# Oasmia Pharmaceutical AB (publ)

INTERIM REPORT FOR THE PERIOD May 1 2008 - January 31 2009

## THE PERIOD IN BRIEF May 2008 - January 2009

- Net sales for the period amounted to TSEK 70 536 (TSEK 53 224)<sup>1</sup>
- Operating income amounted to TSEK 6 160 (TSEK -4 822)
- Income for the period amounted to TSEK 5 997 (TSEK -4 937)
- Earnings per share amounted to SEK 0,18 (SEK -0,15)

## The third quarter November 2008 – January 2009

- Net sales for the Group amounted to TSEK 10 750 (TSEK 31 718)
- Operating income amounted to TSEK -10 833 (TSEK 11 632)
- Income for the period amounted to TSEK -11 089 (TSEK 11 866)
- Earnings per share amounted to SEK -0,33 (SEK 0,36)

<sup>&</sup>lt;sup>1</sup> The numbers in parentheses concerns results for the corresponding period previous year



## KEY EVENTS DURING THE PERIOD

## OASMIA HUMAN HEALTH

In January 2009 the final results of the first study in humans with Paclical® were presented. The maximum tolerable dose for the product candidate was established to be 250 mg/m². In total 34 patients with advanced cancer disease were treated. In the Phase I/II study on solid tumours, which was carried out in Sweden during 2007, both men and women were treated with Paclical®. Paclical® as given in three cycles with three weeks interval between each treatment. The starting dose was low, 90 mg/m², and was increased successively to the highest level of 275 mg/m². The side-effects that occurred suggested that the latter dose was too high. No hypersensitivity reactions occurred as expected. Doses up to 250 mg/m² was tolerated by most patients. The observed side-effects were effects related to paclitaxel, which Paclical® contains. The cancer diseases were stabilized in about half of the patients who were treated with three cycles, which must be considered a very promising result with respect to the serious condition of the patients. Paclical® will be administered with the dose 250 mg/m² in six cycles. This must be compared to Taxol® which is administered in six cycles at a dose level of 175 mg/m² in six cycles.

The work on the Phase III study on ovarian cancer with the pharmaceutical candidate Paclical® has continued in the period. Participating hospitals have been identified and on September 13 an investigator's meeting was held in Uppsala, where representatives for the majority of all clinics participated. Regulatory and ethical approvals have been obtained from the participating countries. Apart from this the company is performing a pharmacokinetic study on the pharmaceutical Paclical®. In the study Paclical® is compared to the well-known pharmaceutical Taxol®. Paclical® and Taxol® has the same active substance (paclitaxel) and the study investigates whether paclitaxel behaves in the same was in both Taxol® and Paclical®. This study is estimated to be concluded during 2009.

### OASMIA ANIMAL HEALTH

As a consequence of an European approval of a new name in the end of 2008, Oasmia changes the product name from Paclical® Vet to Paccal® Vet. The purpose is to use the same name globally. An application of change of name has been approved in the USA.

The centre for veterinary medicine at the American Food and Drug administration (FDA) granted Oasmia Expedited Review Status (ERS) on December 10, 2008 for the product Paccal® Vet. ERS is granted for products which are classified as especially important advances in veterinary medicine and entails a halved audit time compared to products without ERS. ERS is reserved only for products which are indicated for life-threatening or seriously debilitating diseases that today have no approved treatment.

Two clinical studies on dogs with Oasmia's product candidate Paccal® Vet has been completed. In the first Phase I/II study on different forms of severe cancer in dogs a response rate of 74% was observed. In the following Phase III study on mastocytoma grade II and III a response rate of 70% was observed. No unexpected side-effects were visible in any of the studies.

### EXTRAORDINARY GENERAL MEETING

At the extraordinary general meeting on January 30, 2009 the Board's proposal of guidelines for establishment of salaries and other remuneration for the Chief Executive Officer and other senior managers was adopted. The guidelines concerns the time from the Annual General Meeting 2008 to the Annual General Meeting 2009. The guidelines can be read in their entirety on www.oasmia.se where also a communiqué from the Annual General Meeting 2008 is available.

### OASMIA CHANGES MARKETPLACE

The work with the previously initiated process of stock list change from NGM Equity to NASDAQ OMX has continued in the period. The reasons for the change of list is that Oasmia considers NASDAQ OMX to be a more suitable marketplace for the company shares, to increase interest in the company, reach an increased liquidity and an more effective pricing of the share and to attract new categories of shareholders.



## MARKET MAKER AND FINANCIAL ADVISOR

Oasmia has appointed E. Öhman J:or Fondkommission AB as market maker concerning Oasmia's share, which is listed on NGM Equity. The purpose is to reduce the difference in buy and sales price and to increase the liquidity of the share. The commitment began on December 1, 2008 and will at first concern trade on NGM Equity and, in case a change of stock list occurs to NASDAQ OMX during the agreed term, on NASDAQ OMX. Oasmia has also appointed Öhman as financial advisor in connection to the move to NASDAQ OMX and a collaboration on capital market activities has been initiated in order to increase the reach of the company information to shareholders and other interested parties.

### LICENSE AND DISTRIBUTION AGREEMENT

In the end of June 2008 Oasmia expanded the license and distribution agreement with Orion Corporation for the product Paccal® Vet which was closed in March 2008. The previous agreement only comprised the Nordic Countries and a few other European countries, at a value of 2 million Euro. The expanded agreement comprises the major part of Europe. Oasmia receives another 8 million Euro, 3.25 million at the close of the agreement, which is accounted for as revenue in the first quarter of the fiscal year. Altogether the agreement with Orion Corporation for Paccal® Vet amounts to 10 million Euro. Oasmia will thus receive another 6 million Euro when the company fulfils certain other criteria in the agreements. Furthermore Oasmia will receive royalties on all sales in the region. Orion receives sales and marketing rights to the product in Europe.

