

## Annual Flash Report (unaudited)

Year ended March 31, 2002

# ONO PHARMACEUTICAL CO., LTD.

May 17, 2002

Ono Pharmaceutical Co., Ltd. has announced its consolidated financial results for the year ended March 31, 2002.

This Annual Flash Report 2002 (unaudited) is a summary information extracted from the financial statements announced, and the financial statements contained herein are prepared for 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 down to the nearest million yen.			
	Millions of yen		Thousands of US\$	
	2002	2001	2002	
Net sales	¥ 133,353	¥ 130,728	\$ 1,002,654	
Net income	22,754	22,359	171,082	
Shareholders' equity	305,058	303,887	2,293,669	
Total assets	356,478	357,227	2,680,285	
		Yen		US\$
Net income per common stock	¥ 186.66	¥ 182.05	\$ 1.40	

## **MESSAGE FROM THE MANAGEMENT**

### **(1) Basic management policy**

The Ono Pharmaceutical Group, in keeping with its philosophy of “Dedication to Man’s Fight against Disease and Pain,” has always striven to achieve its medium-term goal of serving as an R&D-oriented, international pharmaceutical company specializing in defined areas. In this endeavor, we have placed our emphasis on R&D, aiming to meet the diverse medical needs of an aging society, to create innovative medicines for previously incurable diseases.

Our R&D division focuses its resources on the company’s four priority fields: prostaglandins, enzyme inhibitors, neuroscience and intracellular signaling. Optimizing the technologies we have accumulated in such fields and forging cooperative links with research organizations with leading-edge technologies both within Japan and abroad, we hope to expeditiously market innovative medicines that conform to global standards. In responding to the global trend toward harmonization of pharmaceutical registration standards, we seek to develop new pharmaceuticals simultaneously in Japan, the US and Europe, based on clinical trials performed in the latter areas. With regard to genomic drug design, we have succeeded in identifying the relationship between certain diseases and ten genes, covered by patents owned by ourselves. Seeking to develop new drugs, we will continue to search for compounds that act specifically on such genes.

The marketing division is actively working to enhance the reputation of Ono’s innovative pharmaceuticals, through the presentation of scientific data, mainly at study and lecture meetings, and through the rapid dissemination of accurate information by optimal use of information technology. We envision that the NHI price revision to be implemented along with reforms of the health insurance system will greatly affect our business. However, we will strive to attain stable growth by launching new products and by enhancing the competitiveness of existing products.

With top priority given to the pursuit of global-level quality assurance of our products, the manufacturing division is placing stronger emphasis on improving both hardware and software, and establishing a computerized production management system.

## **(2) Basic policy concerning dividends**

With regard to dividends, distribution of profits to shareholders is one of our key management policies, and we place great importance on the maintenance of stable dividends based on achievement. With regard to reserves, we allocate sufficient funds to meet the demand for research and development of new drugs, and for expansion and renovation of our production facilities; this serves to maintain and enhance our profitability and to strengthen our financial position.

## **(3) Ideas and policy concerning reduction in the minimum trading unit**

Reduction of the minimum trading unit is an effective measure to enhance liquidity in the stock market and to increase the number of individual investors. Taking into consideration cost effectiveness, number of shareholders, and the balance of supply and demand in the stock market, thoughtful discussions will be made on a reduction of the minimum trading unit. At present, a detailed plan and schedule have not been determined.

## **(4) Policy concerning development of corporate governance**

To improve our corporate governance, we have appointed external auditors (a lawyer in 1993 and an accountant in 2000) to reinforce our auditing system, for more effective management. During Board meetings, an appropriate number of Directors frankly discuss management strategies, resulting in prompt decision making. Therefore, we consider that there is no need to largely change the management system at present. As for the development of corporate governance, we should examine the need for this, after confirming the nature of future, significant revisions of commercial law.

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### Consolidated Balance Sheets

