

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 and sales)	
	President	Morifumi Wada	
	HQ Address	7 Yamaguchi building, 4-19-9 Taito, Taito-ku, Tokyo 110-8408, Japan	
	Business Description	Major manufacturer of clinical diagnostics. Its fecal immunochemical test reagents occupies over 50% share of the domestic market. The Company is also aggressively implementing overseas deployment. It is strengthening genetics-related test and 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
2,670Yen	18,256,040 Shares		48,743 million yen	8.3%	100 shares
DPS (Est.)	Dividend yield (Est.)	EPS (Est.)	PER (Est.)	BPS (Actual)	PBR (Actual)
40.00 Yen	1.5%	119.41Yen	22.4times	1,448.81Yen	1.8times

*Share price is as of the end of May 20. 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 previous 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 (actual)	31,014	2,826	3,013	2,100	115.13	35.00
March 2016 (estimate)	32,820	3,330	3,350	2,180	119.41	40.00

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

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[Reference: New Management Plans "EIKEN WAY" and "EIKEN ROAD MAP 2009"](#)

Key Points

- Eiken Chemical is a general manufacturer of clinical diagnostic agents. It offers fecal immunochemical test reagents that occupy about 57% of the domestic market share, as well as many other products that occupy high market share including urinalysis test strips and microbiological reagents. Its unique gene amplification technology “LAMP” is globally renowned. With fecal occult blood tests and LAMP, Eiken aims to grow into a global corporation.

- Net sales for fiscal year (FY) 2015 were 31,000 million yen, up 3.3% compared to the previous year. Domestic sales increased slightly as they were affected by such factors as a negative rebound from increased demand before the consumption tax hike. Overseas sales increased greatly at 34.1% compared to the previous year with a concentration in fecal immunochemical test reagents and medical devices. The gross profit margin rate increased 0.3% but at the same time operating income decreased 6.0% due to augmented research and development costs and such. Corporate taxes decreased due to the revised tax system and net income increased 5.8% compared to the previous year.

- In FY 2016, sales are projected to increase 5.8% compared to the previous year to 32,800 million yen. Overseas sales will also increase greatly especially in Europe. The increase in business activities will bring about greater SG&A expenses but these will be absorbed into the sales increase and operating income is projected to increase 17.8% compared to the previous year to 3,300 million yen. With improved productivity and expansion of high profit margin products, the operating income margin will increase 1%. Dividends are expected to increase 5 yen/share to 40 yen/share. The expected dividend payout ratio is 33.5%.

- In the last report we stated that “there is possibility that the recovery of the American marketplace for fecal immunochemical test reagents and medical devices and their adoption in France may increase overseas sales for the fiscal year.” Although sales in China did not reach projected levels, confirmed adoption in France led to a substantial increase in overseas sales. Further expansion will continue in FY 2016, and Eiken will aim to reach the current goal of having an overseas sales ratio of over 10%. The next goal of having overseas sales ratio of 30% is by no means a low hurdle as it will require approximately 9,000 to 10,000 million yen even at the current sales base but, we would like to pay attention to the progress in this initiative including expanding FIND business with tuberculosis and developing new products.

1. Company Overview

EIKEN CHEMICAL is a general manufacturer of clinical diagnostics, including immunological and serological, microbiological, clinical chemistry, urine analysis and genetic test. It also develops and sells medical devices.

It offers many products that occupy high market share including fecal immunochemical 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 immunochemical test reagents and LAMP, EIKEN is aiming to become a global corporation.

【History】

1939	Established Koa Kagakukogyo Co., Ltd. and began manufacturing and sales of nourishing food articles and pharmaceuticals using livestock internal organs as raw materials.
1949	First in Japan to successfully commercialize a powder medium (SS agar) for bacteriological examination.
1955	Published the monthly scholar journal “Modern Media.”
1961	Established Clinical Laboratory Division and began R&D on clinical diagnostics.
1965	Completed construction on the Nogi plant.