## ANNUAL GENERAL MEETING

The Annual General Meeting on September 11 2008 decided to adopt the proposal of the Board of Directors for a private placement. After the implementation in October 2008 the share capital was increased with SEK 12 500 to a total of SEK 3 350 000 and the number of shares increased with 125 000 to 33 500 000.

## KEY EVENTS AFTER THE CLOSE OF THE PERIOD

## LARGE SUPPORT FOR PHASE III STUDY

Oasmias on-going international Phase III study on Paclical® has generated a large interest and commitment among participating physicians in Europe. The study comprises 75 cancer clinics in 17 different countries. Altogether 650 women with ovarian cancer will participate in the study and the first patients have started treatment. Paclical® is compared to the well-known pharmaceutical Taxol® in the study. The results of the two treatments will be compared with respect to effects and side-effects. Half of the women will be treated with Paclical® and half with Taxol®. Both Paclical® and Taxol® is given in combination with carboplatin which is another cytostatic and part of the standard treatment for ovarian cancer today. The goal of the study is to show better effect on the tumour disease and a lessened risk of side-effects, especially hypersensitivity reactions. Paclical® is therefore given in a higher dose than Taxol®. The patients are treated in six cycles and are followed up in six months. Recruitment of patients are expected to be concluded in 2009. Paclical® has many advantages compared to Taxol®, most importantly is the excipient Cremophor EL which is known to cause serious side effects not present. The need for an improved treatment and quality of life for this group of patients is very high. Paclical has previously been granted Orphan Drug designation by the European Medicines Agency, EMEA. An Orphan Drug designation entails market exclusivity for 10 years after market approval has been obtained for the pharmaceutical candidate.

## OASMIA AIMS FOR WORLD-WIDE REGISTRATION OF PACCAL® VET

Oasmia are currently conducting a clinical study on mast cell tumours in dogs. The study will form the foundation of an application for registration of the first cytotoxic pharmaceutical ever on the veterinary market. The study has been approved by both the FDA and EMEA (EU). FDA has also committed themselves to process Oasmia's application with priority, so called Expedited Review, which leads to a much faster approval process. Today, about 40 % of the dogs which are planned to be enrolled in the study have already been included. Results form the study are planned to be reported during the second half of 2009. In the study participates 19 larger clinics in the US and 7 in Europe, both university and private clinics which all have specialized in treatment of cancer. The interest among cancer specialists, including a number of world leading specialists in mast cell tumours, to par-



ticipate in the study has been very large. The study is comparing response to treatment with Paccal® Vet and CCNU (Lomustine).

## **BUSINESS ACTIVITIES**

### **GENERAL**

The main business activity of Oasmia is the development of novel, patented formulations of existing pharmaceuticals and thereby improve and create new therapy opportunities. The company focuses on human and veterinary oncology. The product furthest in development is Paclical® Vet for treatment of cancer in dogs. The pharmaceutical contains paclitaxel which is one of the most effective cytostatics that exists today. Paclical® Vet has shown a reduction of side-effects and has been given in higher doses than existing pharmaceuticals based on the same active substance (paclitaxel). A Phase III study for treatment of ovarian cancer has been initiated with Paclical® for human use.

Oasmia owns 100% of the subsidiary Qdoxx Pharma AB. The main business activity of the subsidiary is parallel import of pharmaceutical products. The business idea behind Qdoxx Pharma is by parallel import supply high-quality and price worthy pharmaceutical products for the Swedish market. Oasmia also owns 51 % of the company GlucoGene Pharma AB, which is a research company that develops xylosides for use in cancer treatment. Oasmia has at present 56 employees, all located at the company office, research and production facility in Uppsala. During the rapid expansion since 2006, a large number of new recruitments have been made which have strengthened the company's research and production capacity. Oasmia continues to recruit personnel in an effort to strengthen all parts of the business. One change in the company organization have been made as a new management group has been formed that acts as link between the Board of Directors and the department managers. This management group consists as of February 1 2009 of Julian Aleksov (Chief Executive Officer), Hans Sundin (Executive Vice President Technical Services), Weine Nejdemo (Chief Financial Officer) and Annette Ljungmark (Head of Accounting and Human Resources).

## RESEARCH AND DEVELOPMENT

The basis for the business activity which Oasmia conducts today is a research project which started in the beginning of the 90s, focused on the ageing of the human cell. The research consisted of among other things studies on the effect of retinoids on the cellular cycle. The research resulted in a new class of retinoids. These formed a molecular complex which had excellent properties to dissolve substances. After another few years of research, a decision was made to commercialize and utilize these these discoveries in the form of new pharmaceuticals. In connection to this the company name Oasmia Pharmaceutical AB was founded in 1999.

The Oasmia research and development is mostly directed towards oncology within human and veterinary medicine, but the company also conducts research in infectious and neurologic diseases as well as asthma. The company research in the natural ageing and death of the cell has formed the platform for the development of novel pharmaceuticals. The first of which is Paclical® where the substance paclitaxel has been made water-soluble by the use of nanoparticles and a new unique excipient. Oasmia's novel platform can be used in combination with a number of different substances in order to improve their profile, safety and effect, especially substances that are hard to solve. This nanotechnology opens up completely new treatment methods within oncology.

## PRODUCT PORTFOLIO

The company product portfolio consists of the pharmaceutical candidates Paclical®, Paccal®, Carbomexx®, Docecal® and Doxophos® and the above mentioned with the suffix "Vet". These products theoretically covers 80 % of the standard treatments available today for the most common types of cancer. Oasmia considers that the company has a complete patent protection on the markets which the company considers to be most important, such as Europe, USA and Japan.

