

# Nycomed First Quarter 2009 Results

## Nycomed Reports a Solid Start to 2009

### First Quarter 2009 highlights

- Adjusted EBITDA increased 1.0% to €307.0m (Q1 2008: €304.0m)
- Total net turnover increased 1.2% to €839.9m (Q1 2008: €830.2m)
- Key Products grew by 2.0% to €510.7m worldwide
- Daxas<sup>®</sup> filed for approval in Europe; outlicensing discussions in the US progressing well
- Positive CHMP opinion received for Pantoprazole OTC
- Positive CHMP opinion received for Instanyl<sup>®</sup>

### Key figures

	Q1 2009 (€m)	Q1 2008 (€m)	Change	2008 Full year (€m)
Net turnover	839.9	830.2	+1.2%	3,348.0
Gross profit margin	622.0 74.1%	614.2 74.0%	+1.3% +0.1%	2,463.4 73.6%
Operating profit (EBIT)	130.9	83.0	+57.7%	352.0
EBITDA margin	302.0 36.0%	298.6 36.0%	+1.1% 0.0%	1,142.8 34.1%
Adjusted EBITDA margin	307.0 36.6%	304.0 36.6%	+1.0% 0.0%	1,207.6 36.1%

The full results are on page 10.

For a full explanation of Adjusted EBITDA, please see page 10.

Håkan Björklund, CEO, commented on the company's first quarter performance:

"Nycomed has made a good start to the year, with first quarter net turnover reaching €839.9 million and a continued satisfactory performance despite the challenging economic environment. Pantoprazole continued to perform well, reaffirming our confidence in its longer-term potential despite generic competition in some markets.

In February, Pantoprazole OTC received a positive EMEA CHMP opinion. We are now awaiting approval, enabling us to launch the product in 2009 as part of our strategy of carefully managing the Pantoprazole franchise.

The most significant development for the future of the company this year will be the progress of Daxas<sup>®</sup>, which was filed for approval in Europe for the treatment of COPD after the end of the reporting period in early May. We are now working to complete filing of Daxas<sup>®</sup> in the US, and we are making good progress in our search for a US marketing partner. We were also encouraged to receive a positive opinion from the European CHMP in April, recommending approval of Instanyl<sup>®</sup>, our product for managing breakthrough pain in cancer patients.

The current global downturn is having some impact on our business, mainly on OTC products in the emerging markets. The trading environment will remain challenging for the full year, but we believe our strategy of identifying and inlicensing promising new products and expanding our focus on emerging markets such as the Asia-Pacific region positions us well for continued success in 2009 and beyond."

# Financial Highlights

Total net turnover increased by 1.2% to €839.9 million, compared to €830.2 million in the first quarter of 2008, despite adverse impact from currency movements. Excluding the effects of currency, the increase was 3.8%, underlining the solid performance of the main product Pantoprazole and other Key Products.

Global net turnover of Pantoprazole decreased by 1.2%, with continued solid overall sales offset by a marked decline in Canada from generic erosion. Pantoprazole OTC received a positive CHMP opinion during the quarter, and European approval and launch of the product is anticipated during 2009. In the United States, the FDA granted a Paediatric Extension of the substance patent for Pantoprazole, to January 2011 from July 2010.

On a regional basis, most of our markets performed in line with or above our expectations, despite increased uncertainty created by the global economic crisis. Total net turnover in Europe increased 2.3%. While net turnover in Russia/CIS was up 3.6% in the quarter (+14.0% in local currencies), we anticipate that these markets will prove challenging this year as a result of difficult local economic conditions.

Net turnover in Latin America decreased by 7.6%, mainly due to currency effects – sales were up 7.8% on a constant currency basis. Strong growth of 20.7% was achieved in the Asia-Pacific, Africa, Middle East region. Net turnover in North America declined by 12.4%, reflecting the impact of generic Pantoprazole in Canada. Nycomed US increased turnover by 52.9%. In local currency terms, Nycomed US turnover was up 32.3%. OTC turnover declined by 11.9% to €88.2 million, and decreased by 3.8% in local currencies. Turnover of Specialty and Respiratory products increased by 12.7% and 67.3% respectively.

