Flash Report for the First Three Quarters of FY 2008 (on a consolidated basis)

February 12, 2009

(¥ million)

Name of the listed company: NIPPON SHINYAKU CO., LTD. Code No.: 4516 Listing stock exchange: Tokyo, Osaka URL http://www.nippon-shinyaku.co.jp/ Representative: Shigenobu Maekawa, President and Representative Director Contact: Taro Sakurai, General Manager of Finance & Accounting Dept. Tel. +81-75-321-9114 Scheduled date for submission of Quarterly Report: February 13, 2009

* All amounts are rounded down to the nearest million yen.

1. Results for the First Three Quarters (April 1 to December 31, 2008)

(1) Operating results

| | Net | sales | Operatin | g income | Ordinar | y income |
|--|---------|-------|----------|----------|---------|----------|
| Three quarters ended December 31, 2008 | ¥48,661 | % | ¥7,052 | % | ¥7,058 | % |
| Three quarters ended December 31, 2007 | 44,017 | 4.8 | 5,231 | 40.8 | 5,986 | 44.4 |

| | Net i | ncome | Earnings per share (¥) | Diluted EPS (¥) |
|--|--------|-------|------------------------|-----------------|
| Three quarters ended December 31, 2008 | ¥3,861 | % | ¥57.11 | ¥— |
| Three quarters ended December 31, 2007 | 3,430 | 53.7 | 50.69 | — |
| | | | | |

Note: Percentage figures for net sales, operating income, ordinary income and net income represent year-on-year comparisons.

(2) Financial position

| (2) Financial position | | | | (¥ million) |
|-------------------------|--------------|------------|--------------|-----------------------------|
| | Total assets | Net assets | Equity ratio | Net assets per share (¥) |
| As of December 31, 2008 | ¥ 98,735 | ¥76,667 | 77.5% | ¥1,132.18 |
| As of March 31, 2008 | 103,115 | 76,951 | 74.5 | 1,135.40 |

Note: Owners' equity

As of December 31, 2008: ¥76,519 million As of March 31, 2008: ¥76,804 million

2. Dividends

| | | Cash di | vidends per sl | hare (¥) | |
|---------------------------------------|-----|-------------|----------------|------------|--------|
| | | Quarter-end | | | Annual |
| | 1st | 2nd | 3rd | - Year-end | Annuar |
| Year ended March 31, 2008 | ¥— | ¥7.00 | ¥— | ¥9.00 | ¥16.00 |
| Year ending March 31, 2009 | _ | 9.00 | | | |
| Year ending March 31, 2009 (forecast) | | | | 9.00 | 18.00 |

Note: Revisions to dividend payment forecasts during the period: not applicable

3. Business Performance Forecasts for the Year Ending March 31, 2009

(April 1, 2008 to March 31, 2009)

| | | | | | | | | | (¥ million) |
|-----------|---------|------|-----------|----------|----------|--------|--------|------|---------------------------|
| | Net s | ales | Operating | g income | Ordinary | income | Net in | come | Earnings per share (¥) |
| Full term | ¥63,000 | 6.0% | ¥7,000 | 8.3% | ¥7,300 | 6.4% | ¥4,400 | 9.2% | ¥65.09 |
| N 1 D | C" | | | | | | | | |

Notes: 1. Percentage figures represent year-on-year comparisons.

2. Revisions to performance forecasts during the period: not applicable

The above forecasts are based on data available as of the date of release of this document as well as assumptions based on uncertain factors, which might have a material effect on the Company's performance in the future. Readers are advised that actual results may differ substantially from the above forecasts due to various unforeseeable factors.

4. Others

- (1) Changes in the scope of consolidation Inclusion: none Exclusion: none
- (2) Significant methods applied for accounting: applicable
- (3) Changes in significant accounting policies

Changes in accounting standard: applicable Other: not applicable

Effective from the reporting period, the company has applied Accounting Standards for the Preparation of Quarterly Financial Statements and Application Guidelines for Accounting Standards for the Preparation of Quarterly Financial Statements. In addition, our quarterly financial statements have been prepared in accordance with "Regulations governing the preparation of consolidated quarterly financial statements."

