America, Chagas disease is an infectious disease transmitted by Reduviidae, a kind of blood-sucking Triatominae. The disease does not develop symptoms immediately after infection; it usually has a latency period of about 30 years. It causes symptoms such as inflammation of sinews, liver and spleen, myalgia, myocarditis, cardiomegalia, cardiac disturbance, etc.

3. First Half of Fiscal Year March 2015 Earnings Results

(1) Overview of Consolidated Performance

(Unit: Million yen)

	1H FY 2014	Composition ratio	1H FY 2015	Composition ratio	Year-on-year comparison	Estimate at the beginning of term
Sales	15,065	100.0%	15,819	100.0%	+5.0%	-0.9%
Gross margin	6,211	41.2%	6,622	41.9%	+6.6%	-
SG&A	4,573	30.4%	4,767	30.1%	+4.2%	-
Operating income	1,638	10.9%	1,855	11.7%	+13.3%	+18.2%
Ordinary income	1,692	11.2%	1,955	12.4%	+15.6%	+22.2%
Quarterly net income	1,085	7.2%	1,349	8.5%	+24.4%	+33.6%

Performing well domestically and abroad. Increased Revenue and Profit above initial plan with double-digit profit increase.

Net sales were 15.8 billion yen, up 5.0% year-on-year. Domestic sales were affected by a rebound from the increased demand before the consumption tax increase in Q1, but recovered from June onwards. By product, general test reagents, ABC category test reagents and fecal occult blood test reagents all contributed. Overseas sales significantly increased by 45.7%, mostly with fecal occult blood test reagents and devices.

With the 280 million yen in research and development costs planned for Q2 shifted to Q3, operating income increased 13.3% year-on-year and ordinary income increased 15.6% year-on-year, both double-digit increases. With the tax reform in 2014 leading to decreased corporate taxes, the quarterly net profit also increased by 24.4% year-on-year.

Sales did not quite reach planned amounts, but income surpassed planned amounts.

(2) Sales by Products

(Unit: Hundred million yen)

	1H FY 2014	1H FY 2015	Year-on-year Comparison
Microbiological reagents	2,375	2,327	-2.0%
General test reagents(e.g. test strip for urinal test)	1,051	1,082	+2.9%
Immunological and serological reagents	8,585	9,211	+7.3%
Clinical chemistry test reagents	357	338	-5.2%
Equipment/Culture medium related to food and environment	1,192	1,179	-1.1%
Other (medical devices, genetics related)	1,501	1,678	+11.8%
Overseas market	850	1,238	+45.7%

○Microbiological reagents

The rebound in demand after the consumption tax increase led to lower sales year-on-year.

○General test reagents

The sales of the “URO PAPER α III EIKEN,” dedicated test strip for fully automated urine analyzer, increased.

○Immunological and serological reagents

Sales of immunological and serological reagents increased 13.5% year-on-year. With the increase of colon cancer tests in Japan and success of domestic marketing strategies, domestic sales increased 6.6% year-on-year. Overseas sales increased significantly, by 48.0%. North American and Asian sales performed well.

The sales of the “E Plate EIKEN helicobacter pylori antibody II” and “LZ Test EIKEN helicobacter pylori antibody,” which measure helicobacter pylori antibody in the blood, and the sales of the “LZ Test EIKEN Pepsinogen I / II ,” which are used as a test for the condition of stomach (ABC classification) in combination with helicobacter pylori test, increased.

○Clinical chemistry test reagents

Sales decreased due to prices being lowered to compete for market share.

○Equipment/ culture medium related to food and environment

The rebound in demand after the consumption tax increase led to lower sales year-on-year.

○Other (medical devices, genetics related)

For medical devices, fecal occult blood test devices, the fully automated urine analyzer and microbiological test devices performed well.

For genetics-related sales, patent royalties totaled 197 million yen including initial fees for new client contracts.