Adjusted EBITDA increased by 1.0% to €307.0 million (Q1 2008: €304.0 million). Excluding the effect of currencies, adjusted EBITDA grew by 3.6%. Total costs rose slightly, with a significant decrease in research and development costs (-13.1%) offset by an increase in marketing and sales expenses.

# Business Review

## Regional overview

Region	Sales Q1 2009 (€m)	Sales Q1 2008 (€m)	Growth	Growth in local currencies
Europe	456.2	445.9	+2.3%	+4.8%
Latin America	71.4	77.3	-7.6%	+7.8%
Russia/CIS	78.7	76.0	+3.6%	+14.0%
Asia-Pacific, Africa, Middle East	44.5	36.8	+20.7%	+28.1%
North America	98.1	112.0	-12.4%	-14.9%
Outlicensing	72.0	63.3	+13.7%	+2.9%
Contract Manufacturing	18.9	18.9	+0.2%	+4.4%
<b>Total</b>	<b>839.9</b>	<b>830.2</b>	<b>+1.2%</b>	<b>+3.8%</b>

Most markets performed in line with or above expectations in the first quarter, even though the global economic crisis added some uncertainty to the business environment, primarily related to the emerging markets, currency fluctuations and inventory levels.

### Europe

Total European turnover grew in the first quarter by 2.3% compared to the same period in 2008, lifted by growth in Key Products and the positive development of Pantoprazole. In Germany, our largest market, sales grew by 7.6% due to increased Pantoprazole sales. Growth in sales in France, of 33.8%, was supported by regaining the rights to Inipomp from Sanofi-Aventis. Sales in Italy were particularly robust, up 25.9% year-on-year, boosted by the continuing strength of Pantoprazole. Sales in Greece increased 17.2% year-on-year, largely from Pantoprazole and development of Preotact<sup>®</sup>. Eastern Europe came in ahead of expectations, despite the impact of difficult economic conditions.

### Latin America

Net turnover within Latin America fell 7.6% year-on-year to €71.4 million, although was up by 7.8% on a constant currency basis. Nycomed regained the rights to Pantoprazole in Venezuela earlier than expected, which provided a material uplift to activities there. Solid sales in Mexico, where Nycomed is growing ahead of the market, and Argentina were somewhat offset by a decline in OTC sales in Brazil.

### Russia/CIS

Net turnover in Russia/CIS increased by 3.6%, to €78.7 million (+14.0% in local currencies), despite the economic crisis. Strong sales in Key Products and Rx products were partially

offset by weaker-than-expected OTC sales. In Ukraine, in-market sales of Nycomed products increased by 21.0%. Nycomed is in a strong position to take advantage of future recovery in the Russia/CIS region.

Looking ahead, we anticipate that the trading environment will be challenging for the rest of 2009. Local economies continue to struggle as a result of the economic crisis.

### **Asia-Pacific, Africa, Middle East**

Total net turnover from Asia-Pacific, Africa, Middle East increased by 20.7% in the first quarter of 2009 compared to 2008, helped by sales of Pantoprazole in South Korea and China.

During the quarter, Nycomed acquired the remaining shares in its South African subsidiary, and is now a 100% shareholder of the company.

### **North America**

Net turnover in North America was down 12.4% versus the prior year, largely from continuing generics erosion of Pantoprazole in Canada. Offsetting this, Nycomed US turnover increased by 52.9%, benefiting from strong growth of PharmaDerm products and the integration of Bradley. In local currencies, sales of Nycomed US increased by 32.3%. Bradley was only consolidated in February 2008, and as such had only a partial impact on the first quarter 2008 results. Excluding Bradley, turnover of Nycomed US in the first quarter of 2009 was up 29.4% year-on-year.