1969	Company name changed to Eiken Chemical Co., Ltd. in recognition of its 30 th anniversary.
1972	Commencement of the sales of “Uropaper Eiken,” a urine analysis test strip.
1984	Completed construction on the Nasu plant.
1987	Commencement of the sales of “Hexabrix 320,” a low osmolality contrast agent.
1987	Commencement of the sales of “OC-hemodia” (visual determination method), the immunochemical fecal occult blood test reagent.
1989	Commencement of the sales of “OC Sensor,” the automated fecal occult blood analyzer.
1990	Listed stock in the second section of the Tokyo Stock Exchange.
1992	Commencement of the sales of “US-2100,” an automated urine analyzer.
1998	Developed LAMP, an innovative gene amplification technology, and filed patent applications.
Apr. 2001	Began sales of in-house clinical reagents and devices.
Mar. 2002	Listed stock in the first section of the Tokyo Stock Exchange.
Mar. 2002	Obtained patent for LAMP method in the United States.
Mar. 2002	Commencement of the sales of “Loopamp Bovine Embryo Sexing Kit,” the first product to use the LAMP method, and of specialized equipment.
May 2002	Obtained patent for LAMP method in Japan.
Dec. 2003	Commencement of the sales of “Loopamp SARS Coronavirus Detection Kit.”
Sep. 2004	Established Eiken Shanghai Co., Ltd.
Nov. 2004	Acquired FDA approval for fecal immunochemical test reagents and analyzer and began U.S. sales.
Jun. 2005	Transition to a company with a committee governance structure (currently referred to as a company with a nomination committee, etc.).
Jul. 2005	Entered into an agreement with the Foundation for Innovative New Diagnostics (FIND) for joint development of a LAMP-based rapid diagnostic test for tuberculosis.
Oct. 2005	Succession of contrast agent manufacturing and sales agreement.
Oct. 2005	Obtained ISO 13485 and ISO 9001 certification.
Aug. 2006	Construction completed on the Eiken Shanghai Co., Ltd. plant and office building (presently Eiken China Co., Ltd.)
Oct. 2008	Entered into a new agreement with FIND for joint development of drugs and therapies against malaria, African sleeping sickness, and HIV.
Mar. 2009	Established new management vision “EIKEN WAY” and “EIKEN ROAD MAP 2009.”
Apr. 2010	Obtained ISO 14001 certification.
Jun. 2011	Commencement of the Japan sales of the “Loopamp MTBC Detection Kit” that was developed in collaboration with FIND.
Jun. 2011	Established a European office (now the European branch) in Amsterdam, the Netherlands.
Dec. 2011	Entered into an agreement with FIND for joint development to treat and prevent leishmaniasis.
Aug. 2012	Commencement of the sales of “BLEIA-1200,” the fully automated biochemistry photogenetic immunoassay device and of “BL-NV ‘EIKEN’,” a Norovirus detection agent.
Nov. 2012	Commencement of the sales of “Immuno Catch Noro” which uses the immunochromatographic analysis method.
Mar. – Jul.	Commencement of the sales of screening kits for BLEIA-1200: “BLEIA ‘EIKEN’ HCV Antibody,”

2013	“BLEIA ‘EIKEN’ HCV Antigen,” and “BLEIA ‘EIKEN’ HBs Antigen.”
Jan. 2014	Entered into an agreement with FIND for joint development to treat and prevent Chagas disease.
Mar. 2014	Commencement of the sales of “DPS192iX,” the drug sensitivity testing device and 3 types of “Dry Plate ‘EIKEN’ (192).”
Jan. 2015	Developed next-generation compact fully automatic genetic testing device and multi-item testing chip, using the LAMP method.

* For further information about the LAMP method and FIND, please refer to “2. Characteristics and Strengths (4) Competitive Advantages of the LAMP Method.”

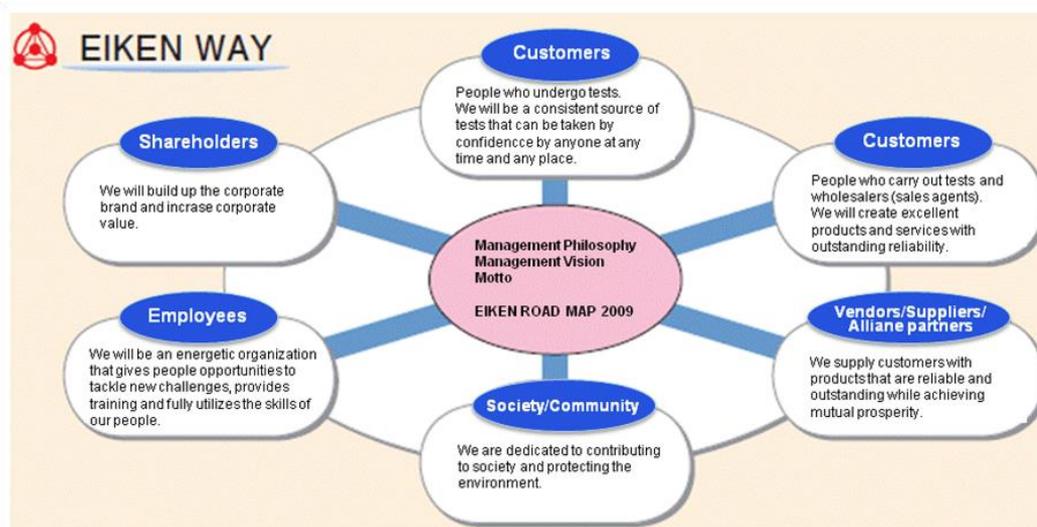
【Management Philosophy】

“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 (excluding diagnostic devices) is about 338 billion yen as of 2013 (survey by the Japan Association of Clinical Reagents Industries, or JACRI).