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

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

ASSETS	Millions of yen		Thousands of US\$
	2002	2001	2002
<b>Current assets</b>			
Cash and bank deposits	¥ 15,880	¥ 23,913	\$ 119,398
Notes and accounts receivable	40,612	38,304	305,353
Marketable securities	94,221	81,525	708,428
Inventories	9,747	8,722	73,285
Deferred taxes	7,199	5,530	54,127
Others	673	753	5,060
Allowance for doubtful receivables	(1,291)	(1,233)	(9,706)
<b>Total current assets</b>	<b>167,043</b>	<b>157,516</b>	<b>1,255,962</b>
<b>Property, plant and equipment</b>			
Land	18,222	21,363	137,007
Buildings and structures	48,534	46,862	364,917
Machinery and equipment	24,334	23,883	182,962
Construction in progress	6,277	4,571	47,195
Accumulated depreciation	(44,356)	(41,177)	(333,503)
<b>Net property, plant and equipment</b>	<b>53,012</b>	<b>55,502</b>	<b>398,586</b>
<b>Investments and other assets</b>			
Investment securities	112,073	126,516	842,654
Deferred taxes	15,643	7,463	117,616
Intangible assets	1,656	1,782	12,451
Others	7,049	8,496	53,000
<b>Total investments and other assets</b>	<b>136,422</b>	<b>144,258</b>	<b>1,025,729</b>
<b>Total assets</b>	<b>¥ 356,478</b>	<b>¥ 357,277</b>	<b>\$ 2,680,285</b>

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

LIABILITIES AND SHAREHOLDERS' EQUITY	Millions of yen		Thousands of US\$
	2002	2001	2002
<b>Current liabilities</b>			
Current portion of long-term debt	¥ 8	¥ 46	\$ 60
Notes and accounts payable	2,747	4,437	20,654
Income taxes	11,495	15,562	86,428
Others	12,151	11,043	91,360
<b>Total current liabilities</b>	<b>26,402</b>	<b>31,088</b>	<b>198,511</b>
<b>Long-term liabilities</b>			
Long-term debt, less current portion	144	243	1,082
Accrued retirement benefits	23,295	20,678	175,150
<b>Total long-term liabilities</b>	<b>23,439</b>	<b>20,922</b>	<b>176,233</b>
<b>Minority interests</b>	<b>1,578</b>	<b>1,378</b>	<b>11,864</b>
<b>Shareholders' equity</b>			
Common stocks	17,358	17,358	130,511
Additional paid-in capital	17,002	17,002	127,834
Revaluation surplus	(3,598)	—	(27,052)
Retained earnings	282,832	264,350	2,126,556
Unrealized gain on securities (*)	1,596	5,240	12,000
Translation adjustments	15	2	112
Less, treasury stocks	(10,147)	(66)	(76,293)
<b>Total shareholders' equity</b>	<b>305,058</b>	<b>303,887</b>	<b>2,293,669</b>
<b>Total liabilities and shareholders' equity</b>	<b>¥ 356,478</b>	<b>¥ 357,277</b>	<b>\$ 2,680,285</b>

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

## Annual Flash Report (unaudited)

Year ended March 31, 2002

### Consolidated Statements of Income

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

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

	Millions of yen		Thousands of US\$
	2002	2001	2002
<b>Net sales</b>	¥ 133,353	¥ 130,728	\$ 1,002,654
<b>Cost of sales</b>	21,841	20,981	164,218
Gross profit	111,511	109,746	838,428
<b>Selling, general and administrative expenses</b>	61,179	55,941	459,992
Operating income	50,332	53,805	378,436
<b>Other income (expenses)</b>			
Interest and dividend income	2,224	3,901	16,721
Interest expenses	(14)	(230)	(105)
Other, net	(8,844)	(14,682)	(66,496)
	(6,634)	(11,011)	(49,879)
Income before income taxes and minority interests	43,697	42,794	328,548
<b>Income taxes</b>			
Current	25,321	28,570	190,383
Deferred	(4,600)	(8,316)	(34,586)
	20,721	20,253	155,796
Income before minority interests	22,975	22,540	172,744
<b>Minority interests</b>	(220)	(180)	(1,654)
<b>Net income</b>	¥ 22,754	¥ 22,359	\$ 171,082
		Yen	US\$
<b>Amounts per common stock</b>			
Net income	¥ 186.66	¥ 182.05	\$ 1.40
Cash dividends applicable to the period	¥ 34.00	¥ 34.00	\$ 0.26

