

## First Quarter (April 1 – June 30, 2013) Flash Report (unaudited)

Three months ended June 30, 2013

# ONO PHARMACEUTICAL CO., LTD.

August 2, 2013

Ono Pharmaceutical Co., Ltd. has announced its consolidated financial results for three months ended June 30, 2013.

This First Quarter Flash Report 2014 (unaudited) is summary information extracted from financial statements announced, and the financial statements contained herein are prepared for the reference only for the convenience of readers outside Japan with certain modifications and reclassifications made from the original financial statements presented in Japanese language.

## Financial Highlights

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

(Note) All yen amounts are rounded off to the nearest million yen.

	Millions of yen			Thousands of US\$
	1st Quarter 3 months ended Jun 30 2013	1st Quarter 3 months ended Jun 30 2012	Annual 12 months ended Mar 31 2013	1st Quarter 3 months ended Jun 30 2013
Net sales	¥ 37,910	¥ 37,652	¥ 145,393	\$ 382,929
Net income	6,471	8,422	24,120	65,364
Total Net assets	420,740	396,583	423,291	4,249,899
Total assets	454,575	432,162	455,573	4,591,667
		Yen		US\$
Net income per common share	¥ 61.04	¥ 79.43	¥ 227.51	\$ 0.62

**First Quarter (April 1 – June 30, 2013) Flash Report (unaudited)**

Three months ended June 30, 2013

**Consolidated Forecast of Consolidated Results for the Six Months  
Ending September 30, 2013 and for the Year Ending March 31, 2014**

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Six months ending		Year ending	
	September 30, 2013		March 31, 2014	
	Millions of yen	Thousands of US\$	Millions of yen	Thousands of US\$
Net sales	¥ 72,600	\$ 733,333	¥ 148,300	\$ 1,497,980
Operating income	11,700	118,182	27,900	281,818
Ordinary income	12,900	130,303	29,000	292,929
Net income	9,000	90,909	20,400	206,061
	Yen	US\$	Yen	US\$
Net income per common share	84.89	0.86	192.42	1.94

(\*)The foregoing are forward-looking statements based on a number of assumptions and beliefs in light of the information currently available to management and are subject to risks and uncertainties. Actual financial results may differ materially depending on a number of economic factors, including conditions and currency exchange rate fluctuations.

## First Quarter (April 1 – June 30, 2013) Flash Report (unaudited)

Three months ended June 30, 2013

### Consolidated Balance Sheets

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

(Note) All amounts are rounded off to the nearest million yen.

ASSETS	Millions of yen		Thousands of US\$
	1st Quarter		1st Quarter
	June 30 2013	March 31 2013	June 30 2013
<b>Current assets</b>			
Cash and bank deposits	¥ 23,447	¥ 24,262	\$ 236,838
Notes and accounts receivable	43,516	37,823	439,556
Marketable securities	94,829	105,877	957,869
Inventories	24,919	23,409	251,707
Others	24,780	23,377	250,303
Allowance for doubtful receivables	(6)	(6)	(61)
<b>Total current assets</b>	<b>211,485</b>	<b>214,742</b>	<b>2,136,212</b>
<b>Property, plant and equipment</b>			
Land	23,479	23,479	237,162
Buildings and structures	21,547	21,780	217,646
Machinery, equipment and others	2,803	2,933	28,314
Construction in progress	2,083	1,438	21,040
<b>Net property, plant and equipment</b>	<b>49,912</b>	<b>49,630</b>	<b>504,162</b>
<b>Investments and other assets</b>			
Investment securities	181,827	180,200	1,836,636
Intangible assets	1,713	1,384	17,303
Others	9,638	9,617	97,354
<b>Total investments and other assets</b>	<b>193,178</b>	<b>191,201</b>	<b>1,951,293</b>
<b>Total assets</b>	<b>¥ 454,575</b>	<b>¥ 455,573</b>	<b>\$ 4,591,667</b>

(Note) All amounts are rounded off to the nearest million yen.

