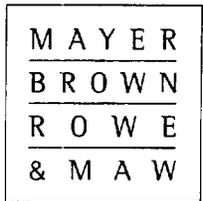


RECEIVED

2004 OCT 27 P 2:32

OFFICE OF INTERNATIONAL  
CORPORATE FINANCE



October 26, 2004

Office of International Corporate Finance  
Securities and Exchange Commission  
450 Fifth Street, NW  
Washington, DC 20549



Mayer, Brown, Rowe & Maw LLP  
1675 Broadway  
New York, New York 10019-5820

Main Tel (212) 506-2500  
Main Fax (212) 262-1910  
www.mayerbrownrowe.com

**Sharon N. Purcell**  
Direct Tel (212) 506-2604  
Direct Fax (212) 849-5604  
spurcell@mayerbrownrowe.com

Re: Schwarz Pharma AG (File No. 82-4406)

SUPPL

By UPS

Dear Sir or Madam:

Enclosed herewith is the following document, furnished on behalf of Schwarz Pharma AG (File No. 82-4406) (the "Company"), pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934:

- 1. Nine Months Report, dated October 25, 2004.

This information is being furnished under paragraph (b)(1)(iii) of Rule 12g3-2, with the understanding that such information will not be deemed "filed" with the SEC or otherwise subject to the liabilities of Section 18 of the Exchange Act, and that neither this letter nor the furnishing of such documents and information shall constitute an admission for any purpose that the Company is subject to the Securities Exchange Act of 1934.

Please do not hesitate to contact me at 212-506-2604 in connection with this matter. Thank you for your assistance.

Sincerely,

*Sharon Purcell*  
Sharon N. Purcell

Encl

cc: Sylvia Heitzer  
Schwarz Pharma AG  
Philip O. Brandes  
Reb D. Wheeler

PROCESSED Se  
NOV 01 2004  
INTERNATIONAL  
FINANCIAL

*Sharon Purcell*  
10/28

17255594

Brussels Charlotte Chicago Cologne Frankfurt Houston London Los Angeles Manchester New York Palo Alto Paris Washington, D.C.  
Independent Mexico City Correspondent: Jauregui, Navarrete, Nader y Rojas, S.C.

Mayer, Brown, Rowe & Maw LLP operates in combination with our associated English limited liability partnership in the offices listed above.

## Nine Months Report 2004

RECEIVED

2004 OCT 27 P 2:32

OFFICE OF INTERNATIONAL  
CORPORATE FINANCE

### Important Milestones in Research and Development

- Sales: €711.8 million
- Operating income: €16.3 million, net income: €0.6 million
- Outlook unchanged: Marginally positive net income
- R&D: Neupro<sup>®</sup> - First pipeline project filed for approval

---

**SCHWARZ**  
**P H A R M A**

## Important Milestones in Research & Development

▣ **Sales: €711.8 million**

In the first nine months of 2004, the SCHWARZ PHARMA Group achieved sales of €711.8 million, 43% less than in the previous year. The reason for this decline was the expected decrease in sales of generic omeprazole in the U.S. due to the entry of multiple generic competitors.

▣ **Operating income: €16.3 million; net income: €0.6 million**

In spite of a further and significant increase in research and development expense SCHWARZ PHARMA posted operating income of €16.3 million. Net income totaled €0.6 million and €2.1 million on an adjusted basis.

▣ **Outlook unchanged: Marginally positive net income**

The development of the business is allowing SCHWARZ PHARMA to take advantage of the opportunities from clinical development and to further expand R&D activities. SCHWARZ PHARMA therefore projects R&D expense of significantly more than €170 million for 2004 with a sales volume in excess of € 850 million. Expectations for a marginally positive net income remain unchanged.

▣ **R&D: Rotigotine patch Neupro™ - First pipeline project filed for approval**

Seven projects in the area of neurology and urology are currently being developed by SCHWARZ PHARMA. Neupro™ (rotigotine transdermal system) was the first compound from the innovative development pipeline to be submitted for marketing approval with the U.S. and European regulatory authorities at the end of September 2004. In addition, there was positive news for a number of other development projects. The phase IIb study program with rotigotine for the treatment of Restless Legs Syndrome (RLS) was successfully completed as well as a phase III study for the treatment of patients in advanced stages of Parkinson's disease. Furthermore, the phase IIb trial with lacosamide (harkoseride) for the treatment of epilepsy showed positive results.