○Overseas Sales

As mentioned above, sales of fecal occult blood test reagents increased significantly, by 48.0% year-on-year. Other products including devices increased as well by 39.9% year-on-year.

<Breakdown of Overseas Sales by Region> (Unit: Million yen)

	1H FY 2014	1H FY 2015	Year-on-year Comparison
North America	240	415	+72.9%
Europe	346	463	+33.8%
Asia/Other	263	359	+36.5%
Total	850	1,238	+45.7%

***North America**

Since the U.S. Food and Drug Administration (FDA) instructions on quality management system were closed in September 2014, sales of fecal occult blood test reagents and devices increased.

***Europe**

Efforts are being made for the adoption of fecal occult blood tests in countries including France and England. Plans were for bidding in France to occur in Q1, with results announced in Q2, but it is slightly behind schedule.

Sales of the fully automated urine analyzer and dedicated test strips increased significantly in Italy.

***Asia, Other**

In Thailand, Hong Kong, and New Zealand, EIKEN CHEMICAL is making focused efforts to accelerate new adoption and sales expansion of fecal occult blood tests.

In China, EIKEN CHINA CO., LTD. is promoting the sales expansion of LAMP reagents, LAMP devices and fecal occult blood test reagents.

(3) Other Activities

◎FIND Business

The progress of the alliance business with FIND was as follows.

①Tuberculosis

Assessments in developing countries to obtain WHO recommendation continued to be carried out in 14 countries in Africa, South East Asia, etc.

A private-public initiative project funded by the Ministry of Foreign Affairs was conducted in the Republic of Haiti.

Application process to the China Food and Drug Administration continued.

Although WHO recommendation is slower than originally planned, additional data collection and analysis are being carried out to acquire recommendation.

②Malaria

EIKEN CHEMICAL sold reagents for screening to eradicate malaria.

③African trypanosomiasis (sleeping sickness)

Clinical tests continued to be conducted in the Democratic Republic of the Congo and Uganda.

Reagents for the eradication project were sold in 6 African countries.

④Leishmaniasis

The assessment of samples by FIND continued to be carried out.

⑤Chagas disease

Based on a joint research and development agreement with FIND, development of a prototype proceeded.

◎Increasing Productivity, Training Human Resources, CSR, etc.

- ✓ In order to increase productivity, SG&A expenses were reduced by optimizing work flow and improving the cost to sales ratio (manufacturing cost decreased).
- ✓ Continued training was implemented to improve skills and for operation of the new quality control system.
- ✓ Personnel were trained as part of the skill development vision.
- ✓ Brave Circle (campaign to eliminate colon cancer) activities were continued.

[Brave Circle: Campaign to Eliminate Colon Cancer]

The number of people affected by colon cancer increased by about 6 times over the past 30 years, to 110,000, making it the second most common cancer. Since 2003, it has become the most common cancer to cause death in women.

There are almost no noticeable symptoms at early stages, but since early detection and treatment can completely cure more than 90% of cases, early testing is important.

Fecal occult blood tests are used for cancer testing, but the number of people eligible for the testing (generally 40 years or older) who are actually tested is low, at 41.1% of males and 34.5% of females. (Ministry of Health, Labour and Welfare "National Livelihood Survey 2013")

In light of this situation, the specified non-profit corporation Brave Circle Executive Committee has been collaborating with companies and government organizations since July 2009 in the Brave Circle: Campaign to Eliminate Colon Cancer, to spread awareness of the importance of periodic testing for colon cancer. (Activities of the previous incarnation began in 2007.)

EIKEN CHEMICAL, along with Olympus Medical Systems, is an official supporter of the Brave Circle Executive Committee.

Based on the Basic Law for Cancer Countermeasures implemented in 2007, the Basic Plan for Promotion of Cancer

Bridge Report



Countermeasures was passed by the Cabinet the same year, with the goal of increasing cancer test recipients to 50% or more within 5 years. The initial 5 year period ended in 2012, but the 50% goal was not met, and so stage two of the plan is underway to reach a 50% test ratio.