LIABILITIES AND EQUITY	Millions of yen		Thousands of US\$
	1st Quarter June 30 2013	March 31 2013	1st Quarter June 30 2013
<b>Current liabilities</b>			
Current portion of long-term debt	¥ 104	¥ 104	\$ 1,051
Notes and accounts payable	4,119	4,244	41,606
Income tax payable	2,672	5,606	26,990
Others	20,499	15,833	207,060
<b>Total current liabilities</b>	<b>27,394</b>	<b>25,787</b>	<b>276,707</b>
<b>Long-term liabilities</b>			
Long-term debt, less current portion	151	176	1,525
Liabilities for retirement benefits	1,118	1,076	11,293
Asset retirement obligations	54	54	545
Others	5,118	5,189	51,698
<b>Total long-term liabilities</b>	<b>6,441</b>	<b>6,495</b>	<b>65,061</b>
<b>Equity</b>			
Common stock	17,358	17,358	175,333
Capital surplus	17,080	17,080	172,525
Retained earnings	427,755	430,824	4,320,758
Treasury stock-at cost	(59,219)	(59,214)	(598,172)
<b>Total equity</b>	<b>402,974</b>	<b>406,048</b>	<b>4,070,444</b>
<b>Other comprehensive income</b>			
Unrealized gain on securities (*)	22,743	22,451	229,727
Land revaluation surplus	(8,577)	(8,577)	(86,636)
Deferred gains on hedges	49	—	495
Foreign currency translation adjustments	216	67	2,182
<b>Total other comprehensive income</b>	<b>14,431</b>	<b>13,941</b>	<b>145,768</b>
<b>Minority interests</b>	<b>3,335</b>	<b>3,302</b>	<b>33,687</b>
<b>Total net assets</b>	<b>420,740</b>	<b>423,291</b>	<b>4,249,899</b>
<b>Total liabilities and total net assets</b>	<b>¥ 454,575</b>	<b>¥ 455,573</b>	<b>\$ 4,591,667</b>

(\*) Unrealized gain on securities classified as available for sale, net of tax

## First Quarter (April 1 – June 30, 2013) Flash Report (unaudited)

Three months ended June 30, 2013

### Consolidated Statements of Income

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

(Note) All amounts are rounded off to the nearest million yen.

	Millions of yen			Thousands of US\$
	1st Quarter 3 months ended Jun 30 2013	1st Quarter 3 months ended Jun 30 2012	Annual 12 months ended Mar 31 2013	1st Quarter 3 months ended Jun 30 2013
<b>Net sales</b>	¥ 37,910	¥ 37,652	¥ 145,393	\$ 382,929
<b>Cost of sales</b>	8,433	8,442	33,983	85,182
Gross profit	29,477	29,210	111,410	297,747
<b>Selling, general and administrative expenses</b>	21,355	17,130	79,489	215,707
Operating income	8,122	12,080	31,921	82,040
<b>Other income (expenses)</b>				
Interest and dividend income	1,328	1,204	2,575	13,414
Interest expenses	(1)	0	(2)	(10)
Other, net	(210)	(462)	165	(2,121)
	1,117	742	2,738	11,283
Income before income taxes and minority interests	9,239	12,822	34,659	93,323
<b>Income taxes</b>	2,732	4,360	10,318	27,596
Income before minority interests	6,507	8,462	24,341	65,727
<b>Minority interests</b>	(36)	(40)	(221)	(364)
<b>Net income</b>	¥ 6,471	¥ 8,422	¥ 24,120	\$ 65,363
<b>Per share of common stock</b>				
Basic net income	¥ 61.04	¥ 79.43	¥ 227.51	\$ 0.62
Cash dividends applicable to the period	¥ —	¥ —	¥ 180.00	\$ —

**First Quarter (April 1 – June 30, 2013) Flash Report (unaudited)**

Three months ended June 30, 2013

**Consolidated Statements of Comprehensive Income**

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

(Note) All amounts are rounded off to the nearest million yen.

	Millions of yen			Thousands of US\$
	<b>1st Quarter 3 months ended Jun 30 2013</b>	1st Quarter 3 months ended Jun 30 2012	Annual 12 months ended Mar 31 2013	<b>1st Quarter 3 months ended Jun 30 2013</b>
<b>Net income before minority interests</b>	¥ <b>6,507</b>	¥ 8,462	¥ 24,341	\$ <b>65,727</b>
<b>Other comprehensive income</b>				
Unrealized gain (loss) on available-for-sale securities	<b>294</b>	(3,177)	16,722	<b>2,970</b>
Deferred gain (loss) on hedges	<b>49</b>	(21)	—	<b>495</b>
Foreign currency translation adjustments	<b>148</b>	(96)	344	<b>1,495</b>
Share of other comprehensive income in associates	<b>(1)</b>	(0)	17	<b>(10)</b>
<b>Total other comprehensive income</b>	<b>490</b>	(3,294)	17,083	<b>4,950</b>
<b>Comprehensive income</b>	<b>6,997</b>	5,168	42,424	<b>70,677</b>
<b>Total comprehensive income attributable to</b>				
Owners of the parent	<b>6,961</b>	5,125	41,190	<b>70,313</b>
Minority interests	<b>36</b>	43	234	<b>364</b>