(4) Number of ordinary shares issued at the end of the period (including treasury stock) As of December 31, 2008: 70,251,484 shares As of March 31, 2008: 70,251,484 shares

Number of shares in treasury at the end of the period As of December 31, 2008: 2,665,732 shares As of March 31, 2008: 2,606,466 shares Average number of shares during the period

Three quarters ended December 31, 2008: 67,612,590 shares Three quarters ended December 31, 2007: 67,673,760 shares

Consolidated Balance Sheets

(¥ million)

| | As of December 31, 2008 | As of March 31, 2008 |
|------------------------------------|-------------------------|----------------------|
| Assets | | |
| Current assets: | | |
| Cash and deposits | ¥ 8,519 | ¥ 11,234 |
| Notes and accounts receivable | 29,987 | 27,036 |
| Marketable securities | 4,900 | 4,599 |
| Merchandise and finished products | 5,844 | 6,332 |
| Semi-finished products | 1,070 | 972 |
| Work in process | 434 | 260 |
| Raw materials and supplies | 3,366 | 3,030 |
| Deferred tax assets | 983 | 1,743 |
| Other current assets | 1,004 | 1,071 |
| Allowance for doubtful accounts | (0) | (0) |
| Total current assets | 56,111 | 56,281 |
| Noncurrent assets: | | |
| Tangible fixed assets: | | |
| Buildings and structures – net | 9,004 | 8,919 |
| Land | 8,164 | 8,172 |
| Other – net | 3,443 | 3,213 |
| Total tangible fixed assets | 20,612 | 20,304 |
| Intangible assets | 284 | 259 |
| Investments and other assets: | | |
| Investment securities | 13,186 | 19,212 |
| Deferred tax assets | 46 | 55 |
| Investments in real estate – net | 1,337 | 1,356 |
| Long-term prepaid expenses | 6,366 | 4,527 |
| Other | 844 | 1,172 |
| Allowance for doubtful accounts | (54) | (53) |
| Total investments and other assets | 21,725 | 26,270 |
| Total noncurrent assets | 42,623 | 46,834 |
| Total assets | ¥98,735 | ¥103,115 |

| | | (¥ million) |
|---|-------------------------|----------------------|
| | As of December 31, 2008 | As of March 31, 2008 |
| Liabilities | | |
| Current liabilities: | | |
| Notes and accounts payable | ¥ 4,529 | ¥ 5,061 |
| Short-term borrowings | 60 | 30 |
| Current portion of long-term debt | 308 | 1,162 |
| Accrued liabilities | 3,751 | 3,034 |
| Income taxes payable | 692 | 1,649 |
| Reserve for bonuses | 1,232 | 2,402 |
| Reserve for sales returns | 46 | 22 |
| Other current liabilities | 2,506 | 1,708 |
| Total current liabilities | 13,127 | 15,071 |
| Long-term liabilities: | | |
| Long-term debt | 32 | 59 |
| Deferred tax liability | 343 | 2,207 |
| Liability for retirement benefits | 8,342 | 8,536 |
| Other long-term liabilities | 222 | 290 |
| Total long-term liabilities | 8,940 | 11,093 |
| Total liabilities | 22,067 | 26,164 |
| Net assets | | |
| Shareholders' equity: | | |
| Common stock | 5,174 | 5,174 |
| Capital surplus | 4,444 | 4,441 |
| Retained earnings | 64,914 | 62,270 |
| Treasury stock | (1,977) | (1,900) |
| Total shareholders' equity | 72,556 | 69,986 |
| Valuation and translation adjustments: | | |
| Unrealized gain on available-for-sale securities | 3,991 | 6,822 |
| Deferred loss on derivatives under hedge accounting | (13) | (0) |
| Foreign currency translation adjustments | (14) | (4) |
| Total valuation and translation adjustments | 3,962 | 6,818 |
| Minority interests | 148 | 147 |
| Total net assets | 76,667 | 76,951 |
| Total liabilities and net assets | ¥98,735 | ¥103,115 |

