



FY2015

The First Half-year Results

(April 1, 2015 – September 30, 2015)

Miraca Holdings Inc.

November 4, 2015

Please be aware of the following:

* Figures and ratio in this material are rounded to the appropriate unit in principle.

* The sums of the individual figures in each table do not always correspond to the total, because of rounding.

* Abbreviations:

IVD: In Vitro Diagnostics (business)

CLT: Clinical Laboratory Testing (business)

HR: Healthcare Related (business)

Op. income: Operating income

Ord. income: Ordinary income

LP: LUMIPULSE

MLS: Miraca Life Sciences, Inc.

BMGL: Baylor Miraca Genetics Laboratories, LLC



Summary of 1H/FY2015 Consolidated Results (1)

Net sales reached **record-high** and Op. income decreased

(¥ billion)

	1H/FY2014 Results	1H/FY2015 Results	Y/Y Variation	
Net sales	102.22	105.98	+3.76	+3.7%
IVD	20.90	22.73	+1.83	+8.7%
CLT	67.08	69.03	+1.95	+2.9%
HR	14.24	14.23	-0.01	-0.1%
Op. income	(*) 14.52	(*) 13.77	-0.75	-5.1%
IVD	5.06	5.82	+0.76	+14.9%
CLT	7.75	6.38	-1.37	-17.7%
HR	1.65	1.48	-0.17	-10.3%
EBITDA (**)	21.78	21.20	-0.58	-2.7%

(*) Segmentation adjustments (¥ billion): 0.05 in 1H/FY2014; 0.09 in 1H/FY2015

(**) EBITDA = Operating income + Depreciation + Amortization of goodwill

※ Exchange rate: 1H/FY2014: 1USD=103.03JPY, 1EURO=138.90JPY
1H/FY2015: 1USD=121.81JPY, 1EURO=135.08JPY

● **Increase in Net sales: Contribution of sales growth in global IVD/ CLT businesses (incl. currency exchange gain)**

● **Decrease in Op. income: Profit increase in IVD could not offset profit decline in CLT** *1*

Summary of 1H/FY2015 Consolidated Results (2)

Each income (excl. income before income taxes) did not reach FY2014 results and initial forecast

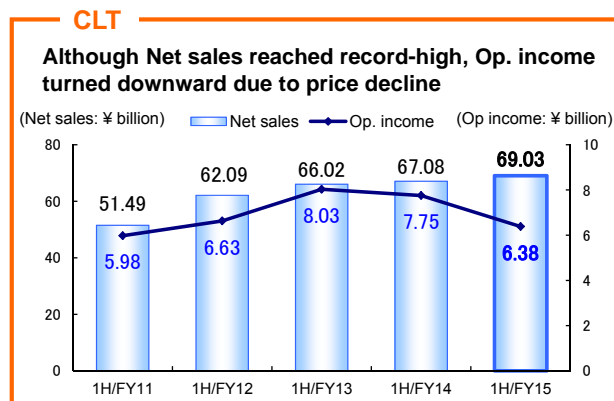
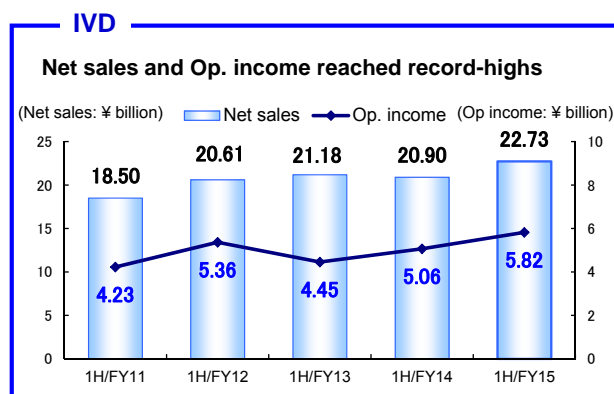
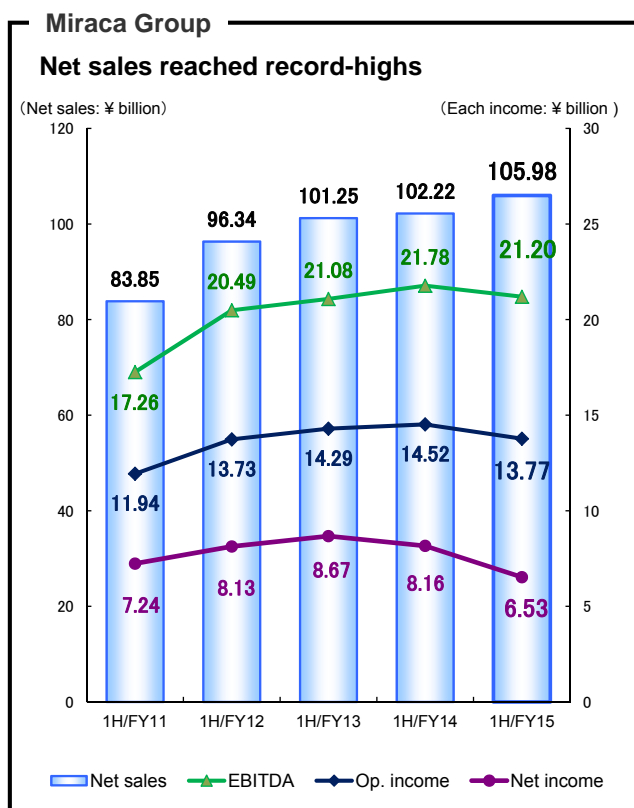
(¥ billion)