## First Quarter (April 1 – June 30, 2013) Flash Report (unaudited)

Three months ended June 30, 2013

### Consolidated Statements of Cash Flows

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

(Note) All amounts are rounded off to the nearest hundred million yen.

	Hundred millions of yen		Hundred thousands of US\$
	1st Quarter 3 months ended Jun 30 2013	1st Quarter 3 months ended Jun 30 2012	1st Quarter 3 months ended Jun 30 2013
Operating activities: <sup>(*)</sup>	¥ 0	¥ (22)	\$ 3
Investing activities:	49	115	494
Financing activities:	(87)	(87)	(880)
Net decrease in cash and cash equivalents	(38)	6	(383)
Cash and cash equivalents, ending	¥ 853	¥ 856	\$ 8,616
(*)Depreciation and amortization is included in "Operating activities"	¥ 7	¥ 7	\$ 71

## **First Quarter (April 1 – June 30, 2013) Flash Report (unaudited)**

Three months ended June 30, 2013

### **Notes to Consolidated Financial Statements**

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

- Note 1 This First Quarter Flash Report 2014 (unaudited) is a summary information extracted from the financial statements announced by the Company on August 2, 2013. The financial statements announced have been prepared and stated in accordance with accounting principles generally accepted in Japan. The financial statements and figures contained in this First Quarter Flash Report 2014 (unaudited) are prepared for the reference only for the convenience of readers outside Japan with certain modifications and reclassifications made from the original financial statements presented in Japanese language.
- Note 2 All amounts expressed herein in millions of Japanese yen are rounded off to the nearest million yen, which are to follow the basis of presentation in the above original announcement.
- Note 3 U.S. Dollar amounts herein are given solely for the convenience of readers outside Japan and are stated, as a matter of arithmetical computation only, at the rate of Japanese yen 99 = US\$ 1, the approximate exchange rate prevailing on June 30, 2013



## First Quarter (April 1 – June 30, 2013) Flash Report (unaudited)

Three months ended June 30, 2013

### Sales of Major Products

Supplemental Data

For information purpose only

(Note) All amounts are rounded off to the nearest hundred million yen.

		1st Quarter 3 months ended Jun 30, 2013			Year ending March 31,2014
		Results	Increase/Decrease		Forecast
<b>Glactiv</b>	Agent for type II diabetes	¥ 96	¥ + 9	10.8 %	¥ 400
<b>Opalmon</b>	Circulatory system agent	86	Δ 4	Δ 4.6 %	310
<b>Onon</b>	Agent for bronchial asthma and allergic rhinitis	34	Δ 8	Δ 18.2 %	125
<b>Recalbon</b>	Agent for osteoporosis	26	+ 10	61.8 %	105
<b>Emend/Proemend</b>	Agent for Chemotherapy-induced nausea and vomiting	22	+ 2	8.0 %	95
<b>Foipan</b>	Agent for chronic pancreatitis and postoperative reflux esophagitis	22	Δ 3	Δ 10.7 %	80
<b>Kinedak</b>	Agent for diabetic peripheral neuropathy	20	Δ 5	Δ 19.1 %	80
<b>Staybla</b>	Agent for overactive bladder (pollakiuria and urinary incontinence)	16	Δ 1	Δ 7.6 %	70
<b>Onon dry syrup</b>	Agent for pediatric bronchial asthma and allergic rhinitis	17	Δ 1	Δ 7.7 %	70
<b>Rivastach</b>	Agent for Alzheimer's disease	14	+ 8	133.2 %	65
<b>Onoact</b>	Agent for tachyarrhythmia during and post operation	10	+ 1	8.1 %	45
<b>Elaspol</b>	Agent for acute lung injury associated with SIRS	9	Δ 1	Δ 10.9 %	35

Note: Sales of products are shown in a gross sales basis.