## Annual Flash Report (unaudited)

Year ended March 31, 2002

### Consolidated Statements of Cash Flows

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

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

	Millions of yen		Thousands of US\$
	2002	2001	2002
<b>Cash flows from operating activities:</b>			
Income before income taxes and minority interests	¥ 43,697	¥ 42,794	\$ 328,549
Adjustments:			
Depreciation and amortization	4,108	4,155	30,887
Increase in allowance for doubtful receivables	63	365	474
Increase in provision for bonuses	51	68	383
Increase (decrease) in provision for retirement benefits, net	2,579	8,491	19,391
Interest and dividend income	(2,224)	(3,901)	(16,722)
Interest expenses	14	230	105
Loss from valuation of investment securities	5,941	5,878	44,669
Increase (decrease) in notes and accounts receivable	(2,308)	(4,964)	(17,353)
Others	(1,445)	(1,154)	(10,865)
Interest and dividend income received	1,744	2,811	13,113
Interest paid	(14)	(230)	(105)
Income taxes paid	(29,390)	(25,102)	(220,977)
<b>Net cash provided by operating activities</b>	<b>22,819</b>	<b>29,443</b>	<b>171,571</b>
<b>Cash flows from investing activities:</b>			
Payments for purchases of marketable securities	(52,355)	(2,819)	(393,647)
Proceeds from sales of marketable securities	29,469	26,549	221,571
Transfer from (to) time deposits	7,026	(365)	52,827
Payments for purchases of property, plant and equipment	(8,240)	(8,355)	(61,955)
Payments for purchases of investment securities	(39,156)	(19,077)	(294,406)
Proceeds from sales of investment securities	27,868	7,681	209,534
Other payments	427	420	3,211
<b>Net cash generated from (used in) investment activities</b>	<b>(34,960)</b>	<b>4,031</b>	<b>(262,857)</b>
<b>Cash flows from financing activities:</b>			
Repayment of current portion of long-term debt	(45)	(41)	(338)
Increase in long-term debt	7	108	53
Repayment of long-term debt	(99)	(3)	(744)
Payments for obtaining treasury stock	(10,201)	(537)	(76,699)
Proceeds from sales of treasury stock	116	526	872
Cash dividends	(4,167)	(4,171)	(31,331)
Cash dividends to minority shareholders	(3)	(2)	(23)
Repayment of convertible bonds	-	(19,962)	-
<b>Net cash used in financing activities</b>	<b>(14,394)</b>	<b>(24,083)</b>	<b>(108,226)</b>
Effect of exchange rate changes on cash and cash equivalents	11	14	83
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>(26,523)</b>	<b>9,405</b>	<b>(199,421)</b>
<b>Cash and cash equivalents, beginning</b>	<b>80,908</b>	<b>71,503</b>	<b>608,331</b>
<b>Cash and cash equivalents, ending</b>	<b>¥ 54,385</b>	<b>¥ 80,908</b>	<b>\$ 408,910</b>

## Annual Flash Report (unaudited)

Year ended March 31, 2002

### Consolidated Statements of Retained Earnings

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

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

	Millions of yen		Thousands of US\$
	2002	2001	2002
Balance, beginning of period	¥ 264,350	¥ 246,271	\$ 1,987,593
Net income for the period	22,754	22,359	171,082
Cash dividends paid	(4,176)	(4,176)	(31,398)
Bonuses to directors and statutory auditors	(96)	(104)	(721)
Balance, end of period	¥ 282,832	¥ 264,350	\$ 2,126,556

### Notes to Consolidated Financial Statements

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

- Note 1 This Annual Flash Report 2002 (unaudited) is a summary information extracted from the financial statements announced by the Company on May 17, 2002.  
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 Annual Flash Report 2002 (unaudited) are prepared for reference only for the convenience of readers outside Japan with certain modifications and reclassifications made to the original financial statements, which are presented in Japanese language.
- Note 2 All amounts expressed herein in millions of Japanese yen are rounded down 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 133 = US\$ 1, the approximate exchange rate prevailing on March 31, 2002.

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Year ended March 31, 2002

Ono Pharmaceutical Co., Ltd. and  
Consolidated Subsidiaries

### Sales of Major Products

Supplemental Data

For information purpose only

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

		Hundred Millions of yen	
		2002	2001
<b>Onon</b>	Agent for bronchial asthma	<b>235</b>	218
<b>Onon drysyrup</b>	Agent for pediatric bronchial asthma	<b>31</b>	14
<b>Kinedak</b>	Agent for diabetic peripheral neuropathy	<b>249</b>	257
<b>Foipan</b>	Agent for chronic pancreatitis and postoperative reflux esophagitis	<b>179</b>	186
<b>Cataclot</b>	Agent for (acute phase ) cerebral thrombosis and cerebrovascular spasms	<b>116</b>	131
<b>Prostandin 500</b>	Agent for perioperative hypotension	<b>34</b>	38
<b>Prostandin</b>	Circulatory system agent	<b>101</b>	110
<b>FOY</b>	Agent for pancreatitis and DIC	<b>32</b>	36
<b>FOY 500</b>	Agent for DIC	<b>76</b>	81
<b>Opalmon</b>	Circulatory system agent	<b>131</b>	81
Total		<b>1,188</b>	1,157
Percentage to total net sales		<b>89%</b>	89%

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Ono Pharmaceutical Co., Ltd.  
and Consolidated Subsidiaries

### Supplemental Information

## New Drugs in Development

In our ongoing effort to create products that will promote the health of more people worldwide, Ono has many new drug formulations under development, including the following major drugs:

### ***Elaspol® 100 for Injection (ONO-5046 Na)***

Elaspol® for Injection is for the treatment of acute lung injury in patients using mechanical ventilation in the ICU. Elaspol, a selective inhibitor of neutrophil elastase, which is believed to induce acute lung injury, was approved on April 11, 2002 as the world's first drug for this disease. We believe this drug will markedly contribute to improved medical care, since no effective drugs have been available for the disease until now.