### SCHWARZ PHARMA key figures

<i>(US-GAAP; € million)</i>	Jan. - Sept. 2003	Jan. - Sept. 2004	Change in %
Net sales	1,247.7	711.8	-43.0
Research and development expense	96.1	140.7	46.4
Operating result	275.5	16.3	-94.1
Net income	145.8	0.6	-99.6
Cash flow from operating activities	177.1	(5.3)	n.a

**Sales Development January – September 2004:**  
**Sales volume: €712 million**

The SCHWARZ PHARMA Group achieved a sales volume of €711.8 million in the first nine months of 2004. This is 43% less than in the comparable period of 2003. The reason for this

**Breakdown of sales by regions**

USA	44%
Europe	31%
Germany	22%
Asia	3%

decline was the expected substantial decrease in sales of the generic omeprazole in the U.S. due to the entry of multiple generic competitors. After adjustments for currency effects, sales decreased by 40% to €747.1 million.

**USA**

The U.S. business reported sales of €313.8 million after €843.4 million in the previous year (-62.8%). Calculated in U.S. dollars, the sales volume was \$384.4 million, down from \$935.1 million (-58.9%) in the same period of the previous year.

This development is primarily attributable to the expected decrease in sales of generic omeprazole by the U.S. affiliate KUDCo, which fell by 72.7% to €192.5 million (\$235.7 million). The reported sales also include €32.6 million (\$40.0 million) from the partial reversal of provisions in the second quarter of 2004 in connection with the recent changes in the overall omeprazole market in the U.S. The established U.S. business continued on its recovery trend. In September, just prior to a court hearing Teva Pharmaceuticals immediately ceased sales of its generic product for SCHWARZ PHARMA's cardiovascular drug Univasc™ (moexipril). Teva had introduced the generic drug to the U.S. market in May 2003.

The development and launch of new products for the U.S. market is advancing as scheduled. These products convert well-established compounds into new, special formulations or dosage forms, and offer patients an additional benefit. With the market launch of Parcopa™ at the end of September, the third product is already on the U.S. market in addition to the gastrointestinal products GlycoLax™ (polyethylene glycol) and Trilyte™ (polyethylene glycol). Parcopa™ (carbidopa-levodopa orally disintegrating tablets) for the treatment of Parkinson's disease has a unique formulation that dissolves rapidly in the mouth easing the patient's daily therapeutic management. Sales representatives are intensively discussing Parcopa™ with neurologists. This establishes SCHWARZ PHARMA with specialists in advance of launching clinical development projects, especially Neupro™ (rotigotine transdermal system). Additional new product launches in the U.S. market are expected in the coming 18 months.

**Europe**

The situation of the European markets continues to be impacted by drastic governmental interventions on pricing in a number of countries. Overall, European sales declined by 2.5% to €375.4 million. After adjustments for currency effects and product divestitures, sales fell by 1.9% to €376.3 million compared to the previous year. SCHWARZ PHARMA is expanding its European presence with new sales organizations in Switzerland and Austria, in order to

strengthen its existing business and to have its own sales force ready for product expansion with future drugs from its clinical development.

At €154.6 million (-0.2%), sales in Germany remained almost at the previous year's level despite the difficult environment marked by the health care reform. Sales of SCHWARZ PHARMA's actively promoted and patent-protected drugs even grew for the most part at double digit rates. This positive development, bucking the market trend, shows the company's marketing strength.

The remaining European business showed a mixed picture with governmental price interventions as the key negative factor:

in € million	Jan. - Sept. 2004	Change in %	Adjusted* in %
France	39.6	0.7	
Italy	44.8	4.6	
Spain	24.8	-26.0	-21.9
Great Britain	24.1	6.7	4.2
Poland	18.5	-14.2	-8.5
Eastern Europe	17.2	5.3	
License business	40.2	-1.0	-0.6
Production business with third parties	11.8	-13.9	-13.4

\* for product divestitures, currency effects

### Asia

The Asian affiliates of SCHWARZ PHARMA increased their sales contribution by 18.2% to €22.6 million. After adjustments for currency effects, sales increased even by 26.5% to €24.1 million.