## First Quarter (April 1 – June 30, 2013) Flash Report (unaudited)

Three months ended June 30, 2013

### Supplemental Information

## Status of Development Pipeline

as of August 2, 2013

### Developments in Japan

#### *NDA approved (New Formulations):*

- **Orencia® SC (ONO-4164 SC / BMS-188667SC) \*1**  
(Co-development with Bristol-Myers Squibb Company)  
Rheumatoid Arthritis [T-cell activation inhibitor]
- **Glactiv® Tablets 25mg (ONO-5435 / MK-0431) \*2**  
(Co-development with Merck & Co., Inc.)  
Type II diabetes with severe renal dysfunction [DPP-4 inhibitor]

#### *NDA filed (New Formulations):*

- **Glactiv® Tablets 12.5mg (ONO-5435 / MK-0431)**  
(Co-development with Merck & Co., Inc.)  
Type II diabetes with severe renal dysfunction [DPP-4 inhibitor]

#### *NDA filed (Additional Indication):*

- **Onoact® 50 for Injection (ONO-1101)**  
Tachyarrhythmia in low cardiac function  
[Short acting beta-1 blocker]

#### *Ongoing clinical studies (New Chemical Entities):*

- **ONO-4538 / BMS-936558 (injection)**  
Renal cell cancer (Phase III) [Fully human anti-PD-1 antibody]
- **ONO-2745 / CNS 7056 (injection)**  
(In-licensed from PAION AG)  
Short acting general anesthetic (Phase II / III)  
[GABA<sub>A</sub> receptor modulator]
- **ONO-7165 / EMD531444 (injection)**  
(Co-development with Merck KGaA)  
Non-small cell lung cancer (Phase II) [Therapeutic cancer peptide vaccine targeting the tumor antigen MUC-1]
- **ONO-4641 (tablet)**  
Multiple sclerosis (Phase II) [S1P receptor agonist]
- **ONO-3849 / Methylaltraxone bromide (injection)**  
(In-licensed from Progenics Pharmaceuticals, Inc.)  
Opioid-induced constipation (Phase II)  
[Mu-opioid receptor antagonist]
- **ONO-7643 / RC-1291 (tablet)**  
(In-licensed from Helsinn Therapeutics (U.S.), Inc.)  
Cancer anorexia / cachexia (Phase II)  
[Ghrelin mimetic]
- **ONO-4538 / BMS-936558 (injection)**  
Melanoma (Phase II) [Fully human anti-PD-1 antibody]
- **ONO-4538 / BMS-936558 (injection)**  
Non-small cell lung cancer (Phase II) [Fully human anti-PD-1 antibody]
- **ONO-7057 / Carfilzomib (injection)**  
(In-licensed from Onyx Pharmaceuticals, Inc.)  
Multiple Myeloma (Phase I / II) [Proteasome inhibitor]
- **ONO-5163 / AMG-416 (injection)**  
(In-licensed from Amgen Inc.)  
Secondary hyperparathyroidism (Phase I / II) [Calcium sensing receptor agonist]
- **ONO-6950 (tablet)**  
Bronchial asthma (Phase I) [LT receptor antagonist]

- **ONO-7056 / Salirasib (tablet)**  
(In-licensed from Kadmon Corporation LLC)  
Solid tumor (Phase I) [Ras signal inhibitor]
- **ONO-7268 MX1 (injection)**  
(In-licensed from OncoTherapy Science, Inc.)  
Hepatocellular carcinoma (Phase I) [Therapeutic cancer peptide vaccines]
- **ONO-1162 / Ivabradine (tablet)**  
(In-licensed from Les Laboratoires Servier)  
Chronic heart failure (Phase I) [If channel inhibitor]
- **ONO-2160/CD (tablet)**  
Parkinson's disease (Phase I) [levodopa pro-drug]

#### *Ongoing clinical studies (Additional Indications):*

- **Glactiv® Tablets (ONO-5435 / MK-0431)**  
(Co-development with Merck & Co., Inc.)  
Type II diabetes: combination therapy with a rapid-acting insulin secretagogue (Phase III) [DPP-4 inhibitor]
- **Proemend® for i.v. infusion (ONO-7847 / MK-0517)**  
(In-licensed from Merck & Co., Inc.)  
Chemotherapy-induced nausea and vomiting in pediatric patients (Phase III) [NK1 receptor antagonist]
- **Orencia® IV (ONO-4164IV / BMS-188667IV)**  
(Co-development with Bristol-Myers Squibb Company)  
Juvenile Rheumatoid Arthritis (Phase III) [T-cell activation inhibitor]
- **Orencia® IV (ONO-4164IV / BMS-188667IV)**  
(Co-development with Bristol-Myers Squibb Company)  
Lupus nephritis (Phase III) [T-cell activation inhibitor]