	FY2014 Results	FY2015 Results	Y/Y Variation	FY2015 Forecast	Variation from Forecast
Net sales	102.22	105.98	+3.76 +3.7%	105.30	+0.68 +0.6%
Op. income	14.52 14.2%	13.77 13.0%	-0.75 -5.1%	14.00 13.3%	-0.23 -1.6%
Non-operating income/ expense	-0.03	-0.89	-0.86		
Ord. income	14.49 14.2%	12.88 12.2%	-1.61 -11.1%	13.35 12.7%	-0.47 -3.5%
Extraordinary income/ loss	-0.98	1.85	+2.83		
Income before income taxes	13.51 13.2%	14.72 13.9%	+1.22 +9.0%		
Income taxes	5.34	8.20	+2.86		
Net income	8.16 8.0%	6.53 6.2%	-1.64 -20.1%	7.45 7.1%	-0.92 -12.4%

【Factors of Y/Y variation】

- **Non-operating loss:**
 - Shares of loss of entities accounted for using equity method (mainly BMGL)
- **Extraordinary income/loss and Income taxes:**
 - Provision of tax expenses related to a legal action against MLS (Actual effect: ¥1.6 billion, conservative estimation)
 - Business structure improvement expenses at FRE (¥0.64 billion) and MLS (¥0.14 billion) in 1H/FY2014