Consolidated Statement of Income

| | (¥ millior |
|--|--|
| | Three quarters ended December 31, 2008 |
| Net sales | ¥48,661 |
| Cost of sales | 21,704 |
| Provision for reserve for sales returns | 24 |
| Gross profit | 26,933 |
| Selling, general and administrative expenses: | |
| Salaries and benefits | 5,710 |
| Provision for bonuses | 788 |
| Sales promotion expenses | 941 |
| Provision for retirement benefits | 738 |
| Depreciation | 263 |
| R&D expenses | 5,967 |
| Other | 5,470 |
| Total selling, general and administrative expenses | 19,880 |
| Operating income | 7,052 |
| Non-operating income: | |
| Interest income | 163 |
| Dividend received | 254 |
| Rent income | 231 |
| Other | 193 |
| Total non-operating income | 842 |
| Non-operating expenses: | |
| Interest expenses | 12 |
| Donation | 130 |
| Loss on disposal of noncurrent assets | 33 |
| Expenses for dismantling plant | 70 |
| Leasing expenses | 72 |
| Foreign exchange loss | 408 |
| Other | 108 |
| Total non-operating expenses | 837 |
| Ordinary income | 7,058 |
| Extraordinary losses: | |
| Loss on valuation of investment securities | 339 |
| Total extraordinary losses | 339 |
| Income before income taxes and minority interests | 6,719 |
| Income taxes - current | 1,971 |
| Income taxes - deferred | 884 |
| Total income taxes | 2,856 |
| Minority interests in net income | 1 |
| Net income | ¥ 3,861 |

Consolidated Statement of Cash Flows

| | (¥ millio |
|---|----------------------|
| | Three quarters ended |
| | December 31, 2008 |
| Cash flows from operating activities | |
| Income before income taxes and minority interests | ¥ 6,719 |
| Depreciation and amortization | 2,093 |
| Decrease in liability for retirement benefits | (193) |
| Decrease in other reserves | (1,145) |
| Interest and dividend income | (417) |
| Interest expenses | 12 |
| Foreign exchange loss | 508 |
| Loss on valuation of investment securities | 339 |
| Loss on disposal of noncurrent assets | 33 |
| Increase in notes and accounts receivable | (2,951) |
| Increase in inventories | (120) |
| Decrease in other current assets | 103 |
| Decrease in notes and accounts payable | (532) |
| Increase in consumption taxes payable | 173 |
| Increase in other current liabilities | 509 |
| Other – net | (3) |
| Subtotal | 5,128 |
| Interest and dividends received | 418 |
| Interest paid | (12) |
| Income taxes paid | (12) |
| - | |
| Net cash provided by operating activities | 2,632 |
| Cash flows from investing activities | |
| Deposit of funds into time deposits | (70) |
| Proceeds from withdrawal of time deposits | 100 |
| Proceeds from redemption of marketable securities | 400 |
| Purchases of investment securities | (36) |
| Proceeds from redemption and sale of investment securities | 45 |
| Purchases of tangible fixed assets | (1,150) |
| Proceeds from sale of tangible fixed assets | 35 |
| Purchases of intangible assets | (84) |
| Provision of loans | (26) |
| Collection of loans | 71 |
| Long-term prepaid expenses | (2,206) |
| Other – net | 0 |
| Net cash used in investing activities | (2,921) |
| Cash flows from financing activities | |
| Net increase in short-term borrowings | 30 |
| Repayment of long-term debt | (881) |
| Cash dividend paid | (1,152) |
| Purchase of treasury stock | (83) |
| Other – net | 8 |
| Net cash used in financing activities | (2,078) |
| Foreign currency transaction adjustments on cash and cash equivalents | (518) |
| Vet decrease in cash and cash equivalents | (2,886) |
| Cash and cash equivalents at beginning of period | |
| | 15,153 |
| Cash and cash equivalents at end of period | ¥12,267 |