Prioritized events for Oasmia is the international clinical Phase III studies on Paclical® and Paccal® Vet. Docecal®, Doxophos® and Carbomexx® will soon enter Phase I/II. The foundation of Oasmias product portfolio is a group of novel, unique and patented substances. One of these, XR-17, is specifically developed with the ability to form micelles around the active part of the pharmaceutical. XR-17 can be used with a number of different substances



in order to improve their profile and effect, especially insoluble substances. All candidates that today are part of the company product portfolio are based on XR-17.

#### Human Health

Indication and development status

| Product candidate | Active substance | Indication          | Clinical Phase | Period (tentative) | Stage    |
|-------------------|------------------|---------------------|----------------|--------------------|----------|
| Paclical®         | Paclitaxel       | Solid tumours       | 1/11           | 2007               | reported |
| Paclical®         | Paclitaxel       | Ovarian cancer      | III            | 2008/09            | on-going |
| Paclical®         | Paclitaxel       | Malignant melanoma  | III            | 2009               | planned  |
| Paclical®         | Paclitaxel       | NSCLC               | III            | 2010               | planned  |
| Doxophos®         | Doxorubicin      | Breast cancer       | 1/11           | 2010               | planned  |
| Docecal®          | Docetaxel        | NSCLC               | 1/11           | 2010               | planned  |
| Carbomexx®        | Carboplatin      | Combination therapy | 1/11           | 2011               | planned  |

### Animal Health

Indication and development status

| Product candidate | Active substance | Indication     | Clinical Phase | Period (tentative) | Stage    |
|-------------------|------------------|----------------|----------------|--------------------|----------|
| Paccal® Vet       | Paclitaxel       | Solid tumours  | 1/11           | 2007               | reported |
| Paccal® Vet       | Paclitaxel       | Mastocytoma    | III            | 2008               | reported |
| Paccal® Vet       | Paclitaxel       | Mastocytoma    | III            | 2008/09            | on-going |
| Doxophos® Vet     | Doxorubicin      | Lymphoma       | 1/11/111       | 2009               | planned  |
| Docecal® Vet      | Docetaxel        | Mammary tumour | 1/11/111       | 2010               | planned  |
| Carbomexx® Vet    | Carboplatin      | Osteosarcoma   | 1/11           | 2010               | planned  |

## **MARKET**

## Human Health

The global oncology market is estimated to grow twice as fast as the rest of the pharmaceutical sector until the year 2012. It will then be the largest therapeutic area in worth (92 billion USD). The total market for cytostatics, amounts today to about 20 billion USD with an annual growth of 7 %. Paclical® belongs to the group taxanes, which is a subgroup in the market for cytostatics, where pharmaceuticals such as Taxol®, Taxotere® and Abraxane® are also parts. The market size for taxanes was in 2007 about 4.5 billion USD with an annual growth of about 5 %. The cytostatics that have the largest growth are those who have a clear improved treatment results and safety profile. The aim is that patients treated with Paclical® will live longer than patients treated with other therapy choices, connected to a higher dose and more treatment occasions. Nanoparticular taxanes, to which Paclical® belongs, is expected to grow about 20 % each year.

### **Animal Health**

There are about 140 million dogs today in the world's industrially developed countries. The number of dogs are increasing faster than the number of inhabitants. About 40 percent of all dogs will suffer from cancer in their lifetime as a result of an increased age. In the USA it is estimated that there annually are about 500 000 treatable dogs where treatment with cytostatics is an alternative. There is no cytostatic registered for treatment of cancer in dogs today. Therefore has Oasmia's pharmaceutical candidate Paclical® Vet a great opportunity to be the first registered cytostatic for cancer treatment in dogs in the world.

The world market for Paclical® Vet is estimated to 500 – 700 million USD. Within the market for cytostatics there are today no known on-going studies with cytostatics for dogs, and Oasmia thinks it will be a market leader for at least three to five years.

## **FINANCING**

An important part of the Oasmia business model is license and distribution agreements with companies which have strong positions on current markets. The company allows the rate in which such agreements are closed affect the scope and speed of clinical trials and thus registration matters. The Board estimates that there are good conditions for more business of this kind relatively shortly. The estimate of the Board of Directors that such business will fill the capital requirements of the company for the time before Oasmia's products are registered and regular deliveries to the marked has begun.



## FINANCIAL INFORMATION

## **Group Income Statement in summary**

|   | 2008/09 | 2007/08 | 2008/09 | 2007/08 | 2007/08   |
|---|---------|---------|---------|---------|-----------|
| TSEK  | Nov-Jan | Nov-Jan | May-Jan | May-Jan | May-April |
| Net sales   | 10 750  | 31 718  | 70 536  | 53 224  | 71 158    |
| Income for the period                               | -11 089 | 11 866  | 5 997   | -4 937  | -5 067    |
| Earnings per share (SEK), before and after dilution | -0,33   | 0,36    | 0,18    | -0,15   | -0,16     |

#### Net sales

Net sales for the Group for the period May 2008 – January 2009 amounted to TSEK 70 536 (TSEK 53 224). Revenue from closing of license and distribution agreements amounted to TSEK 30 347 (TSEK 18 667) Additional net sales consisted mostly of sales of parallel imported pharmaceuticals, which amounted to TSEK 39 725 (TSEK 34 519).

Net sales for the third quarter of the fiscal year amounted to TSEK 10 750 (TSEK 31 718) and consisted mostly of sales of parallel imported pharmaceuticals. The reduction is mostly attributable to the license revenue which was obtained in the corresponding period previous year.

## Capitalized development cost

Capitalized development cost for the period amounted to TSEK 22 513 (TSEK 6 311) and concerns development costs for Phase III studies for the products Paclical® and Paccal® Vet. The increase is a result of intensified Phase III studies.

Capitalized expenditures in the third quarter of the fiscal year amounted to TSEK 9 419 (TSEK 2 660).