Change in 1st Half Results over 5 years

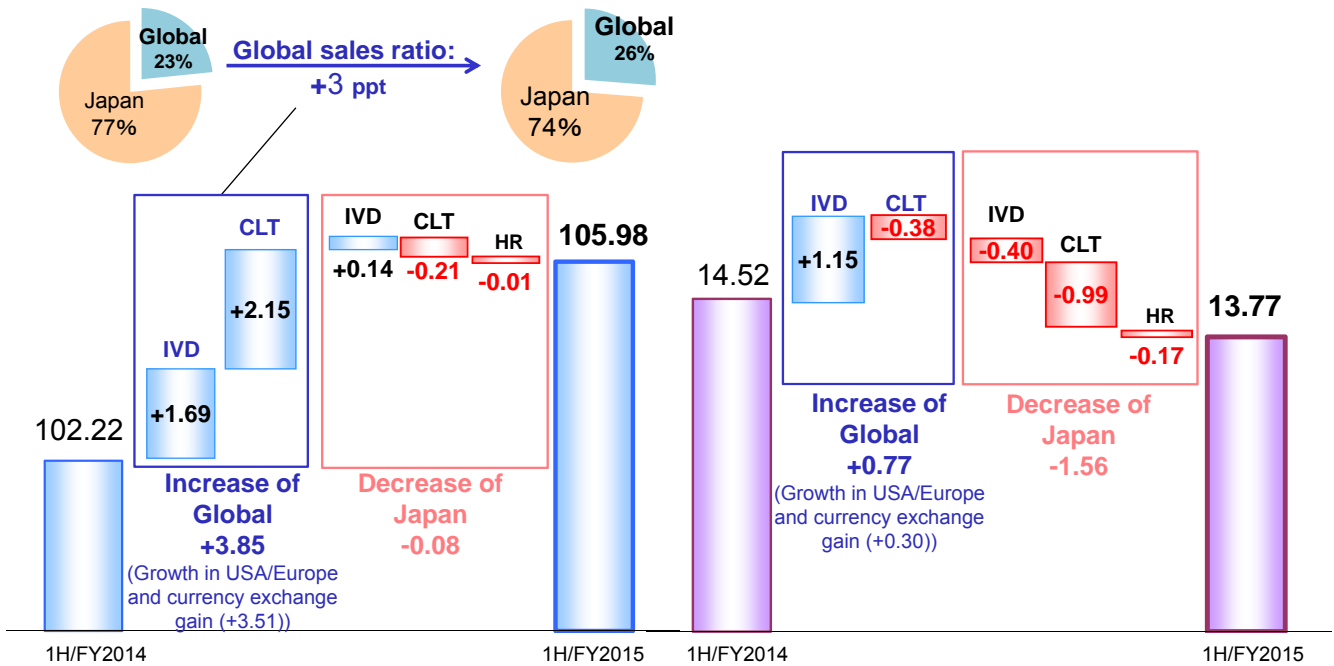


Analysis of Changes (Y/Y) in Net sales and Op. income

Net sales +3.76 bn yen (+3.7%), Op. income -0.75 bn yen (-5.1%)

■ Consolidated Net Sales (¥ billion)

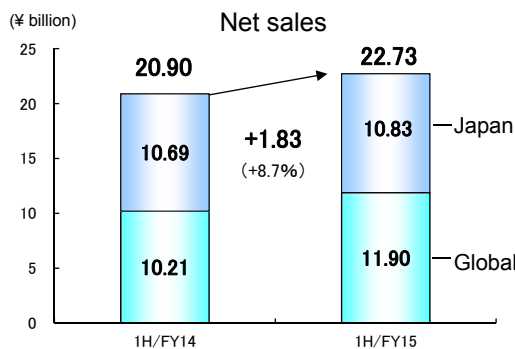
■ Consolidated Op. Income (¥ billion)



1H/FY2015 Segment Performance Review

1. In Vitro Diagnostics:

Increase in Net sales and Op. income



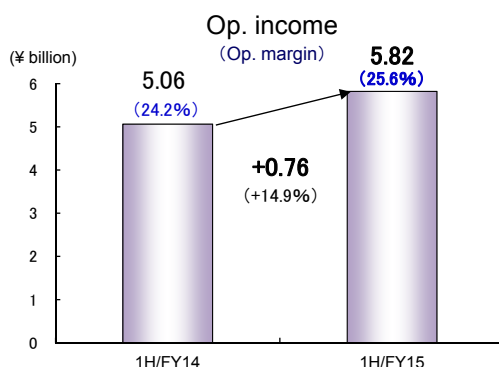
◆ Japan

◇ Increase in Net sales: +0.14

- Sales growth of LUMIPULSE(LP) reagents
- Decline of low-profit product sales (Non-LP)

◇ Decrease in Op. income: -0.40

- Increase of R&D expenses for launch of LP sales in USA



◆ Global (Non-Japan)

◇ Increase in Net sales: +1.69

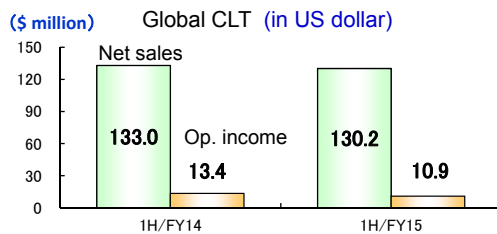
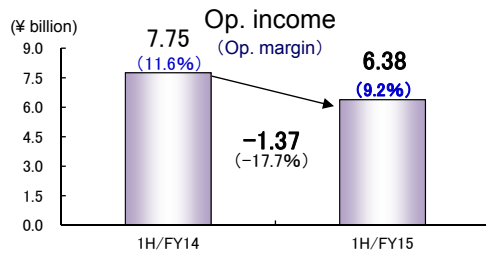
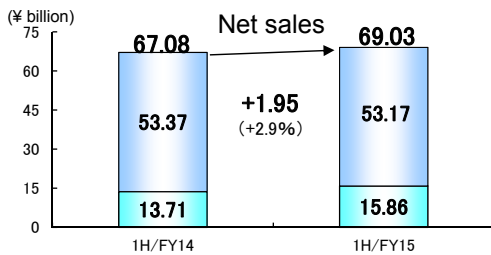
- Growth in raw material supply and LP business
- One-time royalty income
- Currency exchange gain: 1.1

◇ Increase in Op. income: +1.15

- Increase in profit generated by sales increase: 0.5
- Currency exchange gain: 0.4
- Royalty income etc.

