

Actelion announces Full Year 2005 financial results

Total net revenue up 41% to CHF 663.6 million – Tracleer® sales up 41 % to CHF 633.2 million - Op Net income of CHF 125.5 million – Rapidly growing PAH market – Expanding R&D pipeline – Ongoing investment forecasted for 2006

ALLSCHWIL/BASEL, SWITZERLAND – 23 February 2006 – Actelion Ltd (SWX: ATLN) today announced its net revenue of CHF 663.6 million (FY 2004: 471.9 m) and operating expenses of CHF 511.3 million (FY 2004: 386.3 m). Operating income was CHF 152.3 million (FY 2004: 85.6 m).

Net income was CHF 125.5 million (FY 2004: 87.2 m, including a gain from discontinued operations of 9.6 m). 2005 improved to CHF 5.62 compared to EPS of CHF 3.96 in 2004.

On 31 December 2005, the company had a gross cash position of CHF 382.9 million (31 December 2004: 300.3 million) and cash flow from operations of CHF 138.4 million (FY 2004: 91.7 m).

Jean-Paul Clozel, M.D and Chief Executive Officer commented: "In 2005, our educational efforts resulted in a record outstanding Tracleer® sales growth. We are well prepared for future growth, with Tracleer® being the best documented product, a highly experienced marketing and sales team as well as by many label expansion studies. Unforeseen events excluded, I expect Actelion's 2006 total net revenues to reach between 810 and 840 million Swiss Francs by no later than 2009."

Jean-Paul Clozel concluded: "With a rapidly expanding pipeline, operating profitability, cash generation from over 1000 worldwide, Actelion has achieved full strategic freedom to pursue multiple options to further accelerate growth."

Andrew J. Oakley, Chief Financial Officer commented: "With the PAH market continuing to expand, the outstanding pipeline and a highly experienced marketing and sales team as well as by many label expansion studies, I expect Actelion's 2006 total net revenue to reach between 810 and 840 million Swiss Francs by no later than 2009."

Andrew J. Oakley added: "Our operating expenses in 2005 increased to CHF 511.3 million, in line with the overall term value creation, we will manage our 2006 cost base to result in an expected operating profit of 165 to 180 million Swiss Francs, of between 655 and 725 million Swiss Francs, we can therefore continue to both invest in our marketed products and expand our R&D pipeline. Accordingly, I expect Actelion will generate the necessary positive cash flow from operations to further strengthen operational and strategic flexibility."

Andrew J. Oakley concluded: "As a reminder, Actelion started to account for its Employee Stock Option Program in 2005. This will result in a non-cash charge of approximately 30 million Swiss Francs for the FY 2006, corresponding to the program's 123R as from

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Financial result 2005

In CHF thousands	Results FY 2005	Results FY 2004	Variance	in %
Net Revenues	663'589	471'880	191'709	+41
Operating Expenses	511'299 ⁽¹⁾	386'295	125'004	+32
Operating Income	152'290	85'585	66'705	+78
Net Income	125'538	87'219 ⁽²⁾	38'319	+44
Basic EPS in CHF	5.62	3.96	1.66	+42
Diluted EPS in CHF	5.54	3.78	1.76	+47
Cash & cash equivalents	382'917	300'336	82'581	+27

(1) includes non-cash charge for employee stock options of CHF 13.6 million

(2) includes income from discontinued operations of CHF 9.6 million

The Actelion Ltd consolidated financial statements for FY 2005 can be found on <http://www.actelion.com>.

Outstanding growth of total net revenues

In 2005, total net revenue increased to CHF 663.6 million (2004: 471.9 m), including Tracleer® sales revenue of CHF 633.2 million (2004: 469.1 m), contract revenue of CHF 14.4 million (2004: 6.1 m) and contract revenue of CHF 16.0 million (2004: 16.5 m).

On a quarter-to-quarter basis, net revenues increased 3% percent to CHF 186.5 million (Q3 2005: CHF 180.8 million).

Strong Tracleer[®] sales

In 2005, Tracleer[®] sales were CHF 633.2 million (FY 2004: CHF 449.2 m). On a quarter-to-quarter basis, Tracleer[®] sales were CHF 172.9 million (Q3 2005: 172.9 m). This increase may partially be attributed to buying pattern variations similar to the

At the end of December 2005, Tracleer[®] was available in 36 countries worldwide, including all major pharmaceutical markets in Japan, Brazil, Taiwan and several new EU member states, such as the Czech Republic and the Slovak Republic. Tracleer[®] also signed a distribution agreement for Tracleer[®] in Korea with Handok Pharmaceuticals, a Korean public company.