The Executive Committee is cooperating with the government to carry out several ongoing projects promoting the importance of colon cancer testing as follows:

- *Colon cancer related investigative studies project
- *Colon cancer awareness promotion project
- *Colon cancer related events, seminars and lectures
- *Colon cancer related awareness and research organization support
- *Colon cancer related organization information exchange and network building

- *Colon cancer awareness promotion business



(From the Brave Circle website)

(4) Financial Status

◎Major BS

(Unit: Million yen)

	End of March 2014	End of September 2014		End of March 2014	End of September 2014
Current assets	26,579	25,074	Current Liabilities	9,861	10,354
Cash and deposits	11,032	8,309	Notes and accounts payable-trade	6,295	6,684
Notes and accounts receivable-trade	9,242	10,354	Short-term loans payable	270	50
Inventory	4,948	4,927	Noncurrent liabilities	2,255	1,729
Noncurrent assets	9,815	12,663	Liabilities related to retirement benefits	942	466
Property, plant and equipment	6,786	6,897	Total liabilities	12,117	12,084
Intangible assets	493	542	Net assets	24,278	25,653
Investment and other assets	2,535	5,223	Shareholder equity	24,568	25,849
Total assets	36,395	37,737	Total liabilities and net assets	36,395	37,737

Notes and accounts receivable-trade increased, but due to a decrease in cash and deposits current assets decreased by 1.505 billion yen compared to the end of March 2014. Increases in investments and other assets led to noncurrent assets increasing by 2.848 billion yen, with total assets increased by 1.342 billion yen.

While current liabilities increased by 493 million yen due to notes and accounts payable-trade, etc. noncurrent liabilities decreased by 526 million yen due to decreases in liabilities related to retirement benefits, etc. with total liabilities decreased by 33 million yen.

Net assets increased by 1.375 billion yen, due to increased retained earnings, etc. As a result, the capital-to-asset ratio increased by 1.3%, from 66.2% at the end of March 2014 to 67.5%.

4. Fiscal Year March 2015 Earnings Estimates

<Performance forecast>

(Unit: Million yen)

	FY 2014	Composition ratio	FY 2015 (Estimate)	Composition ratio	Year-on-year comparison	Progress rate in 1H
Sales	30,027	100.0%	31,320	100.0%	+4.3%	50.5%
Domestic	28,010	93.3%	28,370	90.6%	+1.3%	51.4%
Overseas	2,017	6.7%	2,950	9.4%	+46.2%	42.0%
Operating income	3,008	10.0%	2,900	9.3%	-3.6%	64.0%
Ordinary income	3,095	10.3%	2,930	9.4%	-5.3%	66.7%
Quarterly net income	1,984	6.6%	1,870	6.0%	-5.8%	72.1%

*The estimates were based on the announcement by the Company.

There will be no change in the estimates. Despite recovery of overseas sales, profit will decrease due to significant increase in testing and research costs.

There will be no change in the estimates. Net sales were 31.3 billion yen, up 4.3% year-on-year.

In the domestic market, EIKEN CHEMICAL will strive to increase sales by placing fecal occult blood test reagents, general test reagents and the "LZ Test EIKEN helicobacter pylori antibody" pylori test reagent as highest priority sales products, AIA-related reagents and HbA1c reagents as products to maintain and strengthen sales, LAMP products and new immunological reagents from the BLEIA method as products to develop and strengthen sales.

In the overseas market, EIKEN CHEMICAL will strive to establish brand of fecal occult blood test reagent and increase its sales, promote the sales of LAMP product, expand the sales of immunological and serological reagents and rapid testing reagents, and move forward the sales of urine testing Uropaper. In addition to the European and Asian markets which are performing well, North American sales expected to recover and overseas sales are estimated to significantly increase over 40% year-on-year.