1H/FY2015 Segment Performance Review

2. Clinical Laboratory Testing: Increase in Net sales, Decrease in Op. income



◆ Japan

◇ Slight decrease in Net sales: -0.21

Net sales was almost flat, excluding impact of less working days

- Growth in high-priced test segment
- Impact of test price decline (Y/Y basis): -3%

◇ Decrease in Op. income: -0.99

- Decrease in marginal profit caused by test price decline
- Initial investment for launch of new testing

◆ Global (USA)

Net sales: +2.15, Op. income: -0.38

- Currency exchange gain: +2.5

【MLS (before goodwill amortization)】

◇ Net sales: -\$2.8M

- Mainly average price decline in GI segment due to GI test mix change and unit price decline :-\$7.0M
- Test volume increase (Growth in Derm) :+\$4.6M

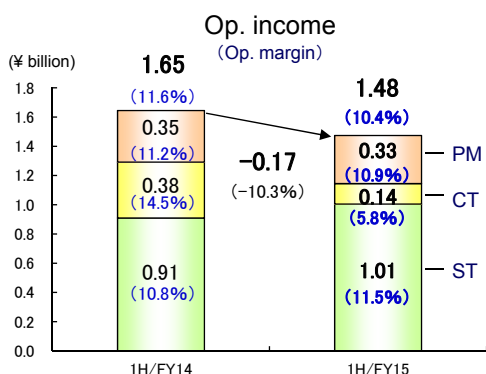
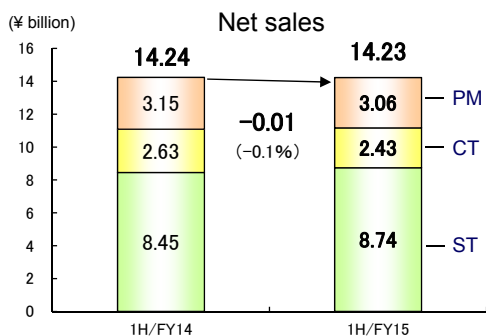
◇ Op. income: -\$2.5M

- Decrease in marginal profit caused by test menu/segment mix change and price decline

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1H/FY2015 Segment Performance Review

3. Healthcare Related: Decrease in Net sales and Op. income



◆ Sterilizing (ST) :

Net sales: +0.29 bn yen, Op income: +0.10 bn yen

- Sales growth achieved through development of new accounts

◆ Clinical Trials (CT) :

Net sales: -0.21 bn yen, Op income: -0.24 bn yen

- Decrease in profitability caused by decline of project price
- Smaller project size (target disease area change)
- Started to improve cost structure corresponding to sales size

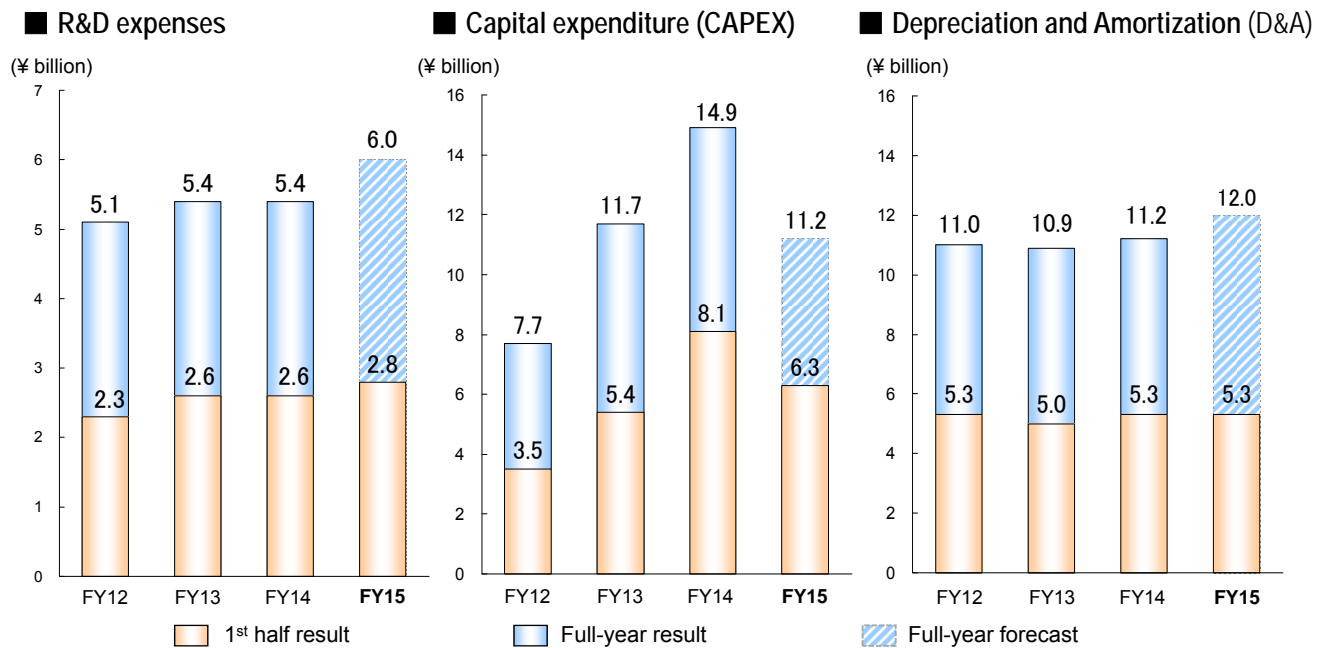
◆ Preventive Medicine Related (PM):