### **Outlicensing**

Outlicensing turnover was up 13.7% compared to the previous year, mainly because Wyeth's Pantoprazole generic was not introduced until the end of January 2008, having only a partial effect on the quarter. Overall, Pantoprazole has continued to regain market share since the introduction of Wyeth's own generic, partially offsetting the losses incurred by the patent infringements.

### **Contract Manufacturing**

Net turnover from Contract Manufacturing was steady at €18.9 million, up 0.2% on the year, helping Nycomed to utilise excess capacity.

## Product net turnover

Area	Sales Q1 2009 (€m)	Sales Q1 2008 (€m)	Growth	Growth in local currencies
Gastrointestinal	362.1	366.7	-1.2%	+0.4%
Specialty Products	122.8	109.0	+12.7%	+20.5%
Respiratory	25.8	15.4	+67.3%	+86.4%
<b>Subtotal Key Products</b>	<b>510.7</b>	<b>491.1</b>	<b>+2.0%</b>	<b>+6.1%</b>
OTC*	88.2	100.1	-11.9%	-3.8%
Regional and local Rx	159.0	185.5	-14.3%	-8.7%
Nycomed US	81.9	53.6	+52.9%	+32.3%
<b>Total</b>	<b>839.9</b>	<b>830.2</b>	<b>+1.2%</b>	<b>+3.8%</b>
Total OTC	106.7	117.6	-9.2%	-2.9%

\*not including Calcium OTC (part of Specialty) and Pantoprazole OTC (part of Gastrointestinal)

Most Key Products performed well, particularly Specialty and Respiratory products. OTC net turnover was affected by the economic crisis and currency effects, as was our Regional and local Rx portfolio, while Nycomed US benefited from the integration of Bradley.

### Pantoprazole

Outside the United States and Canada, Pantoprazole sales increased by 10.0% (+12.5% in local currencies) benefiting from volume growth and the regaining of rights to Inipomp in France. Global sales of Pantoprazole decreased by 1.2%, with continued solid overall sales offset by a marked decline in Canada from generic erosion.

The substance patent for Pantoprazole expired in most of Europe in May 2009. Nycomed is well prepared to manage the situation and is confident that Pantoprazole will remain its largest single product for the next few years. Some 40% of Pantoprazole sales are already generated in countries where the patent has already expired or there has never been patent protection. Furthermore, there is no major successor product in the gastrointestinal industry pipeline to the proton-pump-inhibitor (PPI) class to which Pantoprazole belongs.

In the first quarter, European volumes of Pantoprazole sales increased by 12.7%, most notably in larger countries like Germany and Italy.

To compete on price with PPI generics, Nycomed introduced new Pantoprazole varieties in Belgium and Germany in the first quarter 2009. These have been well received, and gained market share mainly from generic omeprazole.

### **Pantoprazole OTC**

Pantoprazole OTC received a positive EMEA CHMP opinion in February 2009. Pantozol<sup>®</sup> Control is the first proton-pump-inhibitor recommended for EU-wide OTC marketing authorisation. Nycomed hopes to launch the product in its first European markets during 2009 as part of its strategy of carefully managing the Pantoprazole franchise.

### **Pantoprazole Pediatric Extension**

On February 18, the FDA has granted a pediatric extension, which extends the exclusivity for Pantoprazole in the United States until January 2011 (previously July 2010).

### **Pantoprazole US**

Nycomed and its licensee Wyeth remain convinced of the validity and enforceability of its US Pantoprazole patent and will continue to pursue litigation vigorously.

# Product Portfolio Update

## **Daxas<sup>®</sup>**

The outlicensing process for Daxas<sup>®</sup> in the United States has attracted strong interest, confirming our belief that Daxas<sup>®</sup> will be a significant product for Nycomed. We expect to update the market on this process in the coming months.