In order to control rising medical costs, the Japanese government is focusing on preventive medicine such as special health check-ups (metabolic check-ups) and cancer screenings. It is expected that this, along with the aging population, will lead to an increase in the number of samples (number of specimens).

Some negative factors include the 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 insurance (medical laboratory test 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

testing by the entire industry including Eiken. Thus, in the mid to long term, the domestic market is expected to slightly grow by 3% each year.

According to the “Prospect of Clinical Laboratory Test Market, 2009” conducted by Yano Research Institute, Eiken Chemical ranked the 5th largest, 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 US).

Out of the 115 member companies (as of April 2015) of JACRI mentioned above, about 80 are manufacturers, and there are about 15 companies with over 10 billion yen in sales. Most of them are small to medium sized companies. Because the test items of diagnostic tests range widely, each company has its own field of strength, and business segregation is already established in the industry. As a result, collaboration, such as supplying raw materials and products from other companies and manufacturing and selling them, is often observed. Against such a backdrop, the market is modestly growing. Therefore, there is currently no apparent 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 the “biological test” that directly examines the body using medical equipment such as X-ray, CT, MRI, electrocardiogram, and ultrasound. Another type of clinical tests is the “medical laboratory test” that examines biological samples (specimens) 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 amounts of blood contained in stool. They are made to support diagnosis. Most of these reagents are called in vitro diagnostics (IVD) and are regulated by the Pharmaceutical and Medical Device Act so reagent manufacturers file applications with PMDA (Pharmaceuticals and Medical Devices Agency) and obtain its approval. Users include hospitals, clinics, medical offices, medical test centers that carry out tests commissioned by medical institutions, health screening centers, public health centers, and institutions for health research, etc.

2. Major Products

Eiken Chemical mainly manufactures and sells the following types of reagents and medical devices.

As they deal with a wide range of reagents, they not only sell their in-house products but also purchase and sell products from other companies.

Major in-house products include fecal immunochemical test reagents, microbiological reagents, immunological and serological reagents, urinalysis test strips, genetic testing reagents, etc. The sales ratio of in-house products to other companies' products is approximately 60:40. The gross profit margin is approximately 55% for in-house products and

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approximately 35% for other companies' products.

Product Name	Sales	Sales Proportion
Fecal Immunochemical Test Reagents	7,554	24.4%
Immunological and Serological Reagents (Excluding Fecal Immunochemical Test Reagents)	9,873	31.8%
Microbiological Reagents	4,654	15.0%
Urinalysis Test Strips	2,135	6.9%
Clinical Chemistry Test Reagents	658	2.1%
Equipment/ Culture Medium Related to Food and Environment	2,324	7.5%
Medical Devices	2,883	9.3%
Molecular genetics (LAMP Method) (Reagents/Royalties)	929	3.0%
Total Sales	31,014	100.0%

*Results for the fiscal year ended March 2015. Unit: Million Yen

Fecal Immunochemical Test Reagents

The major products for Eiken Chemical are reagents and sampling bottles for fecal immunochemical tests to specifically detect and measure human hemoglobin in feces as a colon cancer screening and diagnosis and are sold globally.

Immunological and Serological Reagents (Excluding Fecal Immunochemical Test Reagents)

Starting with reagents for "LZ Test 'EIKEN'," an automated analyzer, Eiken Chemical develops, manufactures, and sells various reagents to diagnose and measure infectious disease, rheumatism, inflammation, atrophic gastritis, and prostate specific antigens.

They also install and sell reagents for fully automated enzyme immunoassay devices and reagents for automatic glycohemoglobin analyzers from Tosoh Corporation.

Microbiological Reagents

Since its establishment, Eiken Chemical has been developing biological specimens as well as reagents for microbiological tests for food and environment 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 mediums, powder mediums, drug sensitivity test reagents, and rapid test reagents.

Urinalysis Test Strips

Eiken Chemical develops, manufactures, and sells "URO PAPER III 'EIKEN'," a urine analysis test strip for testing various items such as occult blood, protein and glucose, as well as the "URO PAPER α III 'EIKEN'," a specialized test strip for fully automated urine analyzers.

Clinical Chemistry Test Reagents

Eiken Chemical develops, manufactures and sells reagents for clinical chemistry tests including "EXDIA XL 'EIKEN'" series that assist to measure and analyze biological components in blood serum and urine, with a focus on the test items that are related to lifestyle related diseases.