Raw materials, consumables and goods for resale

Expenses for the period related to purchase of raw materials, consumables and goods for resale amounted to TSEK -41 133 (TSEK -35 036) and is mostly attributable to the business activity parallel import. Expenses are also attributable to analyses and purchase of raw materials for manufacture of pharmaceuticals within research and development. At the end of the period an impairment of the inventory with TSEK -1 336 was made attributable to the segment Parallel import.

Corresponding expenses for the third quarter of the fiscal year amounted to TSEK -13 777 (TSEK -12 428).

Other external expenses

Other external expenses amounted to TSEK -25 181 (TSEK -14 842). Of these TSEK -12 634 (TSEK - 1 126) are expenses for clinical Phase III studies which have been capitalized as a development expense. Expenses which are not capitalized are mostly attributable to products in development, which are in preclinical phase or Phase I/II. Expenses are also attributable to repairs and service of production equipment, rent and expenses related to the on-going stock list change to NASDAQ OMX.

During the third quarter of the fiscal year other external expenses amounted to TSEK – 9 022 (TSEK –4 705).

## Employee benefit expenses

Employee benefit expenses increase to TSEK –18 472 (TSEK –12 551) during the period. The increase compared to the previous year was caused by an increase of the number of employees with 15 people to a total of 56 employees as of January 31 2009 (41 employees as of January 31 2008).

Employee benefit expenses for the third quarter of the fiscal year amounted to TSEK -7 371 (TSEK -5 010).

## Income for the period

The Group accounts for a positive income for the period May 2008 – January 2009. It amounted to TSEK 5 997 (TSEK -4 937) and is mainly the result of license revenues for the period. The business activity parallel import resulted in a negative operating income of TSEK -648 (TSEK -450).

For the third quarter of the fiscal year the Group accounts for a negative income for the period amounting to TSEK -11 089 (TSEK 11 866), which is mostly attributable to that no license and distribution agreements were closed in the quarter. The business activity parallel import accounts for a negative income for the period amounting to TSEK -2 866 (TSEK 585), which is a result of the recently diminished value of the Swedish currency. On the



Swedish market for parallel imported pharmaceutical a reduction of sales price in the Pharmacies has been also been made. A result of this is that some parts of the inventory of Qdoxx at the end of the quarter will be sold at a loss. Therefore has the inventory at the end of the third quarter been impaired with TSEK – 1 336.

## Financial position

Liquid assets for the Group amounted to TSEK 1 796 (TSEK 11 313) as of January 31. Cash flow from current operations amounted to TSEK 7 684 (TSEK -6 370) for the period and for the third quarter of the fiscal year to TSEK -10 250 (TSEK 11 328). Net cash flow for the period amounted to TSEK - 8 582 (TSEK -10 856) and for the third quarter TSEK -10 169 (TSEK 7 140). Equity amounted to TSEK 74 310 (TSEK 64 942) and as of January 31 2009, the equity/assets ratio was 70 % (76 %).

## Capital expenditures

Capital expenditures for the period amounted to TSEK 25 271 (TSEK 8 606). They mostly consisted of capitalized expenditure for development, TSEK 22 513 (TSEK 6 311), related to the products Paclical® and Paccal® Vet. In addition, smaller investments in other intangible assets were made, concerning patents and sales authorizations, which

amounted to TSEK 420 (TSEK 1 193). Capital expenditures for the period in property, plant and equipment amounted to TSEK 2 338 (TSEK 1 102) and these were mostly related to development of the company production facilities and equipment. Depreciations/amortization for the period amounted to TSEK -2 323 (TSEK -2 010).

## The Parent Company

Net sales for the Parent company amounted to TSEK 30 811 (TSEK 18 706) and income after financial items net amounted to TSEK 6 146 (TSEK -4 187). Liquid assets amounted to TSEK 1 762 (TSEK 11 282) as of January 31, 2009. In December 2008 Oasmia made a Group contribution to Qdoxx amounting to TSEK 1 000, which was accounted for as a share holder contribution and increases the value of Participations in group companies. The purpose of the contribution was to cover negative equity in Qdoxx. Since the business in Qdoxx has been run at a loss during the third quarter of the fiscal year, impairment of Participations in group companies has been made with TSEK 1 000.

## Key ratios and other information

|   | 2008/09 | 2007/08 | 2008/09 | 2007/08 | 2007/08   |
|---|---------|---------|---------|---------|-----------|
|   | Nov-Jan | Nov-Jan | May-Jan | May-Jan | May-April |
| Number of shares at the close of the period (in thousands), before and after dilution | 33 500  | 33 375  | 33 500  | 33 375  | 33 375    |
| Average number of shares (in thousands) before and after dilution                     | 33 500  | 33 375  | 33 421  | 32 365  | 32 613    |
| Earnings per share in SEK, before and after dilution                                  | -0,33   | 0,36    | 0,18    | -0,15   | -0,16     |
| Equity per share, SEK   | 2,22    | 1,94    | 2,22    | 1,94    | 1,94      |
| Equity/assets ratio, %  | 70      | 76      | 70      | 76      | 74        |
| Net liability, TSEK   | 18 220  | 3 714   | 18 220  | 3 714   | 4 109     |
| Debt/Equity ratio, %  | 25      | 6       | 25      | 6       | 6         |
| Return on total assets, %   | -10     | 15      | 7       | -5      | -5        |
| Return on equity, %   | -14     | 20      | 9       | -7      | -8        |
| Number of employees at the end of the period  | 56      | 41      | 56      | 41      | 40        |

## **Definitions**

Earnings per share, before and after dilution: The income for the period attributable to the equity holders of the parent company divided by a weighted average number of shares, before and after dilution.

**Equity per share:** Equity in comparison with the number of shares at the end of the period

Equity/assets ratio: Equity pertaining to the balance sheet total.

Net liability: Total borrowing (containing the balance sheet items Short-term and Long-term borrowings and liabilities to credit institutions) with deductions for liquid funds Debt/Equity ratio: Net liability with respect to equity.