On May 8, Nycomed announced the submission of a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for Daxas<sup>®</sup> as a once-daily oral treatment for patients with COPD associated with chronic bronchitis. We are now working to complete filing of Daxas<sup>®</sup> in the US. Subject to approval by the regulatory authorities, the first launches of the product are expected in 2010.

## **TachoSil<sup>®</sup>**

On February 17, TachoSil<sup>®</sup> received an expanded indication from the EMA. The existing indication of tissue sealing was expanded by haemostasis in surgery. This will enable its use in patients undergoing lung or other types of surgery requiring rapid air or body fluid sealing. Estimates put the number of additional patients that can now benefit from TachoSil<sup>®</sup> at around 60,000 per year.

## **Instanyl<sup>®</sup>**

On April 23, Instanyl<sup>®</sup> (intranasal fentanyl) received a positive CHMP opinion. Instanyl<sup>®</sup> is an intranasally-applied fentanyl spray that has been developed by Nycomed. It is intended for managing breakthrough pain in adult cancer patients who are already receiving maintenance opioid therapy for chronic pain. Nearly half of all early-stage cancer patients with chronic pain and up to 90% in later stages suffer the sudden onset of brief but acute 'breakthrough' pain.

European approval is expected in the second quarter 2009 and launch soon thereafter.

## **Alendronate**

Nycomed announced the inlicensing of Alendronate effervescent from EffRx in January 2009. The drug will complement Nycomed's strong osteoporosis portfolio. Nycomed is preparing for submission of a marketing authorisation application in Europe at the end of 2009.

# Financial Report

## Net Turnover

Net turnover for the first quarter 2009 grew by 1.2% to €839.9 million. Excluding the effects of currency, the increase was 3.8%, underlining the solid performance of the main product Pantoprazole and other Key Products. For more detail, please refer to the Financial Highlights and Business Review sections.

## Cost of sales

Cost of sales for the quarter was €217.9 million, little changed from the same period last year. As a percentage of net sales the cost of goods sold decreased slightly by 1.3% to 26.3%, mainly as a result of continuing improvement of the cost structure.

## Operating expenses

Operating expenses for the first quarter in 2009 were slightly above those in the first quarter of 2008, mainly driven by marketing and sales expenses, which rose by €10.2 million to €232.6 million. R&D expenses decreased by €7.1 million during the period to €47.6 million, more than offsetting the increase in administration expenses.

## Financial Items

Financial expenses for the period were €100.5 million, including interest costs of €78.2 million. Of the remainder, €17.0 million related to a foreign exchange loss and €3.8 million was from amortisation of financing fees.

Financial income amounted to €100.0 million, of which €74.2 million was related to an unrealised gain on cross currency swaps and €21.8 million was from foreign exchange gains.

## Net result of the period

Net result for the first quarter 2009 was €87.6 million, an increase of €32.0 million, equating to an improvement of 37.4% year-on-year.

## Adjusted EBITDA

Adjusted EBITDA, a key performance measurement for the group, was €307.0 million during the first quarter of 2009, representing a year-on-year increase of 1.0%. Excluding the effect of currencies, adjusted EBITDA grew by 3.6%.

## Cash flow

Cash inflow from operating activities was €233.8 million during the first quarter of 2009, compared to an inflow of €322.5 million during the same period in 2008. The decrease in cash flow from operating activities was primarily related to a negative development in working capital of €40.8 million. During the first quarter of 2009, €33.3 million was paid in taxes.

Cash flow from investing activities showed an outflow of €28.9 million. In the first quarter of 2009 Nycomed acquired the remaining shares in its joint venture in South Africa. The outflow related to tangible and intangible assets was €25.2 million.

Cash flow from financing activities in the quarter showed an outflow of €140.9 million, of which €59.4 million related to the buy back of Nycomed debt. Net financial expenses paid in the period decreased to €78.2 million, compared to €85.0 million during the first quarter of 2008, as a consequence of lower interest rates.