## Earnings Development January – September 2004:

Operating income: €16.3 million, net income: €0.6 million

### SCHWARZ PHARMA Group

Income Statement (US-GAAP, € million)	Jan. - Sept. 2003	Jan. - Sept. 2004	Change in %
<b>Net sales</b>	<b>1,247.7</b>	<b>711.8</b>	<b>-43.0</b>
Cost of goods sold	293.2	237.8	-18.9
<b>Gross profit</b>	<b>954.5</b>	<b>473.9</b>	<b>-50.4</b>
Selling, general and administrative expense	411.7	259.1	-37.1
Research and development expense	96.1	140.7	46.4
Amortization of intangible assets	23.3	22.2	-4.9
Impairment expense FAS 144	26.0	0.0	n.s.
Other operating expense	122.0	35.7	-70.7
<b>Operating result</b>	<b>275.5</b>	<b>16.3</b>	<b>-94.1</b>
Financial result	(3.8)	(0.8)	-79.7
Other income	11.5	2.1	-81.5
<b>Income before income taxes and minority interest</b>	<b>283.2</b>	<b>17.7</b>	<b>-93.8</b>
Taxes on income	137.4	16.9	-87.7
Minority interest	(0.0)	(0.1)	>100
<b>Net income</b>	<b>145.8</b>	<b>0.6</b>	<b>-99.6</b>
Earnings per share in €*	3.24	0.01	
EBITDA (excluding one-time effects)	345.8	76.2	-78.0
EBIT (excluding one-time effects)	306.0	37.4	-87.8
<b>Number of shares</b>			
*Annual average, million units	44.949	45.419	1.0
Annual average, diluted, million units	46.183	45.934	-0.5
Basis, 30.9., million units	45.348	45.485	0.3

In the first nine months of 2004 SCHWARZ PHARMA achieved a gross profit of €473.9 million, 50.4% less than in the same period of 2003. The reasons for this were primarily the decline in the omeprazole business due to the entry of multiple generic competitors, as well as the generic competition to Univasc in the USA. In addition, governmental intervention in Europe, such as the state-mandated rebate of 16% in Germany, had a negative impact on gross profit.

Selling, general and administrative expense declined by 37.1% to €259.1 million. The main reasons were lower licensing fees and profit shares associated with generic omeprazole in the U.S., and the cost reductions from restructuring measures in Germany.

Research and development expense increased significantly by 46.4% to €140.7 million as a result of the progression of the projects. This item also includes the up-front payments to AmorePacific Corp., Korea for the compound PAC20030, which was acquired in February 2004 for the treatment of pain conditions, and the payments to Lipocine Inc., USA for the

marketing rights for an innovative formulation technology purchased in May 2004. For further details on our development projects, please refer to page 12 of this report.

Amortization of intangible assets decreased by 4.9% to €22.2 million.

Other operating expense totaled €35.7 million, down from €122.0 million. The main reason for this decline was significantly lower profit shares associated with generic omeprazole. This item also includes the expense for the settlement of the legal disputes between the U.S. affiliate KUDCo and Mylan Pharmaceuticals Inc. and Esteve Quimica S.A. in June of the current fiscal year.

Operating income declined from €275.5 million to €16.3 million. This significant change is primarily attributable to the competitive situation associated with generic omeprazole in the U.S. and the major increase in research and development expense.

Due to a decreased use of debt, SCHWARZ PHARMA was able to achieve an almost breakeven financial result of €-0.8 million compared to €-3.8 million in the previous year. Other income decreased from €11.5 million to €2.1 million. In 2004, income from currency hedges was not repeated to the same degree as in 2003.

Income before taxes declined to €17.7 million, down from €283.2 million in the previous year. Taxes on income decreased to €16.9 million, compared to €137.4 million in 2003. The significantly higher tax rate of 95.9% is attributable to the fact that profits were achieved in countries with high tax rates while losses incurred in countries with relatively low tax rates. At the same time, non-deductible selling expense, especially in some European countries, has a correspondingly stronger negative effect if only marginal profits are attained.

Consequently, net income was €0.6 million, compared to €145.8 million in the same period of the previous year. Corresponding earnings per share were €0.01. Without the effects from the reversal of provisions for omeprazole and the settlement of legal disputes, a net income of €2.1 million (€0.04 per share) was obtained.

In the first nine months of the 2004 fiscal year there was an average of 45.4 million shares outstanding. As of September 30, 2004, there were 45.5 million outstanding shares. Taking granted stock options into account, the diluted average number of shares was 45.9 million.