Equipment/ Culture Mediums Related to Food and Environment

Eiken Chemical sells reagents for microbiological tests on food to detect food poisoning bacteria as well as reagents for environmental microbiological tests and equipment and devices to measure contamination of work environments.

Medical Devices

Eiken Chemical sells various types of automated analyzers. They contract manufacturing specialized equipment that uses their in-house reagent. Since beginning sales of “OC Sensor” in 1989, they have worked continuously on technological innovation and quality improvement of this fecal immunochemical test analyzer. Also, they offer the “US,” an automated urine analysis device that uses Eiken’s proprietary color CCD sensor, the “BLEIA-1200,” a fully automated biochemistry photogenetic immunoassay device that was the world’s first of its kind in the clinical testing field, and “LoopampEXIA,” a LAMP-based real time turbidity measuring device.

Molecular genetics (LAMP)

In 1998, Eiken Chemical developed and patented an innovative gene amplification technology called “LAMP.” The LAMP is “simple, rapid, and accurate” and is a critical tool for Eiken’s future global expansion of its business. (Details are described below)

3. 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 2015, about 290 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 51 countries (FY 2015). The high proportion of overseas sales is occupied by the sales in the USA, Italy, South Korea, and Taiwan.

In addition to the Europe Branch 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 2015 are 27.04 billion yen, out of which 22.94 billion yen, 84.8%, is from the sales of fecal immunochemical test reagents and medical devices.

【ROE Analysis】

	FY3/11	FY3/12	FY3/13	FY3/14	FY3/15
ROE (%)	8.5	7.0	10.9	8.3	8.3
Net Profit Margin (%)	6.07	5.27	8.56	6.61	6.77
Asset Turnover Ratio (x)	0.89	0.84	0.84	0.84	0.83
Leverage (x)	1.57	1.58	1.52	1.50	1.47

The ROE for FY 2015 was the same as FY 2014 at 8.3%, which is about an average level.

(The reason for the high ROE in FY 2013 was the increased net income margin from posting extraordinary income from land sales.)

However, it is foreseen that there will be a greater call for further increase in ROE. So with the company’s stated goal of developing products with high added value, it will be necessary to further increase productivity and profitability by creating new business and markets as well as lowering cost rate and SG&A expense rate.

【Characteristics and Strengths】

(1) Products that Occupy High Share in the Market

The share of Eiken's fecal immunochemical test reagents is ranked top (approximately 57%) in the domestic market. Furthermore, many of their in-house products occupy high market share in the market, for example, urinalysis test strips occupying approximately 23% (ranked second) of the market, and microbiological reagents occupying approximately 18% (ranked second) of the market.

The background to how Eiken's fecal immunochemical test reagents have come to hold such a high share of the market includes that in 1987, Eiken began sales of "OC-Hemodia," a visual determination method fecal immunochemical test reagents, a product that more closely conformed to user needs when compared to competitor's products, and that in 1989 they adopted the latex photometric immunoassay method and began sales of "OC-Sensor," the world's first fully automated analyzer.

Also, the Health and Medical Service Act for the Aged was revised in 1992, making it possible to have fecal immunochemical test reagents as a method in colon cancer screening and diagnosis using public funds (no cost to the patient) which led to an accelerated spread and increased competition. But in 2001, Eiken began sales of the "OC-Sensor neo," with completely remodeled functions, which increased its market share.

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 immunochemical tests, Eiken will expand its business globally based on the above characteristics.

The immunochemical method used in Japan applies reagents that react only to human hemoglobin, and can process a large volume simultaneously.

Meanwhile, in other countries, reagents for the chemical method (Guaiac method) based on old measuring principles are still used, which presents accuracy challenges. In 2011, the test guidelines in Europe have finally begun recommending automated analyzers that use the immunochemical method. As a result, the market is beginning to undergo a dramatic change.

Furthermore, although the chemical method is also still common in the United States, which has the largest potential market, trends show a gradual shift toward the immunochemical method. This means that, in both developed and emerging countries in Europe, North America, Asia and Oceania, there is a large unexplored market.

Because the fecal immunochemical tests market is a niche market, Japanese companies, the forerunners of the immunochemical method, own the most advanced technique, and hence Eiken's reagents and equipment are the global standard.

(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 the “LAMP”

Thus far the mainstream technology for amplifying genes as a process of gene tests has been what is called “PCR” Under such circumstances, in 1998, Eiken Chemical developed a unique technology called the “LAMP.”

Compared to the PCR, the “LAMP” offers the following superior characteristics and allows users to carry out simple, rapid and accurate gene tests.