### **Capital Resources**

Nycomed expects to generate significant cash flow in 2009, which will be used to support strategic development and servicing of debt.

As of the end of March 2009 Nycomed had a cash position of €560.2 million, compared to a cash position of €402.9 million at the end of March 2008.

Total debt at the end of March 2009 amounted to €4,595.0 million, compared to €4,519.9 million at the end of the first quarter of 2008. The increase derives from the strengthening of the US dollar against the euro. The figure for 2009 includes an amount of debt bought back of €143.5 million.

Nycomed has committed facilities of €450.0 million under the inlicensing/restructuring facility, of which €125.0 million has been utilised. In addition, Nycomed has a revolving facility of €250.0 million, which remains undrawn.

## Income Statement

	Q1 2009 (€m)	Q1 2008 (€m)
Net sales	829.7	812.1
Royalties / other income	10.2	18.1
<b>Net turnover</b>	<b>839.9</b>	<b>830.2</b>
Cost of sales	(217.9)	(216.0)
<b>Gross profit</b>	<b>622.0</b>	<b>614.2</b>
Sales and marketing expenses	(232.6)	(222.4)
Amortisation of fair value adjustments on patents and rights from acquisitions	(141.4)	(189.7)
Total sales and marketing expenses	(373.9)	(412.2)
Research and development expenses	(47.6)	(54.7)
Administrative expenses	(63.7)	(58.9)
Integration / restructuring costs	(5.9)	(5.4)
<b>Operating profit</b>	<b>130.9</b>	<b>83.0</b>
Financial income	100.0	158.6
Financial expenses	(100.5)	(157.1)
<b>Profit / loss before tax</b>	<b>130.4</b>	<b>84.5</b>
Income tax	(42.8)	(28.9)
<b>Net result of the period</b>	<b>87.6</b>	<b>55.6</b>
Attributable to:		
Equity holders of the parent	85.4	
Minority interests	2.2	

<b>EBITDA/ADJUSTED EBITDA</b>		
<b>Net income (loss)</b>	<b>87.6</b>	<b>55.6</b>
<b>Adjustments:</b>		
Net financial items	0.5	(1.5)
Income tax expense (benefit)	42.8	28.9
Depreciation and amortisation	171.1	215.6
<b>EBITDA</b>	<b>302.0</b>	<b>298.6</b>
<b>Adjustments:</b>		
Integration/restructuring costs (exclude depreciation already in EBITDA)	5.0	5.4
Inventory step-up	0.0	0.0
Warrants	0.0	0.0
<b>Adjusted EBITDA</b>	<b>307.0</b>	<b>304.0</b>

## Balance Sheet

	Q1 2009 (€m)	Q1 2008 (€m)
<b>ASSETS</b>		
<b>Non-current assets</b>		
Patents and rights and currently marketed products	2,813	2,956
Goodwill	2,168	2,159
Development projects in progress	503	487
Total intangible assets	5,484	5,602
Total property, plant and equipment	618	624
Other non current assets	39	39
Deferred tax assets	73	97
<b>TOTAL NON-CURRENT ASSETS</b>	<b>6,214</b>	<b>6,362</b>
<b>Current assets</b>		
Total inventories	470	435
Trade receivables	617	579
Income tax receivable	22	18
Other receivables / other current assets	59	70
Marketable Securities	10	12
Cash	560	497
<b>Total cash and cash equivalents</b>	<b>571</b>	<b>509</b>
<b>TOTAL CURRENT ASSETS</b>	<b>1,737</b>	<b>1,610</b>
<b>TOTAL ASSETS</b>	<b>7,951</b>	<b>7,972</b>