Net sales: -0.09 bn yen, Op income: -0.02 bn yen

- Stable growth in Nursing-care related business
- Decrease in sales due to absence of sales of Health checkup business

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1H/FY2015 Consolidated R&D Expenses, CAPEX, and D&A

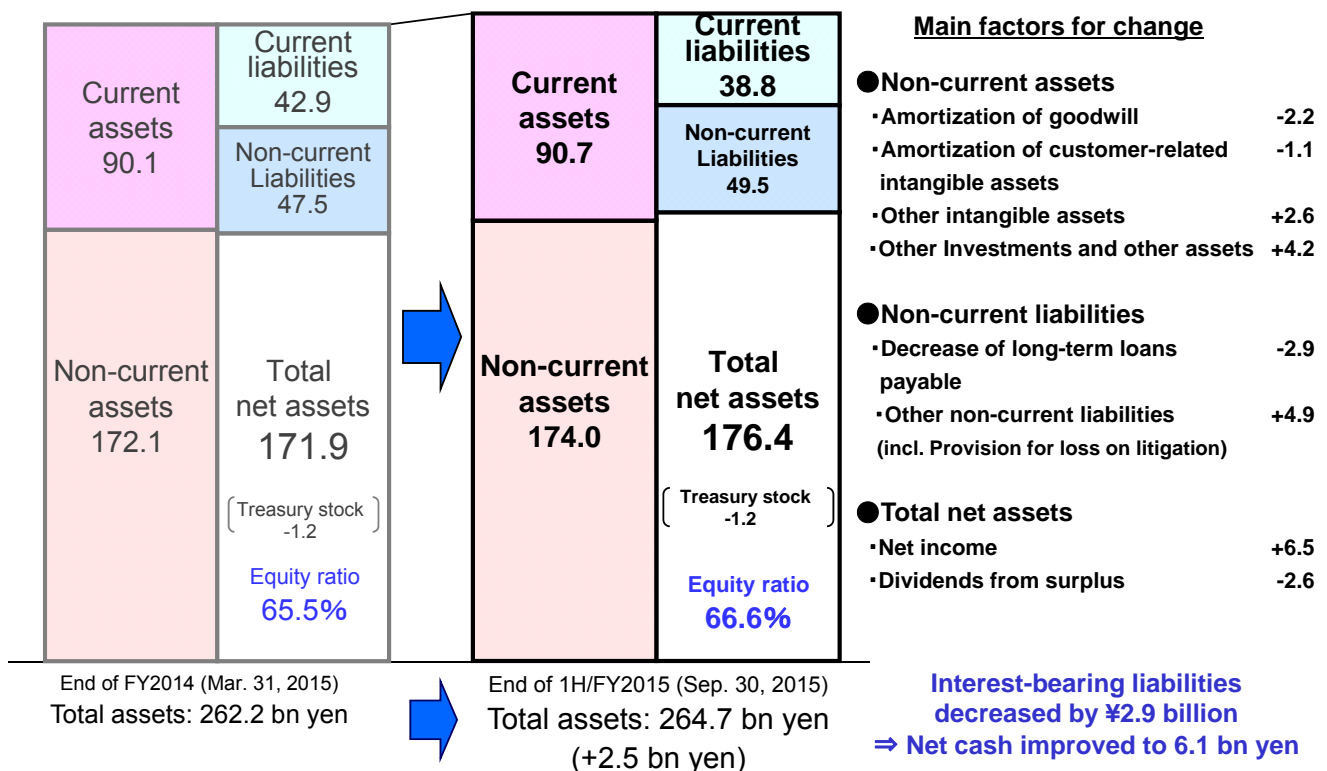


Key points in FY2015

- Increase in R&D expenses for global sales of LP series in IVD business
- Increase in CAPEX and carry-forward of partial D&A due to delay in development/ cutover of Navi-Lab (next-generation IT system) in CLT business
- ※FY2015 Full-year forecast has been revised.