Simple	Amplification response occurs at a constant temperature (with the PCR, the temperature needs to be changed for amplification).
Rapid	High amplification efficiency, with genes being detected within 30 to 60 minutes (with the PCR, it takes 2 to 3 hours).
Accurate	Extremely high specificity.

Currently in the medical field, the LAMP is used to diagnose infectious diseases such as tuberculosis, mycoplasma (a genus of bacteria, it can also cause pneumonia), legionella, influenza, etc.

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

Furthermore, for the same purposes, Eiken Chemical is actively giving licenses to external companies in order to build the LAMP camp.

One of the major actions to spread the LAMP in the world is an alliance with “FIND.”

“FIND” stands for “Foundation for Innovative New Diagnostics” and is a non-profit organization recognized by the Swiss government, launched at a meeting of the United Nations World Health Assembly in May 2003. In its initial five years of existence, it received a grant from the Bill & Melinda Gates Foundation to start up their activities.

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

FIND’s scope of activities includes tuberculosis, malaria, and African sleeping disease. With tuberculosis, collaborative research between Eiken Chemical and FIND for a tuberculosis test using the LAMP began in July 2005. The purpose of this research is to improve the accuracy of tests by replacing the microscopy test (sputum smear test), which is the current practice in developing countries.

As a result of this collaboration, improvements which are not possible with the conventional PCR such as simplified pretreatment (PURE method), improved reagents storage (store at room temperature) and simplified devices have been made to enable the developing countries to carry out the procedure.

This LAMP-based product was already launched in Japan in 2011.

Presently, in order to obtain endorsement from the WHO (World Health Organization), FIND has completed clinical evaluation in 14 developing countries and submitted this information to the WHO.

In addition to tuberculosis and other diseases listed above, Eiken Chemical and FIND also conduct collaborative research of reagents for leishmaniasis and Chagas disease.

Also, Eiken Chemical is developing a next-generation compact fully automated genetic testing device and multi-item testing chip using the LAMP. This equipment fully automates the process from specimen preprocessing (nucleic acid extraction and purification) to amplification and detection. By developing the unique protocol that exploits the LAMP's characteristics, the operation time that used to take over 2 hours with a conventional high purity nucleic acid extraction and purification device and an amplification and detection device combined, is now shortened to less than 30 minutes. First, a clinical performance test will be carried out with the goal of simultaneous detection of several respiratory infection causing germs but the usage application is extensive.

It is anticipated that through these products, Eiken Chemical will accelerate the spread of the LAMP and establish its position as the global standard in a newly created 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 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 develops an anemia and 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, encephalomyelitis, cardiac disturbance, etc.

2. Fiscal Year March 2015 Earnings Results

(1) Overview of consolidated results

(unit: million yen)

	FY 2014	Composition ratio	FY 2015	Composition ratio	Year-on-year comparison	Estimate at the beginning of term
Sales	30,027	100.0%	31,014	100.0%	+3.3%	-1.0%
Domestic	28,010	93.3%	28,310	91.3%	+1.1%	-0.2%
Overseas	2,017	6.7%	2,704	8.7%	+34.1%	-8.3%
Gross margin	12,376	41.2%	12,868	41.5%	+4.0%	-
SG&A	9,367	31.2%	10,041	32.4%	+7.2%	-
Operating income	3,008	10.0%	2,826	9.1%	-6.0%	-2.6%
Ordinary income	3,095	10.3%	3,013	9.7%	-2.6%	+2.8%
Net income	1,984	6.6%	2,100	6.8%	+5.8%	+12.3%

Increase in sales and operating income due to increased overseas sales

Sales increased by 3.3% from the previous term to 31,000 million yen. Domestic sales increased slightly by 1.1% from the previous term despite the negative rebound from the last-minute demand prior to the consumption tax hike and the effect of revised medical treatment fees. In terms of product category, urinalysis test strips, ABC classification reagents, and immunochemical fecal occult blood test reagents contributed. Overseas sales grew significantly by 34.1% from the previous term, mostly from fecal immunochemical test reagents and medical devices.

Gross margin increased by 0.3%, but the increase in R&D expenditures, and drop in Eiken China performance resulted in a 6.0% decrease from the previous term in operating income. Due to the decrease in corporate taxes from the tax reform of 2014, net income increased by 5.8% from the previous term.

The sales and operating income did not reach planned goals.