**Japan:** Obtained manufacturing approval as a medication for acute lung injury associated with systemic inflammatory response syndrome.

**U. S. :** Clinical studies by Eli Lilly and Company.

### ***Onoact® 50 for Injection (ONO-1101)***

Onoact® for Injection is for the treatment of tachyarrhythmia occurring during operation in patients mainly with hypertension or ischemic heart disease. It is very safe and easy to adjust due to its ultra-short duration of action.

**Japan:** Awaiting approval as a medication for tachyarrhythmia during operation. Phase II/III clinical studies as a medication for post-operative tachyarrhythmia.

### ***ONO-5920 (tablet)***

ONO-5920 is under development for the treatment of osteoporosis. This drug, a bisphosphonate of the third generation, inhibits activation of osteoclasts and effectively prevents bone resorption. With the ability to rapidly increase bone mass, it will be safe and effective at low doses.

**Japan:** Phase III clinical study as a medication for osteoporosis.

### ***Proglia for Injection (ONO-2506)***

Proglia for Injection is under development for the treatment of ischemic stroke, to be effective both for cerebral thrombosis and cerebral embolism. The drug inhibits the spread of post-infarction necrosis with a novel mechanism of action, suppressing abnormal activation of astrocytes, a kind of brain cell. The drug holds promise for very convenient administration in medical practice, because it does not act on thrombi or blood vessels; therefore, there is no risk of hemorrhage.

**Japan:** Phase II clinical study as a medication for acute ischemic stroke.

**North America:** Phase II clinical study.

### ***AIO-8507L (capsule)***

AIO-8507L relieves dysuria caused by benign prostatic hyperplasia. This drug is an  $\alpha_1$  blocker with high urethral selectivity, and is unlikely to cause circulatory adverse effects, such as orthostatic hypotension (dizziness on standing up) that occurs with other existing medications, with only a slight effect on blood vessels. It is, therefore, expected to be very safe.

**Japan:** Phase II clinical study as a medication for dysuria resulting from benign prostatic hyperplasia.

**U. S. :** Phase II clinical study.

### ***ONO-8025/KRP-197 (tablet)***

ONO-8025/KRP-197 is under development for the treatment of hyperactive bladder (pollakiuria and urinary incontinence). This drug is unlikely to cause adverse effects such as dry mouth, which is caused by other drugs with similar mode of action, as tests on animals have revealed that it acts as an antagonist by selectively binding to the muscarinic receptors in the bladder.

**Japan:** Phase II clinical study as a medication for hyperactive bladder (pollakiuria and urinary incontinence) (co-development with Kyorin Pharmaceutical Co., Ltd.).

### ***ONO-6818 (tablet)***

ONO-6818 is under development for the treatment of chronic obstructive pulmonary disease (emphysema or chronic bronchitis), in patients who have difficulty in leading normal lives, because of a loss of respiratory function due to smoking or air pollution. As an orally administered inhibitor of neutrophil elastase, which is a cause of injury to respiratory tissue, this drug is expected to alleviate lung injury in such patients. The development of the drug is also being promoted overseas, in patients with  $\alpha_1$  antitrypsin deficiency, who are likely to suffer from lung injury caused by neutrophil elastase, due to inherited factors.

**Japan:**Phase II clinical study as a medication for chronic obstructive pulmonary disease.

**U. S. :** Phase II clinical studies under preparation as a medication for chronic obstructive pulmonary disease and  $\alpha_1$  antitrypsin deficiency.

### ***ONO-4819 CD (for injection)***

ONO-4819 CD is being developed for the treatment of bone fractures, as a selective EP4 agonist to strongly promote osteogenesis. This will be an innovative drug that hastens healing of bone fractures, with a totally different mechanism from conventional drugs.

**Japan:** Phase II clinical study as a medication for vertebral fracture.

### ***ONO-5816 (tablet)***

ONO-5816 is under development for the treatment of diabetes. This drug acts by increasing sensitivity to insulin, to lower the blood glucose levels. It is believed to be more effective than other drugs for non-obese type-2 diabetes patients, who are numerous in Japan. Moreover, as no liver damage was found in tests in animals, it is expected to be very safe.