## Reporting by Operating Segments

<b>SCHWARZ PHARMA AG und Tochtergesellschaften</b>			
<b>Segment Reporting</b> <i>(US-GAAP, € million)</i>	Jan. - Sept. 2003	Jan. - Sept. 2004	Change in %
<b>Net sales</b>			
Europe	416.8	406.4	-2.5
USA/Asia	862.5	336.4	-61.0
Biosciences	0.0	0.0	
Holding	37.4	37.6	0.5
Inter-segment elimination	(69.0)	(68.6)	-0.5
<b>Net sales</b>	<b>1,247.7</b>	<b>711.8</b>	<b>-43.0</b>
<b>Operating income</b>			
Europe	48.1	49.6	3.2
USA/Asia	302.3	49.0	-83.8
Biosciences	(56.1)	(68.6)	22.2
Holding	4.3	4.7	9.2
Inter-segment elimination	(2.3)	(0.2)	-89.6
	296.2	34.5	-88.4
Unallocated corporate expenses	(20.7)	(18.2)	-12.3
<b>Operating income</b>	<b>275.5</b>	<b>16.3</b>	<b>-94.1</b>
	Dec. 31 2003	Sept. 31 2004	Change in %
<b>Long-lived assets</b>			
Europe	182.6	181.4	-0.7
USA/Asia	141.3	133.4	-5.6
Biosciences	8.1	9.0	10.6
Holding	59.3	45.4	-23.5
	391.3	369.2	-5.7
Unallocated long-lived-assets	10.0	10.2	1.7
<b>Long-lived assets</b>	<b>401.4</b>	<b>379.4</b>	<b>-5.5</b>

Sales of the operating segments were already discussed in the section on sales development. The slight increase of operating income in Europe by 3.2% to €49.6 million is mainly attributable to the restructuring measures in Germany. In the USA/Asia region, operating income decreased by 84% to €49.0 million, primarily due to the declining business with generic omeprazole. The rise in the operating loss in the Biosciences segment by 22% to €68.6 million reflects the significant increase in research and development expense as a result of the progression of the projects.

**Statement of Cash Flows and Balance Sheet:**  
**Net Cash Position €87.0 million, Equity Ratio 57%**

**SCHWARZ PHARMA Group**

<b>Cash Flow Statement</b> <i>(US-GAAP, € million)</i>	Jan. - Sept. 2003	Jan. - Sept. 2004	Change in %
Cash Flow (used in)/from operating activities	177.1	(5.3)	n.a.
Cash Flow (used in)/from investing activities	(1.4)	(17.7)	>100
Cash Flow (used in)/from financing activities	(75.5)	(33.2)	-56.0
Effects of exchange rates	(20.1)	4.4	n.a.
<b>Changes in cash and cash equivalents</b>	<b>80.1</b>	<b>(51.9)</b>	
Cash and cash equivalents at beginning of period	161.3	207.7	28.8
<b>Cash and cash equivalents at end of period</b>	<b>241.4</b>	<b>155.8</b>	-35.5
<b>Balance sheet</b> <i>(US-GAAP, € million)</i>	Dec. 31 2003	Sept. 30 2004	Change in %
<b>Current assets</b>			
Cash and cash equivalents	207.7	155.8	-25.0
Marketable securities	4.9	0.0	-100.0
Accounts receivable, less allowances	162.3	191.5	18.0
Inventories	115.8	98.4	-15.0
Other current assets	67.2	76.2	13.4
<b>Total current assets</b>	<b>557.9</b>	<b>521.9</b>	<b>-6.5</b>
Property, plant and equipment	161.0	155.9	-3.2
Goodwill and other intangible assets	214.0	198.3	-7.3
Long-term investments and other assets	100.6	116.4	15.7
	<b>1,033.6</b>	<b>992.5</b>	<b>-4.0</b>
<b>Liabilities</b>			
Short-term debt and current portion of long-term debt	13.7	21.3	55.3
Other current liabilities	271.0	283.4	4.6
<b>Total current short-term liabilities</b>	<b>284.7</b>	<b>304.6</b>	<b>7.0</b>
Long-term debt	63.2	47.4	-24.9
Pension and other non-current liabilities	108.7	79.9	-26.5
Shareholder's equity	577.0	560.6	-2.9
	<b>1,033.6</b>	<b>992.5</b>	<b>-4.0</b>
Number of employees (on the relevant date)	3,794.0	3,817	0.6

In the first nine months of the 2004 fiscal year cash flow used by operating activities was €5.3 million compared to a cash inflow of €177.1 million in the previous year. The cash outflow was mainly due to lower sales of the generic omeprazole and payments by the U.S. affiliate KUDCo to Mylan and Esteve in connection with the settlement of legal disputes.