Return on total equity: Income for interest expenses pertaining to the average balance sheet total.

Return on equity: Income after financial items in relation to the average equity.



## **Group Income Statement**

|  |      | 2008/09 | 2007/08 | 2008/09 | 2007/08 | 2007/08   |
|--|------|---------|---------|---------|---------|-----------|
| TSEK   | Note | Nov-Jan | Nov-Jan | May-Jan | May-Jan | May-April |
| Net sales                                      | 2    | 10 750  | 31 718  | 70 536  | 53 224  | 71 158    |
| Capitalized development cost                   |      | 9 419   | 2 660   | 22 513  | 6 311   | 9 675     |
| Other operating income                         |      | -       | 82      | 224     | 82      | 65        |
| Raw material, consumables and goods for resale |      | -13 777 | -12 428 | -41 133 | -35 036 | -45 310   |
| Other external expenses                        |      | -9 022  | -4 705  | -25 181 | -14 842 | -20 187   |
| Employee benefit expenses                      |      | -7 371  | -5 010  | -18 472 | -12 551 | -17 530   |
| Depreciation/amortization and impairment       |      | -828    | -685    | -2 323  | -2 010  | -2 727    |
| Other operating expenses                       |      | -4      | -       | -4      | -       |           |
| Operating income                               |      | -10 833 | 11 632  | 6 160   | -4 822  | -4 855    |
| Financial income                               |      | 364     | 414     | 831     | 416     | 462       |
| Financial expenses                             |      | -619    | -180    | -993    | -532    | -674      |
| Financial items, net                           |      | -256    | 234     | -163    | -116    | -212      |
| Income of financial items                      |      | -11 089 | 11 866  | 5 997   | -4 937  | -5 067    |
| Taxes  | 3    | 0       | 0       | 0       | 0       | 0         |
| Income for the period                          |      | -11 089 | 11 866  | 5 997   | -4 937  | -5 067    |
| Income for the period attributable to:         |      |         |         |         |         |           |
| Equity holders of the Parent company           |      | -11 086 | 11 869  | 6 006   | -4 929  | -5 057    |
| Minority interest in income for the period     |      | -2      | -4      | -9      | -8      | -9        |
| Earnings per share                             |      |         |         |         |         |           |
| Before dilution, SEK                           |      | -0,33   | 0,36    | 0,18    | -0,15   | -0,16     |
| After dilution, SEK                            |      | -0,33   | 0,36    | 0,18    | -0,15   | -0,16     |
| cc. ddroin DER                                 |      | 0,00    | 0,00    | 0,10    | 0,13    | 0,10      |



## **Group Balance Sheet**

| Group Balance Sheet                                       |         |         |          |
|---|---------|---------|----------|
| '   | 2009    | 2008    | 2008     |
| TSEK  | Jan 31  | Jan 31  | April 30 |
| ASSETS  |         |         |          |
| Non-current assets  |         |         |          |
| Property, plant and equipment                             | 19 833  | 19 091  | 19 180   |
| Capitalized development cost                              | 46 672  | 20 795  | 24 159   |
| Other intangible assets                                   | 8 063   | 8 459   | 8 284    |
| Total Non-current assets                                  | 74 568  | 48 346  | 51 624   |
| Current assets  |         |         |          |
| Inventories   | 16 399  | 18 142  | 19 121   |
| Trade receivables   | 11 398  | 4 712   | 4 059    |
| Other current receivables                                 | 914     | 823     | 772      |
| Prepaid expenses and accrued income                       | 1 700   | 1 736   | 1 717    |
| Liquid assets   | 1 796   | 11 313  | 10 379   |
| Total Current assets                                      | 32 207  | 36 726  | 36 048   |
| TOTAL ASSETS  | 106 775 | 85 072  | 87 672   |
| EQUITY  |         |         |          |
| Equity attributed to equity holders in the Parent Company |         |         |          |
| Share capital   | 3 350   | 3 338   | 3 338    |
| Other capital provided                                    | 99 254  | 95 767  | 95 767   |
| Retained earnings   | -28 383 | -34 261 | -34 389  |
| Total   | 74 221  | 64 843  | 64 715   |
| Minority interests  | 88      | 98      | 97       |
| Total equity  | 74 310  | 64 942  | 64 812   |
| LIABILITIES   |         |         |          |
| Non-current liabilities                                   |         |         |          |
| Long-term borrowings                                      | 2 957   | 7 499   | 6 433    |
| Deferred tax liabilities                                  | 7       | 8       | 8        |
| Total Non-current liabilities                             | 2 965   | 7 507   | 6 441    |
| Current liabilities                                       |         |         |          |
| Liabilities to credit institutions                        | 7 602   | 4 595   | 5 241    |
| Short-term borrowings                                     | 9 457   | 2 933   | 2 814    |
| Trade payables  | 6 186   | 1 096   | 3 933    |
| Other current liabilities                                 | 3 098   | 2 164   | 2 153    |
| Accrued expenses and prepaid income                       | 3 157   | 1 835   | 2 277    |
| Total Current liabilities                                 | 29 500  | 12 623  | 16 418   |
| Total Liabilities   | 32 465  | 20 130  | 22 859   |
| TOTAL EQUITY AND LIABILITIES                              | 106 775 | 85 072  | 87 672   |
| Contingent liabilities                                    | 0       | 0       | 0        |
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## Change in shareholders' equity - Group

|  | 2008/09 | 2007/08 | 2007/08   |
|--|---------|---------|-----------|
| TSEK                                       | May-Jan | May-Jan | May-April |
| Opening balance according to Balance Sheet | 64 812  | 69 879  | 69 879    |
| Income for the period                      | 5 997   | -4 937  | -5 067    |
| Shareholders contribution received         | 3 500   | -       | -         |
| Shareholders contribution refunded         | -3 500  | -61 100 | -61 100   |
| New share issue                            | 3 500   | 61 100  | 61 100    |
| Amount at the close of the period          | 74 310  | 64 942  | 64 812    |