(2) Sales by product

Product	FY 2014	FY 2015	Year-on-year comparison
Fecal immunochemical test reagents	6,791	7,554	+11.2%
Immunological and serological reagents (excluding fecal immunochemical test reagents)	9,636	9,873	+2.5%
Microbiological reagents	4,745	4,654	-1.9%
Urine analysis reagents	2,132	2,135	+0.1%
Clinical chemistry test reagents	686	658	-4.1%
Equipments/ culture medium related to food and environment	2,350	2,324	-1.1%
Medical equipment	2,759	2,883	+4.5%
Molecular genetics (LAMP method) (reagents, royalties)	925	929	+0.4%
Domestic sales	28,010	28,310	+1.1%
Overseas sales	2,017	2,704	+34.1%
Total sales	30,027	31,014	+3.3%

*results for term ended March 2015. unit: million yen

- Fecal immunochemical test reagents

Domestically, the company focused on promotion of colorectal cancer screening and diagnosis. The company also rolled out a new medical device product, "the OC-sensor PLEDIA."

Performance in North America, Europe and Asia were all good.

- Immunological and serological reagents (excluding fecal immunochemical test reagents)

The sales of "AIA related reagents" procured from Tosoh Corp. decreased, but the increase in testing for the evaluation of the health levels of the stomach (ABC classification) (helicobacter pylori test reagents and pepsinogen test reagents) covered this decrease.

- Microbiological reagents

The sales of drug sensitivity test reagents, powder culture medium, and rapid test reagents were all below those for the previous term due to the negative rebound from the last minute demand prior to the consumption tax hike.

- Urinalysis test strips

The income from "Uropaper III Eiken," used for visual observation method, decreased. However, due to the trends toward automated testing, the sales of "URO-PAPER α III EIKEN," dedicated test strip for fully automated urine analyzer, were strong both domestically and overseas. As a result, sales of urine analysis reagents remain flat. The company also released the new analyzer "US-3500."

- Clinical chemistry test reagents

The year-to-year sales decreased due to the drop in price from market share competition.

- Equipment/ Culture medium related to food and environment

The year-to-year sales decreased due to the rebound from the last minute demand prior to the consumption tax hike, and drop in price due to competition.

- Medical equipment

Domestically, the sales of immunological and serological reagents, microbiological test apparatus increased, while fecal immunochemical test analyzer and urine analyzer increased overseas.

- Molecular genetics (LAMP)

Genetic testing reagents and running royalties increased.

(3) Overseas trends

(unit: million yen)

	FY 2014	FY 2015	Year-on-year comparison
Overseas sales	2,017	2,704	+34.1%
North America	576	927	+60.9%
Europe	810	1,049	+29.5%
Asia, others	629	726	+15.4%

Sales of fecal immunochemical test reagents and medical device increased steadily by 36.0% and 48.6%, respectively, from last term.

***North America**

With positive impact from Obamacare, increase in the number of tests lead to significant increase in sales of fecal immunochemical test reagents and apparatus.

***Europe**

Not only was the company's fecal immunochemical test used for the national colon cancer screening and diagnosis in France, but the company was also able to bid successfully for the mass testing in Madrid, Spain. The company also increased activity for the test to be adopted in England. In Italy, fully automated urine analyzer as well as its dedicated test strip grew in sales significantly.

***Asia, etc.**

The company also worked for the fecal immunochemical test to be newly adopted and its sales increase in Thailand, Hong Kong, Australia, New Zealand, etc.

In China, the company worked on the sales promotion of LAMP products, the fecal immunochemical test reagent and apparatus. The company also acquired the permission for the LAMP tuberculosis tests, and started promoting sales.

***FIND business**

The advancement in the business related to the alliance with FIND was as follows:

(i) Tuberculosis

The company continued working to acquire WHO recommendation by conducting evaluation in developing nations, followed by its data processing and analysis. The company is hopeful to obtain this endorsement in the first half of this term. The company is currently preparing the sales structure, and is negotiating with the agent with a global sales force.

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(ii) Malaria

The company sold screening reagents for the malaria eradication project.

(iii) African trypanosomiasis

The clinical studies in the Democratic Republic of Congo and Uganda were continued.

Reagents for the eradication project were sold in Uganda, Malawi, Guinea, the Democratic Republic of Congo, etc.

(iv) Leishmaniasis, Chagas disease

The evaluation of prototype by FIND was continued.

(4) Financial status and cash flow

◎Major BS

(unit: million yen)

	End of March, 2014	End of March, 2015		End of March, 2014	End of March, 2015
Current assets	26,579	25,285	Current liabilities	9,861	9,995
Cash and deposits	11,032	9,590	Notes and accounts payable-trade	6,295	6,480
Notes and accounts receivable-trade	9,242	9,756	Short-term loans payables	270	-
Inventory	4,948	4,965	Noncurrent liabilities	2,255	1,260
Noncurrent assets	9,815	12,610	Liabilities related to retirement benefits	942	-
Property, plant and equipment	6,786	7,118	Total liabilities	12,117	11,255
Intangible assets	493	561	Net assets	24,278	26,639
Investment and other assets	2,535	4,930	Shareholder equity	24,568	26,289
Total assets	36,395	37,895	Total liabilities and net assets	36,395	37,895

An increase in notes and accounts receivable-trade was seen, but current assets decreased by 1,294 million yen from the previous term due to the decrease in cash and deposits and others. Noncurrent assets increased by 2,795 million yen due to the increase in investment from long-term deposits and the increase in other assets, and total assets increased by 1,500 million yen.