Cash outflow from investing activities was €17.7 million, compared to €1.4 million in the first nine months of the previous year. SCHWARZ PHARMA had capital expenditures of €10.7 million for tangible assets such as the expansion of the production sites in Zwickau, Germany,

and in Shannon, Ireland. Investments in intangible assets and financial investments in the amount of €13.3 million primarily related to the acquisition of the rights for a new formulation technology of Lipocine Inc. and the repurchase of the distribution rights for the Swiss market. This cash outflow was offset by an inflow from the disposal of marketable securities as well as product rights in the amount of €6.2 million.

Cash flow used for financing activities was €33.2 million, compared to €75.5 million in the same period of the previous year. The largest item was the dividend payment of €27.2 million on May 27, 2004. Long-term debt decreased by 24.9% to €47.4 million. This decrease is partly attributable to repayments and partly to the reclassification of a loan, due in the next 12 months, to short-term liabilities. Cash and cash equivalents decreased by 25% to €155.8 million by September 30, 2004, as compared to December 31, 2003. Overall, the net cash position was €87.1 million as of the end of September 2004.

Shareholder's equity decreased by 2.9% to €560.6 million. At 56.5%, the equity ratio increased compared to the December 31, 2003 level of 55.8%. Total equity and liabilities decreased by 4.0% to €992.5 million as of September 30, 2004.

As of September 30, 2004, the number of employees of the SCHWARZ PHARMA Group worldwide was 3,817. While the health care reform led to a cut of 170 jobs in Germany at the end of the 2003 fiscal year, primarily in the fields of sales and administration, new employees were hired for research & development, especially in the USA.

### Development of shareholders' equity

#### SCHWARZ PHARMA Group

<i>(US-GAAP, € million)</i>	Jan. - Sept. 2003	Jan. - Sept. 2004	Change in %
<b>Balances as of January 1</b>	<b>530.4</b>	<b>577.0</b>	<b>8.8</b>
Net income	145.8	0.6	-99.6
Dividende to shareholders	(26.8)	(27.2)	1.5
Conversion Stock Option Program	8.7	2.1	-75.4
Sell treasury shares	0.2	0.0	-100.0
Other comprehensive income	(0.9)	(2.3)	>100
Currency translation	(39.6)	10.3	n.a.
<b>Balances as of September 30</b>	<b>617.7</b>	<b>560.6</b>	<b>-9.3</b>

## The third quarter of 2004

### SCHWARZ PHARMA Group

Income Statement (US-GAAP, € million)	July - Sept. 2003	July - Sept. 2004	Change in %
<b>Net sales</b>	<b>269.6</b>	<b>221.4</b>	<b>-17.9</b>
Cost of goods sold	82.3	80.3	-2.4
Gross profit	187.3	141.0	-24.7
Selling, general and administrative expense	115.6	86.2	-25.5
Research and development expense	30.9	43.8	41.7
Amortization of intangible assets	7.5	7.4	-1.4
Impairment expense FAS 144	(0.2)	0.0	-100.0
Other operating expense	(17.6)	4.1	n.a.
<b>Operating result</b>	<b>-15.9</b>	<b>7.7</b>	<b>-51.3</b>
Financial result	(1.1)	(0.5)	-52.5
Other income	(6.2)	(0.5)	-92.3
<b>Income before income taxes and minority interest</b>	<b>8.6</b>	<b>6.7</b>	<b>-21.5</b>
Taxes on income	6.0	4.8	-19.4
Minority interest	(0.0)	(0.1)	>100
<b>Net income</b>	<b>2.5</b>	<b>1.8</b>	<b>-26.1</b>
Earnings per share in €	0.06	0.04	