## Cash flow statement for the Group

| cash now statement for the ordup                         |         |         |         |         |           |
|--|---------|---------|---------|---------|-----------|
|  | 2008/09 | 2007/08 | 2008/09 | 2007/08 | 2007/08   |
| TSEK   | Nov-Jan | Nov-Jan | May-Jan | May-Jan | May-April |
| Operating activities                                     |         |         |         |         |           |
| Operating income   | -10 833 | 11 631  | 6 160   | -4 822  | -4 855    |
| Depreciation/amortization                                | 828     | 686     | 2 323   | 2 010   | 2 727     |
| Impairment of inventory                                  | 1 336   | -       | 1 336   | _       | -         |
| Disposals of intangible assets                           | 4       | -       | 4       | -       | -         |
| Interest received  | 364     | 414     | 831     | 416     | 462       |
| Interest paid  | -619    | -180    | -993    | -532    | -674      |
| Cash flow from operating activities before working       |         |         |         |         |           |
| capital changes  | -8 920  | 12 551  | 9 660   | -2 927  | -2 340    |
| Change in working capital                                |         |         |         |         |           |
| Change in inventories                                    | 3 273   | 265     | 1 386   | 176     | -803      |
| Change in trade receivables                              | -8 264  | 3 455   | -7 339  | -325    | 347       |
| Change in other current receivables                      | 150     | -100    | -125    | -352    | -302      |
| Change in trade payable                                  | 2 339   | -4 387  | 2 253   | -3 468  | -631      |
| Change in other current liabilities                      | 1 173   | -456    | 1 848   | 527     | 959       |
| Cash flow from current operations                        | -10 250 | 11 328  | 7 684   | -6 370  | -2 770    |
| Investing activities                                     |         |         |         |         |           |
| Investments in intangible fixed assets                   | -9 419  | -3 893  | -22 933 | -7 505  | -10 901   |
| Investments in property, plant and equipment             | -929    | -216    | -2 338  | -1 102  | -1 700    |
| Cash flow from investing activities                      | -10 348 | -4 109  | -25 271 | -8 606  | -12 601   |
| Financing activities                                     |         |         |         |         |           |
| Change in liabilities to credit institutions             | 2 394   | 599     | 2 361   | 2 134   | 2 779     |
| New loans  | 8 743   | -       | 8 743   | 4 000   | 3 500     |
| Repayment of loans                                       | -707    | -678    | -2 099  | -2 014  | -2 699    |
| Cash flow from financing activities                      | 10 430  | -79     | 9 005   | 4 120   | 3 580     |
| Cash flow for the period                                 | -10 169 | 7 140   | -8 582  | -10 856 | -11 791   |
| Cash and cash equivalents at the beginning of the period | 11 965  | 4 173   | 10 379  | 22 170  | 22 170    |
| Cash and cash equivalents at the end of the period       | 1 796   | 11 313  | 1 796   | 11 313  | 10 379    |
|  |         |         |         |         |           |



## Parent Company Income statement

|   |      | 2008/09 | 2007/08 | 2008/09 | 2007/08 | 2007/08   |
|---|------|---------|---------|---------|---------|-----------|
| TSEK  | Note | Nov-Jan | Nov-Jan | May-Jan | May-Jan | May-April |
| Net sales                                     |      | 248     | 18 667  | 30 811  | 18 706  | 26 246    |
| Capitalized development cost                  |      | 9 419   | 2 660   | 22 513  | 6 311   | 9 675     |
| Other operating income                        |      | 375     | 48      | 599     | 48      | 31        |
| Raw material, consumables and goods for       |      |         |         |         |         |           |
| resale  |      | -833    | -224    | -1 979  | -938    | -1 241    |
| Other external expenses                       |      | -8 777  | -4 458  | -24 493 | -14 109 | -19 188   |
| Employee benefit expenses                     |      | -7 371  | -5 010  | -18 472 | -12 532 | -17 510   |
| Depreciation/amortization and impairment of   |      |         |         |         |         |           |
| Tangible and intangible assets                |      | -771    | -631    | -2 151  | -1 843  | -2 505    |
| Operating income                              |      | -7 711  | 11 052  | 6 828   | -4 357  | -4 492    |
| Due St. Survey and the street in Comment      |      |         |         |         |         |           |
| Profit from participations in Group companies |      | -1 000  |         | -1 000  |         |           |
| Other interest revenues and similar revenues  |      | 359     | 412     | 826     | 414     | 460       |
|   |      |         |         |         |         |           |
| Interest cost and similar costs               |      | -320    | -75     | -508    | -244    | -324      |
| Financial items, net                          |      | -961    | 338     | -682    | 170     | 136       |
| Income after financial items                  |      | -8 672  | 11 390  | 6 146   | -4 187  | -4 356    |
| Taxes   | 3    | -       | -       | -       | -       |           |
| Income for the period                         |      | -8 672  | 11 390  | 6 146   | -4 187  | -4 356    |