<b>EQUITY AND LIABILITIES</b>		
Capital stock	17	17
Reserves	1,330	1,305
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>1,347</b>	<b>1,321</b>
<b>Non-current liabilities</b>		
Employee benefit liability	293	288
Deferred tax	918	970
Provisions	57	60
Deferred revenue and other non current liabilities	7	7
Financial institutions	4,286	4,275
<b>TOTAL NON-CURRENT LIABILITIES</b>	<b>5,561</b>	<b>5,600</b>
<b>Current liabilities</b>		
Financial institutions	249	238
Trade payables	256	265
Income tax payable	88	50
Provisions	220	209
Other payables	130	204
Deferred revenue-	98	85
<b>TOTAL CURRENT LIABILITIES</b>	<b>1,043</b>	<b>1,051</b>
<b>TOTAL LIABILITIES</b>	<b>6,605</b>	<b>6,651</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>7,951</b>	<b>7,972</b>

## Cash Flow

	Q1 2009 (€m)	Q1 2008 (€m)
<b>Cash flow from operating activities</b>		
Operating profit	130.9	83.0
<b>Adjustments to reconcile operating profit to net cash flows:</b>		
<b>Non cash</b>		
Depreciation and impairment of property, plant and equipment	20.2	20.3
Amortisation and impairment of intangible assets	150.9	195.3
Movements in provisions, pensions, and other liabilities	6.4	48.5
Other non cash adjustments	(0.6)	(3.8)
Change in working capital	(40.8)	2.4
Income taxes received (paid)	(33.3)	(23.3)
<b>Net cash flow from operating activities</b>	<b>233.8</b>	<b>322.5</b>
<b>Cash flow from investing activities</b>		
Acquisition of subsidiaries <sup>1,2</sup>	(6.4)	(228.1)
Purchase of intangible assets	(16.6)	(16.5)
Proceeds from sale of intangible assets	1.9	0.0
Purchase of property, plant and equipment	(8.6)	(11.8)
Proceeds from sale of tangible assets	0.8	0.0
Purchase of other investments	(0.0)	0.0
<b>Net cash flow from investing activities</b>	<b>(28.9)</b>	<b>(256.4)</b>
<b>Cash flow from financing activities</b>		
Repayment of financial institutions	0.0	(62.5)
Repayment of other borrowings	(0.5)	0.0
Acquisition of own shares from minority holders	(2.8)	0.0
Buyback of debt	(59.4)	0.0
Financial income received	4.2	0.0
Financial expenses paid	(82.4)	(85.0)
<b>Net cash flow from financing activities</b>	<b>(140.9)</b>	<b>(147.5)</b>
<b>Net cash flow</b>	<b>64.0</b>	<b>(81.4)</b>
Cash as of 1 January	496.7	484.2
Currency translation adjustments	(0.5)	0.0
<b>Cash as of 31 March</b>	<b>560.2</b>	<b>402.9</b>

1) Acquisitions of 50.0% Nycomed Madaus (Pty) Ltd [South Africa] in 2009

2) Acquisition Bradley Pharmaceuticals Inc. [United States] in 2008

## Notes

In this report, references to “we”, “us”, “our”, “Nycomed” and “the Nycomed Group” are to Nycomed S.C.A. SICAR and its consolidated subsidiaries and affiliates, and with respect to periods prior to the acquisition of Altana Pharma AG, these terms refer to the proforma financial figures for Nycomed S.C.A. SICAR and its consolidated subsidiaries and affiliates. This discussion should be read in conjunction with the audited consolidated financial statement of Nycomed S.C.A. SICAR as of and for the twelve months ended 31 December 2008.

### Comparability of results

For comparative reasons, we have re-stated income statement and cash flow statement for the first quarter 2008 (January through March).

### Forward-looking statements

The forward-looking statements in this report reflect management’s expectations of future events based on the information presently available to us and must be viewed in the context of the business environments, currency markets and regulatory developments which may cause actual results to deviate materially from those projected by Nycomed. For further information on factors which may cause deviations, please see website: [www.nycomed.com](http://www.nycomed.com)

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