Cash Flow Statement (US-GAAP, € million)	July - Sept. 2003	July - Sept. 2004	Change in %
Cash Flow (used in)/from operating activities	98.2	19.8	-79.8
Cash Flow (used in)/from investing activities	(4.8)	(5.1)	6.2
Cash Flow (used in)/from financing activities	8.9	3.9	-56.4
Effects of exchange rates	(10.5)	(1.6)	-84.5
<b>Changes in cash and cash equivalents</b>	<b>91.8</b>	<b>17.0</b>	
Cash and cash equivalents at beginning of period	149.6	138.8	-7.2
<b>Cash and cash equivalents at end of period</b>	<b>241.4</b>	<b>155.8</b>	<b>-35.5</b>

During the quarter from July to September 2004, sales of the SCHWARZ PHARMA Group fell by 17.9% to €221.4 million as compared to the same period of the previous year. In constant currencies, the decline would have been 15.0%. While the new introductions Glycolax™ and Trilyte™ already contributed positively to sales, Parcopa™ had not yet had a considerable effect, because the drug was launched end of September. The generic competitor for the cardiovascular drug Univasc (moexipril) continued to have a negative impact on sales, because Teva only ceased sales of their product in the U.S. in September.

Gross profit fell by 24.7% to €141.0 million, which corresponds to a gross margin of 63.9%. Selling, general and administrative expense declined by 25.5% to €86.2 million. The main

reasons were lower licensing fees and profit shares associated with generic omeprazole in the U.S., and the cost reductions from restructuring measures in Germany.

Due to the continued progress of the development projects, SCHWARZ PHARMA again increased its research and development expense in the third quarter by 41.7% to €43.8 million as compared to the same period of the previous year.

Amortization of intangible assets decreased slightly to €7.4 million (-1.4%) and thus remained almost at the previous year's level. Other operating income totaled €4.1 million as compared to other operating expense of €17.6 million in the previous year. The reasons were lower profit shares associated with generic omeprazole and income from milestone payments for Neupro™.

Accordingly, operating result declined by 51.3% to €7.7 million in the third quarter of 2004.

The improved financial result in the amount of €-0.5 million after €-1.1 million in the same quarter of the previous year results from the reduced use of debt. The significant reduction of other expense from €6.2 million in the previous year to €0.5 million is primarily the consequence of the decline in losses from currency hedging transactions.

Income before taxes decreased from €8.6 million to €6.7 million. Taxes on income totaled €4.8 million. As a consequence, net income decreased by 26.1% to €1.8 million in the third quarter of 2004. Corresponding earnings per share were €0.04.

### **Outlook unchanged: Marginally positive net income**

SCHWARZ PHARMA has made significant progress towards the goal of making its clinical development projects ready for launch. With Neupro™ (rotigotine transdermal system) the first compound in the innovative development pipeline of SCHWARZ PHARMA was submitted for marketing approval at the U.S. and European regulatory authorities. In addition, there was positive news for a number of development projects: The phase IIb study program with rotigotine for the treatment of Restless Legs Syndrome (RLS) was successfully completed as well as a phase III study for the treatment of patients with advanced stage Parkinson's disease. Furthermore, the phase IIb trial with lacosamide (harkoseride) for the treatment of epilepsy showed positive results.

The development of the business is allowing SCHWARZ PHARMA to take advantage of the opportunities from clinical development and to further expand R&D activities. SCHWARZ PHARMA therefore projects R&D expense of significantly more than €170 million for 2004 with a sales volume in excess of € 850 million. Expectations for a marginally positive net income remain unchanged.

## **R&D: Rotigotine patch Neupro™ filed for marketing approval**

There are currently seven projects in clinical development: In the field of neurology, the projects include compounds for the treatment of Parkinson's disease, Restless Legs Syndrome, epilepsy and neuropathic pain. In the area of urology, compounds are being developed for the treatment of overactive bladder syndrome (OAB)/urinary incontinence and benign prostate hyperplasia (BPH). The third quarter was characterized by positive news for a number of development projects.

The highlight was the submission of the applications for marketing approval for Neupro™ (rotigotine transdermal system) for the treatment of early stage Parkinson's disease to the U.S. and European regulatory authorities at the end of September. Neupro™ with the active ingredient rotigotine is a new dopamine receptor agonist and will be applied once a day to the skin as a transdermal patch. The compound is released continuously over 24 hours via the skin. Overall, 15 multinational clinical studies with more than 1,500 patients in early stages of Parkinson's disease were completed. This is the first filing for marketing approval of a new compound from the innovative development pipeline of SCHWARZ PHARMA.