## Parent Company Balance Sheet

| raicht company balance sheet        |         |         |          |
|-------------------------------------|---------|---------|----------|
| ,                                   | 2009    | 2008    | 2008     |
| TSEK                                | Jan 31  | Jan 31  | April 30 |
| ASSETS                              |         |         | _        |
| Non-current assets                  |         |         |          |
| Property, plant and equipment       | 19 833  | 19 091  | 19 180   |
| Capitalized development cost        | 46 672  | 20 795  | 24 159   |
| Other intangible assets             | 7 309   | 7 539   | 7 386    |
| Financial assets                    | 2 118   | 2 118   | 2 118    |
| Total Non-current assets            | 75 932  | 49 543  | 52 843   |
|                                     |         |         |          |
| Current assets                      |         |         |          |
| Inventories                         | 2 619   | 33      | 37       |
| Trade receivables                   | 159     | -       | -        |
| Receivables from group companies    | 11 850  | 17 658  | 14 825   |
| Other receivables                   | 874     | 769     | 713      |
| Prepaid expenses and accrued income | 1 436   | 1 262   | 1 373    |
| Cash and bank balances              | 1 762   | 11 282  | 10 352   |
| Total current assets                | 18 700  | 31 005  | 27 300   |
| TOTAL ACCETS                        | 0.4.000 | 00 5 40 | 00.440   |
| TOTAL ASSETS                        | 94 632  | 80 548  | 80 143   |
| EQUITY                              |         |         |          |
| Restricted equity                   |         |         |          |
| Share capital                       | 3 350   | 3 338   | 3 338    |
| Statutory reserve                   | 4 620   | 4 620   | 4 620    |
| Total restricted equity             | 7 970   | 7 958   | 7 958    |
| Total restricted equity             | 7 370   | 7 330   | 7 330    |
| Non-restricted equity               |         |         |          |
| Share premium reserve               | 99 254  | 95 767  | 95 767   |
| Retained earnings                   | -36 495 | -32 139 | -32 139  |
| Income for the period               | 6 146   | -4 187  | -4 356   |
| Total non-restricted equity         | 68 905  | 59 441  | 59 272   |
|                                     |         |         |          |
| Total equity                        | 76 875  | 67 399  | 67 229   |
|                                     |         |         |          |
| LIABILITIES                         |         |         |          |
| Non-current liabilities             |         |         |          |
| Long-term borrowings                | 2 933   | 7 499   | 6 433    |
| Total non-current liabilities       | 2 933   | 7 499   | 6 433    |
|                                     |         |         |          |
| Current liabilities                 |         |         |          |
| Short term borrowings               | 9 457   | 2 933   | 2 814    |
| Trade payables                      | 1 175   | 195     | 650      |
| Other current liabilities           | 1 041   | 687     | 740      |
| Accrued expenses and prepaid income | 3 150   | 1 835   | 2 277    |
| Total Current liabilities           | 14 823  | 5 650   | 6 481    |
| T-4-1 Colding                       | 17.757  | 10 140  | 10.014   |
| Total Liabilities                   | 17 757  | 13 149  | 12 914   |
| TOTAL COULTY AND LIABILITIES        | 04.022  | 00.540  | 00 142   |
| TOTAL EQUITY AND LIABILITIES        | 94 632  | 80 548  | 80 143   |
|                                     |         |         |          |
| Contingent lighilities              | 8 000   | 0 472   | 0 000    |
| Contingent liabilities              | 8 000   | 8 473   | 8 000    |



## Change in shareholders' equity Parent Company

|                                      | 2008/09 | 2007/08 | 2007/08   |
|--------------------------------------|---------|---------|-----------|
| TSEK                                 | May-Jan | May-Jan | May-April |
| Opening balance according to Balance |         |         |           |
| Sheet                                | 67 229  | 71 585  | 71 585    |
|                                      |         |         |           |
| Shareholders contribution received   | 3 500   | -       | -         |
| Shareholders contribution refunded   | -3 500  | -61 100 | -61 100   |
| New share issue                      | 3 500   | 61 100  | 61 100    |
| Income for the period                | 6 146   | -4 187  | -4 356    |
| Amount at the close of the period    | 76 875  | 67 399  | 67 229    |

## **NOTES**

## Note 1 Accounting policies

This interim report is established in accordance with IAS 34, Interim Reporting. The Group accounts for the Oasmia AB group has been established in accordance with the International Financial Reporting Standards (IFRS) such as they have been adopted by the EU and interpretations of International Financial Reporting Interpretation Committee (IFRIC) RFR 1.1, Complementary accounting regulations for Groups and the Annual Accounts Act. The Parent Company accounts are established in accordance with RFR 2.1, Accounting for legal entities and the Annual Accounts Act. In this report comparative figures in the Cash flow statement been adjusted so that no none cash flow affecting items are accounted for. Change in liabilities to credit institutions are accounted for on a separate line in Financing activities in this Interim Report. In the Annual Report this liability was accounted for as a part of the item Change in other current liabilities belonging to Cash flow from current operations. Accumulated operating deductions in note 3 has been adjusted. The Group accounting policies and calculation methods are in all else unchanged compared to the ones described in the Annual Report May 1 2007 – April 30 2008.

## Note 2 Segment reporting

The period May 1 2008 - Jan 31 2009

|                              | Research and |                 |
|------------------------------|--------------|-----------------|
| TSEK                         | Development  | Parallel import |
| Net sales                    | 30 811       | 39 725          |
| Capitalized development cost | 22 513       | -               |
| Other operating income       | 224          | -               |
| Operating income             | 6 808        | -648            |

The period May 1 2007 - Jan 31 2008

|                              | Research and |                 |
|------------------------------|--------------|-----------------|
| TSEK                         | Development  | Parallel import |
| Net sales                    | 18 706       | 34 519          |
| Capitalized development cost | 6 311        | -               |
| Other operating income       | 48           | 34              |
| Operating income             | -4 372       | -450            |

## Note 3 Taxes

As the Group has accumulated operating deductions amounting to TSEK 67 079 and the Parent Company deductions amounting to TSEK 63 321, no tax expenditures for the period are accounted for. Of the total deficit deductions are for the Group TSEK 16 107 restricted for use through group contribution. This limitation will end by the 2014 tax assessment. The future tax effect concerning these operating deductions has not been marked with a value and no deferred tax asset has been considered in the Balance Sheet.



## Note 4 Essential risks and uncertainty factors

An account is given below of a number of risk factors that can affect the development of the company. There has been no attempt to rank these; nor should they be taken to be all inclusive. Risk factors that, in the current situation, have not been identified, or have not been deemed to be important, can affect the company's future development.