For research and development, EIKEN CHEMICAL will:

- Apply knowledge of customer needs to product development
- Develop BLEIA method products and LAMP/POCT (rapid testing) products
- Product improvement by fine-tuning existing technology
- Research in finding new biomarkers and developing new testing technology
- Continue FIND business (tuberculosis, malaria, HAT; African sleeping disease, leishmaniasis, Chagas disease)

In addition to increasing R&D costs significantly by 775 million yen year-on-year (39.8% increase) to 2.72 billion yen, capital investment also increased for new facilities and upgrading old equipment, for an estimate increase of 300 million yen (26.9% increase) in depreciation.

R&D costs, capital investment and depreciation are all being focused on the second half of the year.

<Transition of costs for R&D, capital investment and depreciation>

(Unit: Million yen)

	1H FY 2013	FY 2013 Full Year	1H FY 2014	FY 2014 Full Year	1H FY 2015	FY 2015 Full Year (Estimate)	Year-on-year comparison
R&D costs	874	1,840	900	1,945	978	2,720	+775
Capital investment	259	693	473	839	544	2,023	+1,184
Depreciation	497	1,040	509	1,114	572	1,414	+300

Other efforts will be continued, including increasing productivity by reducing manufacturing costs and with SG&A expense control, continued training for operating new quality control systems, basic human resource training based on the

ability development vision, and activities for the colon cancer elimination campaign.

Dividends of 35.00 yen/share are planned, the same as the previous year. The estimated dividend payout ratio is 34.1%.

5. Interview with President Morifumi Wada

President Morifumi Wada joined EIKEN CHEMICAL in 1978. After working for years in improving the products that are one of EIKEN CHEMICAL's strengths with manufacturing technology, manufacturing control and quality control, since 2011 he has overseen sales as a whole as the Sales Management Executive Officer. In June of 2014, he was appointed President.

◎Mission as the New President

- "Accurately input customer needs, and output products appropriate to those needs." I believe further enhancing this approach is one of my missions.
- I feel the instructions from the U.S. FDA are a good opportunity, or lesson, to return to our roots in order to provide superior products, by rethinking this system and further approving quality control.
- If we can meet the FDA requirements, we should meet requirements worldwide, so I would like to humbly accept the instructions and use them as a good opportunity to carry out global expansion.

◎Corporate Philosophy

- In order to increase awareness of the philosophy, morning meetings and other opportunities are used to remind employees to consider the purpose, reason for existence and contribution to society of the company and themselves once a day.
- The Eiken Way encourages employees to challenge themselves, and every opportunity is taken to remind employees of the 3 Cs, Charge (effort to improve yourself), Change (constantly improving), and Challenge (challenge yourself, take action).

◎Varied Initiatives

- One of the fundamental policies of EIKEN CHEMICAL is "promoting global expansion," with efforts focused on Europe, America and Asia. In April this year, the number of staff in the European branch in Amsterdam, the Netherlands were increased, as it is optimal for a hub, including logistics. This branch also covers the North American market.
- Currently, the Overseas Department has 20 staff, but it is necessary to increase that number some. Stimulating distributors is also an important policy, and in order to develop win-win relationships, management of the distribution network and development of potential distributors are proceeding. The increase in overseas sales this year is due in part to these efforts.
- Improvement of cost rate and productivity are also important issues. Due to manufacturing facilities aging, proactive capital investment is also necessary to improve efficiency.

◎Message to Investors

- While carrying on the "EIKEN WAY" and "EIKEN ROAD MAP 2009," focus is also being placed on medium-term creation of corporate value. In particular, the creation of a new platform to appropriately input market needs and create relevant output will be undertaken, especially in overseas markets.
- By carrying out approaches such as these, I hope to achieve sustainable growth and increase dividends.

6. Conclusions

It is good news that with the closing of the FDA's warning letter, the American market has begun to recover. As mentioned in President Wada's comment, hopefully this will prove a valuable lesson and further improve the quality of products.