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1H/FY2015 Consolidated Balance Sheet (¥ billion)



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Consolidated Cash Flows (¥ billion)

■ Consolidated Cash Flows

	1H/FY2014	1H/FY2015
Income before income taxes	13.5	14.7
Depreciation and amortization	5.3	5.3
Income taxes payable	-4.4	-3.0
Other	0.2	-1.2
Net cash provided by operating activities	14.7	15.7
Purchase of property, plant and equipment	-6.9	-6.1
Other	0.2	-0.0
Net cash used in investment activities	-6.7	-6.2
Free cash flows	8.0	9.6
Net cash used in financing activities	-4.9	-5.6
Effect of exchange rate change on cash and cash equivalents	0.1	0.1
Net increase/decrease in cash and cash equivalents	3.2	4.1
Cash and cash equivalents at the beginning of financial period	35.7	27.3
Cash and cash equivalents at the end of financial period	38.9	31.4

Main Factors of Change

● **Net cash provided by operating activities and Net cash used in investment activities:**

→ similar level with 1H/FY2014

● **Net cash used in financing activities**

→ similar level with 1H/FY2014
(repayment of loans payable, cash dividends paid, etc.)

⇒ **Cash and cash equivalents increased by 4.1 bn yen from the beginning of financial period**

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FY2015 Forecast and Progress of Business Plans

FY2015 Full-year Revised Forecast (Consolidated)

(¥ billion)

	Full-year Revised Forecast	Full-year Initial Forecast	Rev. Forecast vs. Initial Forecast	FY2014 Actual	Rev. Forecast vs. FY14 Actual
Net sales	210.0	210.00	- -	204.67	+5.33 +2.6%
IVD	46.3	45.65	+0.65 +1.4%	43.46	+2.84 +6.5%
CLT	135.6	136.00	-0.40 -0.3%	132.85	+2.75 +2.1%
HR	28.1	28.35	-0.25 -0.9%	28.36	-0.26 -0.9%
Op. income	25.7 12.2%	27.70 13.2%	-2.00 -7.2%	27.01 13.2%	-1.31 -4.9%
IVD	10.9 23.5%	10.70 23.4%	+0.20 +1.9%	10.42 24.0%	+0.48 +4.6%
CLT	12.0 8.8%	13.85 10.2%	-1.85 -13.4%	13.49 10.2%	-1.49 -11.0%
HR	2.8 10.0%	3.15 11.1%	-0.35 -11.1%	2.93 10.3%	-0.13 -4.5%
Ord. income	24.5 11.7%	26.95 12.8%	-2.45 -9.1%	26.57 13.0%	-2.07 -7.8%
Net income	14.9 7.1%	16.90 8.0%	-2.00 -11.8%	16.00 7.8%	-1.10 -6.9%

【Major Reasons of the Revision】

●CLT Japan:

- Sales will become nearly equal to the initial forecast
- Marginal profit decreases due to price decline and test menu mix change
- Delay of new IT system operation
 - i. Lower expenses related to the system launch
 - ii. Effect of rationalization will be in/after FY2016
 - iii. Operation costs of existing IT system will continue

●Global CLT:

- Increase in test volume
- Decrease in sales and profit rate in high profitable segment (GI)

●Clinical Trials:

- Significant sales decrease due to price drop etc.

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Progress of Business Plan IVD

1st Half

2nd Half ~

LP Global Geographic Expansion	Europe	<ul style="list-style-type: none"> • Strategic markers : Evaluation by KOL and improve awareness • Approach to niche market with G600II (small size analyzer) 	<ul style="list-style-type: none"> Instrument installation Reagent sales expansion
	Asia	<ul style="list-style-type: none"> • China: Expansion of PIVKA II and KL-6 • Korea: Collaboration with multi distributors 	<ul style="list-style-type: none"> Register for national health insurance system's coverage
	USA	<ul style="list-style-type: none"> • G1200 and CA125 obtained FDA approval • Launch new sales organization 	<ul style="list-style-type: none"> Additional reagent registration process in series Start sales activities
LP Japan Increase Market Share	Reagents	<ul style="list-style-type: none"> • Strategic markers: Focus on hepatitis market (high-sensitive HBsAg, HBsAb, HBCAb reagents) • Launch L-FABP 	<ul style="list-style-type: none"> Continuous launch of new items
	Platform (Analyzer)		<ul style="list-style-type: none"> Launch L2400 (high-throughput analyzer)