**Japan:** Phase II clinical study.

**U. S. :** Phase II clinical study by Lipha s.a., France.

### ***Cereact Capsule (ONO-2506PO)***

It has been elucidated that astrocyte dysfunction is greatly involved in the occurrence and progression of neurodegenerative diseases such as Alzheimer's/Parkinson's diseases and amyotrophic lateral sclerosis (ALS). Working through a novel mechanism of action, suppressing abnormal activation of astrocytes, Cereact capsule is expected to inhibit the occurrence and progression of various neurodegenerative diseases.

**Japan:** Phase I clinical study as a medication for neurodegenerative diseases.

**Europe :** Phase I clinical study.

### ***ONO-6126 (tablet)***

ONO-6126 is a selective inhibitor of phosphodiesterase type 4, and is under development for the treatment of bronchial asthma and chronic obstructive pulmonary disease. The drug has shown both suppressive effects on bronchoconstriction and anti-inflammatory effects. Since the drug shows less penetration to CNS system, it is expected to be useful in the treatment of chronic respiratory diseases without any adverse effects such as vomiting and headache.

**Japan:** Phase I clinical study as a medication for bronchial asthma and chronic obstructive pulmonary disease.

**U.K. :** Phase I clinical study.

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### Supplemental Information

## Status of Major Developments

March 31, 2002

### Developments in Japan

#### *Obtained manufacturing approval*

(as of April 11, 2002):

- **Elaspol® 100 for Injection (ONO-5046 Na)**

Sivelestat sodium hydrate for the treatment of acute lung injury associated with systemic inflammatory response syndrome

#### *Awaiting manufacturing approval:*

- **Onoact® 50 for Injection (ONO-1101)**

Landirolol hydrochloride for tachyarrhythmia during operation

- **Prostandin® for Injection**

Alprostadil alfadex for patent ductus arteriosus associated with ductus arteriosus-dependent congenital heart diseases

#### *Ongoing clinical studies:*

##### *New chemical entities:*

- **ONO-5920** Osteoporosis (tablet, Phase III)
- **Proglia for Injection (ONO-2506)** Acute ischemic stroke (injection, Phase II)
- **AIO-8507L** Dysuria resulting from benign prostatic hyperplasia (capsule, Phase II)
- **ONO-8025/KRP-197** Hyperactive bladder (pollakiuria and urinary incontinence) (tablet, Phase II)
- **ONO-1714** Hypotension during dialysis (injection, Phase II)
- **ONO-6818** Chronic obstructive pulmonary disease (tablet, Phase II)
- **ONO-4819 CD** Vertebral fracture (injection, Phase II)
- **ONO-5816** Diabetes (tablet, Phase II)
- **ONO-8815Ly** Imminent premature labor (injection, Phase I completed)
- **ONO-4817** Inflammatory bowel disease and osteoarthritis (tablet, Phase I)

- **Cereact Capsule (ONO-2506PO)**

Alzheimer's/Parkinson's diseases and amyotrophic lateral sclerosis (ALS) (capsule, Phase I)

- **ONO-6126** Bronchial asthma and chronic obstructive pulmonary disease (tablet, Phase I)

#### *Ongoing clinical studies:*

##### *Additional indications:*

- **Onon® Dry Syrup** Pranlukast hydrate for pediatric allergic rhinitis (Phase II/III)
- **Onoact® 50 for Injection (ONO-1101)** Landiolol hydrochloride for post-operative tachyarrhythmia (Phase II/III)
- **Onon® Capsule** Pranlukast hydrate for chronic sinusitis (Phase II)

### Developments abroad

#### *Ongoing clinical studies:*

- **AIO-8507L** Dysuria resulting from benign prostatic hyperplasia (capsule, Phase II)
- **Proglia for Injection (ONO-2506)** Acute ischemic stroke (injection, Phase II)
- **ONO-6818** Chronic obstructive pulmonary disease and  $\alpha_1$  antitrypsin deficiency (tablet, Phase II under preparation)
- **ONO-8815Ly** Imminent premature labor (injection, Clinical pharmacology study completed)
- **Cereact Capsule (ONO-2506PO)** Alzheimer's/Parkinson's diseases and amyotrophic lateral sclerosis (ALS) (capsule, Phase I)
- **ONO-4817** Inflammatory bowel disease and osteoarthritis (tablet, Phase I)
- **ONO-6126** Bronchial asthma and chronic obstructive pulmonary disease (tablet, Phase I)