Current liabilities augmented slightly due to the increase in notes and accounts payable-trade, whereas the noncurrent liabilities decreased by 995 million yen due to the decrease in liabilities related to retirement benefits.

Net assets increased by 2,361 million yen due to the increase in the retained earnings. As a result, the equity ratio increased by 3.6%, from 66.2% of the previous term end to 69.8%.

◎Cash flow

(unit: million yen)

	FY 2014	FY 2015	Changes
Operating CF	3,410	3,393	-17
Investing CF	-779	-6,652	-5,873
Free CF	2,631	-3,259	-5,890
Financing CF	-1,268	-1,107	+161
Cash and cash equivalents	10,940	6,577	-4,363

The Operating CF was more or less on par with those of the previous term, but an increase in the fixed deposit amount further decreased the investing CF, and the free CF became negative. The cash position declined.

3. Fiscal Year March 2016 Earnings Estimates

<Consolidated performance forecast>

(unit: million yen)

	FY 2015	Composition ratio	FY 2016 (Estimate)	Composition ratio	Year-on-year comparison
Sales	31,014	100.0%	32,820	100.0%	+5.8%
Domestic	28,310	91.3%	28,960	88.2%	+2.3%
Overseas	2,704	8.7%	3,860	11.8%	+42.7%
Operating income	2,826	9.1%	3,330	10.1%	+17.8%
Ordinary income	3,013	9.7%	3,350	10.2%	+11.2%
Net income	2,100	6.8%	2,180	6.6%	+3.8%

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

Overseas market development leads to increases in sales and profits

The sales forecast shows a 5.8% increase from the previous term to 32,800 million yen. Overseas sales, especially in Europe, will significantly increase.

Travel and packaging expenses will increase due to the augmentation in the sales promotion activities, and SG&A expenses including IT investments and others required for enhancing efficiency will also increase. However, all these will be offset by an increase in the sales. The operating income is expected to grow by 17.8%, to 3,300 million yen. The growth of productivity and the number of high profit margin products will result in increased operating margin by 1%.

Dividend is expected to increase to 40 yen per share, by 3 yen per share for interim and 2 yen per share for year-end, for a total increase of 5 yen per share. This will be the first increased dividend within four terms, and the dividend payout ratio is expected to be 33.5%.

<Domestic>

The company will attempt to increase the sales of fecal immunochemical test reagents and apparatus, test reagents for general purpose automated analysis apparatus, "LZ test Eiken series," microbiological reagents (drug sensitivity test reagents, industrial field), Tosoh related test reagents, LAMP products, and point-of-care testing (POCT) as one of the sales promotion product group.

<Overseas>

The company will try to increase the share and advance into new market. Overseas sales ratio will increase to 11.8%, topping 10% for the first time.

Europe will grow significantly since the national screenings beginning in France will be fully contributed, and England is expected to hold its first bidding in the latter half of the term.

The company will establish the brand and boost the sales of the fecal immunochemical test reagents, and target national screenings like the one in France in the previous term.

The company will promote the urinalysis test strips and "LZ test Eiken" series in China.

The company will also develop emerging markets such as ASEAN and India.

For the FIND business, the company also expects recommendation from the WHO for products related to tuberculosis, and will work on malaria related products. The company expects sales of 200 million yen this term.

<Research and development>

The following points will be enhanced.

- Firm grasp of customer needs, and its application to product development
- Promotion of development of LAMP method, POCT Rapid Test product group
- Development of OTC test reagents (fecal immunochemical test reagents)
- Product improvement by brushing up existing technology
- Promotion of exploratory research into new biomarkers and new diagnostic technology
- Promotion of the FIND business recommendation (acquisition of endorsement by the WHO for tuberculosis)

The company will quickly develop "next generation compact automatic genetic testing device" and "multiple item test chip" for the LAMP method. These products enable the company to stay on top of other competitors, and the company intends to enhance future efforts.