Lumipulse installation in global markets is on track
(>300 installations cumulatively by the end of 2Q/2015)

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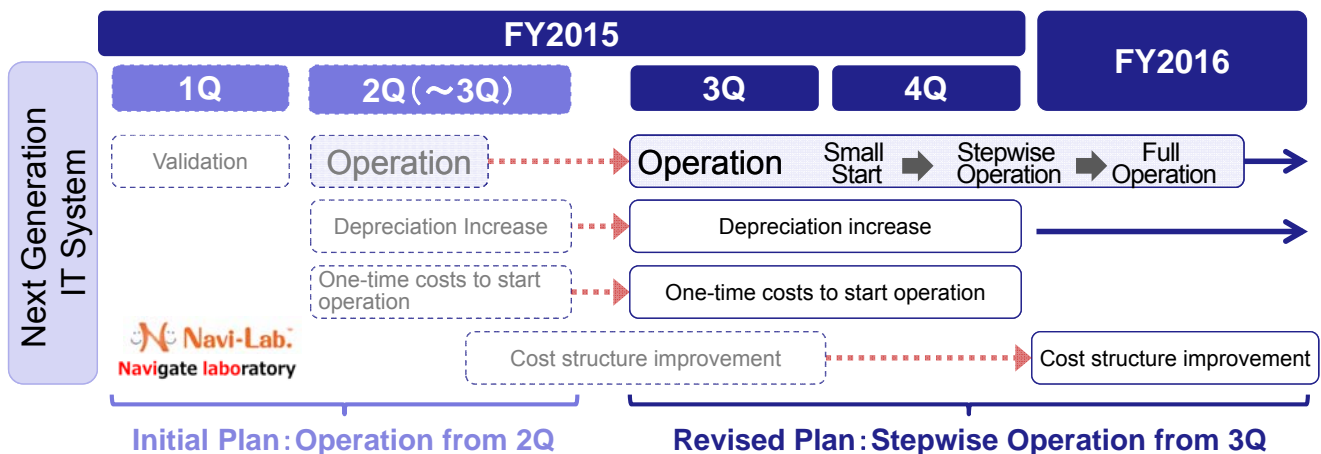
Progress of Business Plan IVD: Lumipulse®L2400 Launch



- Next generation of high-throughput fully automated immuno-assay system (240 test/hr)
- Capable to be integrated with clinical chemistry analyzer BioMajesty™ ZERO JCA-ZS050 (JEOL)
- Designed to satisfy global market requirements
- Utilize existing Lumipulse® Presto-II reagents (nearly 50 items)
- Advantage of space saving
- Improved usability

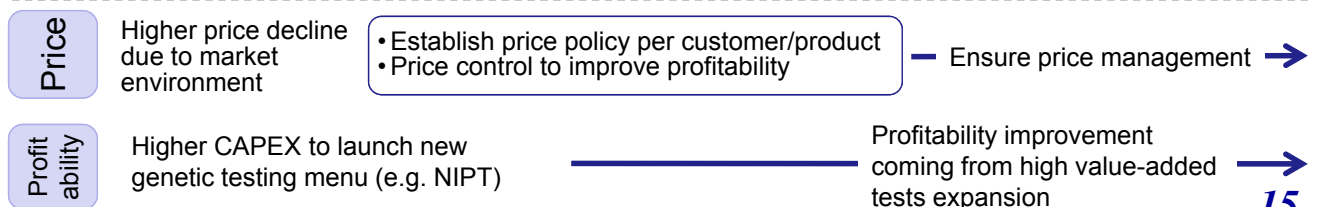
Market launch on 2nd/November in Japan

Progress of Business Plan CLT Japan



■ The Cause of Delay

- The system itself is almost completed, however, additional adjustment between each customer is required for the smooth migration
- Due to the delay of full operation, cost structure improvement will start from FY2016



Progress of Business Plan CLT Global Business

(1) Miraca Life Sciences (Anatomic Pathology Business in US)

	FY2015 Full-year Initial Plan	FY2015 1H Actual	Progress to Full-year Plan
Net Sales	\$263.0M	\$130.2M	49.5%
Op. Income	\$27.0M	\$10.9M	40.4%