### Business and branch related risks

### Research and Development

The company conducts studies both in clinical and preclinical phase for a number of pharmaceutical candidates. The results from every such study can be unpredictable and unwanted and may lead to a review of concepts and studies. This may postpone launches or failed registrations of the company pharmaceutical candidates, which in that case would affect the company's expected growth rate, result and financial position negatively.

#### Production

The company production facility allows production up to pilot scale of both development substances and the final product. Full-scale manufacture will be carried out by contract manufacturers under close observation by the company. Scale-up and transfer of techniques have been started. The technology used by the company are industrial standard both for substances and final product even if they are associated with know-how developed by the company. If it turns out that the technology is more difficult to scale-up that expected, it may delay full-scale production and affect launch dates with a negative effect on the company results and financial position. In connection to scale-up documentation must be submitted to registration authorities in Europe, USA and Japan. These authorities must approve the products at the manufacturer selected by the company. If the documentation is not complete there is a risk that the launch of the product may be delayed.

### Side effects

Since the company's main area of business is in the development of pharmaceuticals, there is a risk that patients that either participate in clinical studies of the company's products, or in some other way, come into contact with the company's products will develop serious side-effects. The consequence of such potential effects could be that further clinical studies of the pharmaceutical candidates must be performed which may affect the credibility of the company, delay launch and thus affect the company revenues, results and financial position.

### Competition

There is keen competition in the field of pharmaceutical development with many available and upcoming products. There is a risk that competing products on the market can affect the success of company's products and thus the company's projected turnover and results.

### Patents and intellectual property disputes

Oasmia holds patents for all steps of product development. There is a risk that competitors will violate these patents and that disputes might arise, which can have a negative effect on the company results and financial position.

### Relations with government agencies

The business operations of Oasmia Pharmaceutical depend on permits granted by various government agencies, international as well as Swedish. There is a risk that a necessary permits can not be obtained without extensive investigations or an expensive modification of business operations.

## Risks specific for the company

## Collaborations

The growth of Oasmia is dependent on establishing partnerships with external partners such as collaboration agreements with other pharmaceutical companies. Oasmia is especially dependent on the license and distribution agreements which have been closed with Orion Corporation. If important partnerships cannot be entered, are terminated or are unsatisfactory, then this may effect the company negatively. The company strives to establish solid agreements with its partners and to create long-term financial growth.

## Key persons

Oasmia depends on a highly qualified workforce in order to conduct high quality research. The company is therefore depends on being able to recruit competent workers. A lack of such workers may have a negative effect on the company.



## Financial risks

## Trade with the company share

The company is currently listed on NGM Equity. The company has closed an agreement with E. Öhman J:or Fondkommission AB for liquidity provision in order to reduce the difference between buy and sale price and promote trade in the share. It is difficult to foresee the amount of trade and interest the company share will receive in connection to a future change of stock list. If trading liquidity does not develop or become lasting, this can make it difficult for shareholders to sell their shares.

## Other financial risks

The Group is subjected to different financial risks in its business activity such as market risk, credit risk, liquidity risk and capital risk. Continuous identification and management of these risks are part of the Group policy in such cases where it is possible. These financial risks are described in more detail on pages 37–39 in the Annual Report for the fiscal year May 1 2007 – April 30 2008.



The Board of Directors and CEO of Oasmia Pharmaceutical AB ensures that this Interim report gives a correct overview of the Parent Company and Group activities, position and result and describes essential risks and uncertainty factors that the Parent Company and the companies that are part of the Group faces.

Uppsala, March 19, 2009

Bo Cederstrand, Chairman of the Board Claes Piehl, Member of the Board

Peter Ström, Member of the Board Julian Aleksov, Member of the Board and Chief Executive Officer

The information in this Interim report is of the kind which Oasmia Pharmaceutical (publ) must make public according to the code of trade in financial instruments. The information was delivered for publication on March 19 at 12.00 CET.

## **Review Report**

To the Board of Directors/Managing Director in Oasmia Pharmaceutical AB, org no 556332-6676

## Introduction

We have reviewed the interim report for Oasmia Pharmaceutical AB from January 31 2009 and the nine month period which ended as of that date. It is the Board of Directors and the CEO who are responsible for the presentation of this interim report in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

## The scope of the Review

We conducted our review in accordance with the Standard on Review Engagements, (SÖG) 2410, Review of the Interim Financial Information Performed by the Independent Auditor of the Entity, issued by the Federation of Authorized Public Accountants. A review of the interim report consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially smaller and less in scope compared to an audit conducted according to Standards on Auditing in Sweden (RS) and other generally accepted auditing practices. The procedures performed in a review do not enable us aware of all significant matters that might be identified in an audit. Accordingly, the conclusion expressed based on a review does not constitute the same level of assurance as an conclusion based on an audit.

## Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report, in al material aspects, is not prepared for the Group in accordance with IAS 34 and the Swedish Annual Accounts Act and for the parent company in accordance with the Swedish Annual Accounts Act.

Uppsala, March 19, 2009

Ernst & Young AB

Björn Ohlsson Certified Public Accountant



## **COMPANY INFORMATION**

Oasmia Pharmaceutical AB (publ) Corporate id: 556332-6676 Seat: Stockholm

Address and telephone number to the Main Office Vallongatan 1 752 28 UPPSALA, SWEDEN +46 18 50 54 40 www.oasmia.com info@oasmia.com

Questions concerning the report are answered by: Julian Aleksov, VD +46 18 50 54 40

## **NEXT REPORT DATE**

| Year-end report May 2008 – April 2009 | 2009-06-11 |
|---------------------------------------|------------|
| Annual Report 2008/09                 | 2009-09-03 |
| Interim Report May - July 2009        | 2009-09-10 |
| Interim Report May – October 2009     | 2009-12-10 |