#### *Ongoing clinical studies (Additional Dosing Regimen):*

- **Rivastach® Patch (ONO-2540 / ENA713D)**  
(Co-development with Novartis Pharma AG)  
Alzheimer's disease (Phase III) [dual inhibitor of AChE and BuChE]

#### *Ongoing clinical studies (New Formulations):*

- **Glactiv® and Metformin Combination Tablets (ONO-5435A / MK-0431A)**  
(Co-development with Merck & Co., Inc.)  
Type II diabetes (Phase III) / Combination product with Glactiv and biguanide

### Developments abroad

#### *Ongoing clinical studies (New Chemical Entities):*

- **ONO-4538 / BMS-936558 (injection)**  
(Out-licensed to Bristol-Myers Squibb Company)  
Renal cell cancer (Phase III) [Fully human anti-PD-1 antibody]
- **ONO-4538 / BMS-936558 (injection)**  
(Out-licensed to Bristol-Myers Squibb Company)  
Non-small cell lung cancer (Phase III) [Fully human anti-PD-1 antibody]
- **ONO-4538 / BMS-936558 (injection)**  
(Out-licensed to Bristol-Myers Squibb Company)  
Melanoma (Phase III) [Fully human anti-PD-1 antibody]
- **ONO-4641 (tablet)**  
(Out-licensed to Merck KGaA)  
Multiple sclerosis (Phase II) [S1P receptor agonist]

- **ONO-6950 (tablet)**  
Bronchial asthma (Phase II) [LT receptor antagonist]
- **ONO-4053 (tablet)**  
Allergic rhinitis (Phase II) [PGD2 receptor antagonist]
- **ONO-2952 (tablet)**  
Irritable bowel syndrome (Phase II) [TSPO antagonist]
- **ONO-8539 (tablet)**  
Gastroesophageal reflux disease (GERD) (Phase I) [PG receptor (EP1) antagonist]
- **ONO-4538 / BMS-936558 (injection)**  
**(Out-licensed to Bristol-Myers Squibb Company)**  
Hepatitis C (Phase I) [Fully human anti-PD-1 antibody]
- **ONO-7746 (capsule)**  
**(In-licensed from Nissan Chemical Industries, Ltd.)**  
Thrombocytopenia (Phase I) [TPO receptor agonist]
- **ONO-9054 (eye drop)**  
Glaucoma, ocular hypertension (Phase I) [PG receptor (FP / EP3) agonist]
- **ONO-4059 (tablet)**  
B cell lymphoma (Phase I) [Bruton's tyrosine kinase (Btk) inhibitor]
- **ONO-8055 (tablet)**  
Underactive bladder (Phase I) [PG receptor (EP2 / EP3) agonist]
- **ONO-4538 / BMS-936558 (injection)**  
**(Out-licensed to Bristol-Myers Squibb Company)**  
Hematological cancer (Phase I) [Fully human anti-PD-1 antibody]
- **ONO-4538 / BMS-936558 (injection)**  
**(Out-licensed to Bristol-Myers Squibb Company)**  
Hepatocellular carcinoma (Phase I) [Fully human anti-PD-1 antibody]
- **ONO-1266 (capsule) \*3**  
Portal hypertension (Phase I) [S1P receptor antagonist]

**Changes from Annual Flash Report for the Fiscal Year ending March 2013 announced on May 13, 2013**

- \*1: Marketing authorization of Rheumatoid Arthritis Drug ORENCIA<sup>®</sup> SC was obtained as an additional formulation.
- \*2: Glactiv<sup>®</sup> Tablets 25mg (ONO-5435 / MK0431) which can be administered as 12.5mg as sitagliptin (QD) was approved. Type II diabetic patients with severe renal dysfunction, or terminal renal failure necessary for hemodialysis or peritoneal dialysis can be treated by this new tablet.
- \*3: Phase I clinical study of ONO1266 (S1P receptor antagonist) was initiated for the treatment of portal hypertension.
- \*: Phase II clinical study of ONO-2745 for ICU sedation was discontinued based on pharmacokinetic feature in long term administration.