Both Sales and Op. Income are behind the initial plan

Reasons of Profitability Decrease

- ◆ GI (>50% of Net sales): Lower profitability
 - Decline in average income per client
 - Shift to in-house pathology lab
 - Less reimbursement by some private payers
 - Client loss
 - Loss to Physician Office Laboratory
 - Loss to hospital lab (acquisition of clients by hospital)
- ◆ GU: Lower volume (collaboration delay with IT vendor)
- ◆ Heme: Influenced by price decline

Improvement Actions

- ◆ GI: Promote customer retention and obtain new accounts
- ◆ GU: Start collaboration with IT vendor
- ◆ Profitability structure improvement through lab operation efficiency (FY2016)
 - Consolidate lab facilities
 - Introduce new LIS
 - Promote lab automation

Performance is forecasted to recover in the 2H

Progress of Business Plan CLT Global Business

(2) BMGL (Genetic Testing Business in US)

	FY2015 Full-year Initial Plan	FY2015 1H Initial Plan	FY2015 1H Actual	Progress to 1H Initial Plan	
Sales	\$68.0M	\$30.0M	\$25.2M	\$-4.8M	84.0%
EBITDA	\$13.0M	\$3.6M	\$-0.3M	\$-3.9M	-8.3%
Share of loss of entities accounted for using equity method (*)	\$-5.0M	\$-4.2M	\$-6.5M	\$-2.3M	-

Reasons of Progress Delay

- ◆ **Pediatrics genetic disorder area**
 - Decline of reimbursement rate
 - Client lost due to increasing competition
- ◆ **Carrier screening (obstetrics/ gynecology)**
 - Delay of cooperation w/ distribution channel partner ⇒ sales lost
 - Develop new test platform ⇒ one-time costs increase

Improvement Actions

- ◆ **Carrier screening**
 - Start cooperation w/ channel partner in Oct.
 - Enhance revenue and profit generation in 2H
- ◆ **Profitability improvement**
 - Higher efficiency of lab-operation
- ◆ **Strengthen in-house sales force**
 - Enhanced sales capability with more reps
- ◆ **Accelerate new test development and market launch**
 - Leverage Baylor's technology

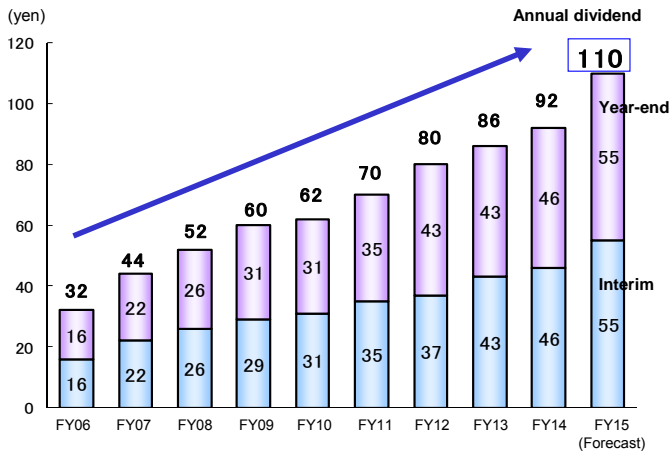
※Result of BMGL is recognized in Ordinary Income line on consolidated P/L

Both sales and profit are forecasted to improve in 2H
(The annual result will not reach the initial plan)

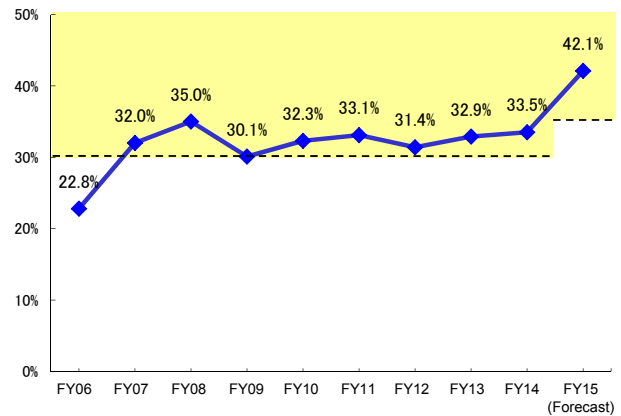
Forecast of Cash Dividends

**Interim dividend per share increased by 9 yen, to 55 yen.
Annual dividend per share is planned to increase to 110 yen.**

◆ Cash dividends (yen per share)



◆ Payout Ratio (%)



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Disclaimer regarding forward-looking statement:

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Factors affecting the performance include, among others, aggravation of the economic situation, fluctuation of the exchange rate, change of regulatory, statutory, and administrative requirements, delayed launch of new products, pressures from the product strategies of competitive companies, and decline of the sales potential of existing products.