In the short term, there is the possibility that the recovery of the U.S. market for fecal occult blood test reagents and devices and their adoption in France may increase overseas sales for the fiscal year. In the mid-term it will be interesting to see how much the expansion speed of the FIND business will be increased, including acquisition of a WHO recommendation for tuberculosis, which will take time.

Reference: New Management Framework “EIKEN WAY” and “EIKEN ROAD MAP 2009”

EIKEN CHEMICAL set a goal for 2018, which will be the 80th anniversary, and established “EIKEN WAY” and “EIKEN ROAD MAP 2009” in March 2009, as a fundamental policy to promote “winning management.”

【Background】

In Japan, the trend of medical system reform to reduce medical costs will remain unchanged. The corporations in the clinical diagnostics industry are forced to enhance efficiency and streamline their business as a result of revision of medical fees and intensification of products and price competition.

Furthermore, securing safety and compliance with laws and ordinances are becoming increasingly important management challenges. As a result, the gap between corporations is expected to be larger.

Under these circumstances, in order to achieve steady growth and sustainable enhancement of corporate values, EIKEN CHEMICAL recognizes that it is essential to clarify the goal of EIKEN group, optimize the efficiency of management resources, and implement the strategies to utilize environmental changes with new visions more quickly and boldly.

Based on this recognition, it established the “EIKEN WAY” as a plan to practice solid management and the “EIKEN ROADMAP 2009” as basic principles to promote “winning management” with long term goals.

【Overview】

1. Business domain

EIKEN CHEMICAL set the “clinical diagnostics business” and “food and environment testing business” among healthcare businesses as their main business domains for which they can utilize the technologies and strengths owned by the EIKEN Group to achieve steady growth and increase in profitability. Furthermore, in these domains, they are aiming at creating new businesses for future growth.

2. EIKEN ROAD MAP 2009 Grand Vision

We will transform EIKEN into a global corporation by 2018 that can leverage expertise as a medical testing pioneer to protect the health of the public.

3. EIKEN ROAD MAP 2009 Principles of Action

- (1) To be proud of and responsible for protecting health of people in the world.
- (2) To enhance trust from stakeholders.
- (3) To pursue highly unique innovative technologies.
- (4) To create top share products that we can be proud of.
- (5) To challenge every possibility and try to achieve self-reform.
- (6) To always take action with global thinking.
- (7) To act for total optimization.

4. Fundamental policy

(1) Increase the market share of EIKEN products in Japan	Adopt the customers' perspective to improve products and services in every possible way. Achieve consistent growth by enlarging the lineup of core products and becoming more competitive.
(2) Expand global operations	To firmly establish the EIKEN brand outside Japan, rebuild the overseas sales infrastructure and network and steadily expand geographic coverage, extending from the U.S. and Europe to emerging markets.
(3) Further upgrade core technologies	Create and expand new sources of demand by leveraging innovative ideas, advanced technologies and other core EIKEN strengths. Accept the challenge of supplying products that exceed customers' expectations through the relentless pursuit of advances in performance and quality.
(4) Improve productivity	As a manufacturer, aim for constant improvements in productivity in all work processes, extending from R&D to manufacturing and sales.
(5) Establish superior competitive positions in markets	Channel resources to market sectors where EIKEN is most competitive and the development of strategic value-added products. The goals are to earn the highest possible returns on capital and achieve market superiority.
(6) Launch new businesses and create new markets	As a pioneer in medical testing, create new businesses and markets by drawing on new and highly specialized technologies. Seek business opportunities of all kinds in order to quickly launch new businesses that can drive the next phase of growth.
(7) Forge strategic alliances	Forge strategic alliances with partners that can produce synergies, such as by reinforcing existing strengths, providing complementary functions and acquiring new technologies.
(8) Make the corporate brand more powerful	Improve the quality of human resources and the company in order to build a base of operations for transforming EIKEN into a global organization.

5. Management goal

To become one of the global medical testing corporations in the future, we will strive to steadily enhance profitability while creating solid business foundation.

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