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

(unit: million yen)

	FY 2013	FY 2014	FY 2015	FY 2016 (Estimate)	Year-on-year comparison
R & D costs	1,840	1,945	2,456	2,766	+12.6%
Capital investment	693	839	1,226	4,181	+241.0%
Depreciation	1,040	1,114	1,253	1,700	+35.7%

This term, new construction of the energy building (boiler facility) in the plant, and the introduction of new facilities and the construction of new plant for the sales area expansion of the urinalysis test strips will begin. The company will attempt to increase production and lower cost. Additionally, the company plans capital investment to improve the production capability of the fecal immunochemical test reagents and the LZ test "Eiken" in FY 2016.

Local production and sales will be promoted for the China plant. New construction of plants outside China is an issue to be investigated in the future.

<Improvement in productivity>

The improvement in production capability and the reduction of production cost will be attempted through the renewal of plants and production facilities. The decrease in the SG&A expenses will also be attempted through improvement to the sales-cost ratio and higher operation efficiency.

4. Interview with President Morifumi Wada

<The first year in retrospect, since Mr. Wada's appointment as President>

- Since the predecessor, the current chairperson, passed on the baton smoothly, we were able to get a good start, such as an increase in overseas sales.
- On the other hand, we were able to extract and organize issues during the compilation of the road map for mid-term growth. We plan to significantly increase our future capital investment in the coming terms according to these. This investment is essential for us to win over competition.

<Breakdown of business>

Product family	Business policy	Domestic sales	Overseas sales	Investment
Fecal immunochemical test	Driving force of growth	Increase	Increase	Increase
Immunological and serological tests	Driving force of growth	Increase	Increase	Flat
Microbiological tests	Stable profits	Flat	Increase	Flat
Urinalysis tests	Driving force of growth	Flat	Increase	Increase
Clinical chemistry tests	Stable profits	Flat	-	Decrease
Apparatus/food and environment tests	Stable profits	Flat	Flat	Decrease
Molecular genetics	Driving force of growth	Increase	Increase	Increase

<Development of overseas market>

- There were several factors leading to the significant increase in overseas sales in the previous term. Among such were the improved relation with our agents.
- We had deeper discussions than before, not only about price, but also the overall quality and future strategies.

Accordingly, our mutual trust became deeper, and the sales force of our agents even more powerful.

- Additionally, the relation we have been forming with related government agencies in various nations, local governments, and academic societies have all contributed to significant growth in the previous term.
- We will further enhance our human resources, especially through local hiring. We will also form alliances with overseas manufacturers of apparatus and reagents, as well as look for more competent agents.
- The European market has also started to bloom with our continuing efforts, but still has room for growth. Since the demand in ASEAN will also grow due to the improvement in their living standard, we will start developing new markets with a long-term vision.
- Overseas sales ratio will reach double digits for the first time this term. Our next target will be 30%. This is not an easy target, but we will try to achieve this goal by developing new products matching market needs.

<Towards a vibrant company>

- Our firm has an internal proposal policy, and attempt to collect new ideas and views in a bottom-up manner. Every year, we receive a lot of new proposals for various topics, to increase productivity, solve environmental problems, increase efficiency, and to improve customer satisfaction, from various sections, both individuals and groups.
- We give out the "annual outstanding proposal award" to the outstanding proposals. We also highlight and award the "president award" and the "executive manager award" to individuals and groups that contributed greatly to the company profits.
- Our company culture is one that anyone can state their views to others. We would like to further promote this culture so that our young employees can also express their views.

<A message to our investors>

- I believe our firm can develop huge overseas markets, can vastly improve efficiency including the indirect departments, and has potential to leap forward with the positive investments to be made starting this term.
- We, as a whole company, will continue to challenge ourselves to realize these possibilities.
- We also intend to improve the company's value to shareholders in terms of ROE, dividends and others in this process. I hope you will support our endeavors from a mid- to long-term perspective.

5. Conclusions

In the last report we mentioned the possibility that the recovery of the US market for immunochemical fecal occult blood test reagents and devices, in addition to France's adoption of such products, may increase overseas sales for the fiscal year. Unfortunately, the overseas sales did not reach planned levels due to sluggish sales in China, but the adoption in France lead to significant growth in sales compared to the previous term. Further expansion will continue in FY 2016, and Eiken will aim to reach the current goal of having an overseas sales ratio of over 10%. The next goal of having overseas sales ratio of 30% is by no means a low hurdle as it will require approximately 9,000 to 10,000 million yen even at the current sales base but, we would like to pay attention to the progress in this initiative including expanding FIND business with tuberculosis and developing new products.

<Reference: New Management Framework "EIKEN WAY" and "EIKEN ROAD MAP 2009">

EIKEN CHEMICAL set a goal for 2018, the company's 80th anniversary year, 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-transformation.
- (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 market superiority	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.

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(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) Enhance the corporate brand	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. Our goal for the time being is to maintain over 10% of overseas sales ratio and over 10% of consolidated sales profit margin.

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