The results of the double blind, placebo-controlled phase III study in the U.S. with Neupro™ suggest that the patch is also suitable for the treatment advanced stage Parkinson's disease as a combination therapy. The study results demonstrated a statistically and clinically significant reduction in symptoms and a good tolerability and safety of the patch. 99% of the patients, who completed the trial continued on Neupro™ in an open-label extension study. The most common adverse events are application site reactions, somnolence, nausea and dizziness. These were not unexpected and are commonly seen with dopamine agonists and transdermal delivery systems. The results of the European phase III study, which started in the second quarter of 2004 with a total of 470 patients, are scheduled for the beginning of 2006. Furthermore, the active compound in rotigotine is being tested in the first clinical stage, phase I, as a nasal spray for the acute treatment of Parkinson's symptoms.

Rotigotine is also being developed for the treatment of the Restless Legs Syndrome. Phase II with a dose range finding trial was successfully completed in July. SCHWARZ PHARMA is currently in the process of preparing the study program of the last phase of clinical development which will begin in the spring of 2005.

The future name of harkoseride will be lacosamide. The new compound name was assigned by the World Health Organization (WHO). The phase IIb study for the treatment of epilepsy was concluded successfully. The results of this multinational, double blind and placebo-controlled study with lacosamide demonstrated a statistically and clinically significant reduction of epileptic seizures with very good tolerability. SCHWARZ PHARMA has already been testing lacosamide for epilepsy in clinical phase III since May 2004. Lacosamide is currently also being developed in phase III for the treatment of the chronic pain condition caused by diabetic neuropathy. The first results should be available in the fourth quarter of 2005.

---

Fesoterodine for the treatment of OAB/urinary incontinence is currently undergoing clinical phase III trials with over 2,000 patients in the U.S. and Europe. First results should be available in the 2nd quarter of 2005. Results of the phase II program with pamirosin (SPM969) to treat benign prostate hyperplasia (BPH) shall be available at the end of 2005.

---

### **Financial Calendar:**

February 22, 2005	Preliminary Annual Report 2004, Analyst's and Press conference
April 27, 2005	1 <sup>st</sup> Quarter Report 2005
May 11, 2005	Annual Meeting of Shareholders
July 26, 2005	Half Year Report 2005
October 10, 2005	Nine Months Report 2005

This third quarter report, our annual report and additional information are available on the Internet at: [www.schwarzpharma.com](http://www.schwarzpharma.com)

SCHWARZ PHARMA AG, Alfred-Nobel-Straße 10, 40789 Monheim

Phone : +49 2173 48 0, Fax : +49 2173 48 1608

Email [info@schwarzpharma.com](mailto:info@schwarzpharma.com)

#### Corporate Communications

Antje Witte

Phone +49 2173 48 1866

Email [antje.witte@schwarzpharma.com](mailto:antje.witte@schwarzpharma.com)

Bettina Hoerstke

Phone +49 2173 48 2329

E-mail [bettina.hoerstke@schwarzpharma.com](mailto:bettina.hoerstke@schwarzpharma.com)

#### **Measurement and Accounting Standards**

Just as the annual financial statements, the quarterly reports of SCHWARZ PHARMA AG and subsidiaries are also prepared pursuant to US-GAAP and in accordance with the standards of the Financial Accounting Standards Board (FASB). The same accounting standards were applied as for the 2003 consolidated financial statements. The notes to the financial statements in the consolidated annual report thus apply correspondingly. This interim report by SCHWARZ PHARMA AG and its subsidiaries complies with the rules in APB 28, "Interim Financial Reporting". The interim report's scope of consolidation comprises 34 fully-consolidated subsidiaries.

This report is not certified. The report contains forward-looking statements based on current plans, estimates and beliefs of the management of SCHWARZ PHARMA AG. These forward-looking statements are subject to various risks and uncertainties that may cause actual results to differ materially from those expressed or implied by such forward-looking statements. Risks and uncertainties that could cause a material difference in future results include changes in business, economic and competitive conditions, regulatory reforms, foreign exchange rate fluctuations, uncertainties in litigation or investigative proceedings and the availability of financing. The Company does not undertake any responsibility to update the forward-looking statements contained in this press release.