Regulatory and/or reimbursement reviews are ongoing in many other countries, such as the remaining new EU member states.

Christian Chavy, President of Business Operations commented: "Tracleer[®] today is the established brand that has led the market. To keep step with its expanding geographical presence and maximize market opportunities for its current and future products, we increased its marketing and sales organization. We will continue to provide a high level of service to both physicians and patients based on long-term safety and outcome data, generated by multiple clinical trials and more than four years of experience. Tracleer[®] is the undisputed cornerstone of PAH therapy."

Further data demonstrates unique clinical features of Tracleer[®] (bosentan)

In mid-July 2005, Actelion reported top-line results of BREATHE-5, the first ever placebo-controlled study conducted in children with a severe form of Congenital Heart Disease (CHD). The results showed that bosentan treatment decreased pulmonary artery pressure without a worsening in oxygen saturation. Discussions with regulatory authorities on an appropriate scientific presentation was held at CHEST in Montreal at the beginning of November 2005.

In mid-August 2005, the Journal of the American College of Cardiology (JACC) published a new study that investigated the efficacy of bosentan in treating pulmonary arterial hypertension (PAH) treated with bosentan with or without concomitant prostanoid therapy. In patients without concomitant prostanoid therapy, in this study was shown to be efficacious for the treatment of PAH in children. The safety profile appears similar to that in adult PAH patients.

In early September 2005, Actelion presented two abstracts at the European Society of Cardiology (ESC) conference on bosentan in treating PAH. The abstracts included data focusing on PAH associated with chronic thrombo-embolic disease and data outlining the safety profile of bosentan in PAH related to congenital heart disease (CHD).

In early August 2005, Actelion announced the preliminary result of a double-blind, placebo-controlled, randomized study of bosentan, RAPIDS-2, in systemic sclerosis patients suffering from digital ulceration. Preliminary analyses indicate that the occurrence of new digital ulcers during the 6-month treatment period was statistically significant. This result compares favorably to RAPIDS-1. Actelion is currently analyzing data for presentation to regulatory authorities. A first scientific presentation is planned for November 2005.

Zavesca[®] sales continue momentum

Zavesca[®] sales contributed CHF 14.4 million (FY 2004: CHF 6.1 m) in 2005. On a quarter-to-quarter basis, Zavesca[®] sales were CHF 4.0 million (Q3 05: CHF 4.0 m). Zavesca[®] is commercially available in the United States and in most European markets.

Operating expenses reflect substantial efforts in both Marketing and R&D

In 2005, operating expenses were CHF 511.3 million (FY 2004: CHF 386.3 m). In Q4 2005, operating expenses were CHF 133.6 million. In the quarter, this represents an increase of 20% (Q3 2005: CHF 133.6 m).

In 2005, research and development expenses were CHF 171.5 million (FY 2004: CHF 136.3 m). In Q4 2005 research and development expenses were CHF 48.0 million. Compared to the previous quarter, this represents an increase of 5% (Q3 2005: CHF 48.0 m).

Increased development expenses were mainly driven by the rapid enrollment of patients into the CONSCIOUS-

vasospasm as consequence of aneurysmal subarachnoid hemorrhage (SAH). In late November 2005, CONSCIOUS-1 increased with the publication of the Phase IIa study results in the July 2005 edition of the *Journal of Neurology*. The study results are expected to reduce the number and severity of cases of vasospasm following SAH.

In 2005, marketing and advertising expenses were CHF 140.0 million (FY 2004: 101.7 m).

In Q4 2005 marketing and advertising expenses were CHF 51.4 million, an increase of 61% compared to the previous quarter. The substantial increase is mainly due to the congress season, but also due to the high start-up costs associated with the effort to evaluate the long-term outcome of either the bosentan/sildenafil combination or sildenafil monotherapy. Actelion is sponsoring several patient registries and similar programs to collect and share real-life experience with Tracleer® in PAH.

In 2005 selling, general and administrative expenses amounted to CHF 132.1 million (FY 2004: CHF 95.7 m). In Q4 2005 selling, general and administrative expenses were CHF 39.4 million, an increase of 13% compared to the previous quarter (Q3 2005: CHF 34.8 million). The increase is due to the increase in headcount and related sales-based remuneration.

Strong operating profit

In 2005, a strong increase in sales revenues resulted in an operating profit of CHF 152.3 million (FY 2004: CHF 108.5 million). In Q4 2005 operating profit of CHF 26.2 million was 45 % lower than the previous quarter (Q3 2005: CHF 47.8 million).

Non-operating items and cash

In 2005, the net profit of CHF 125.5 million (FY 2004: CHF 87.2 m) includes interest income of CHF 3.0 million, interest expense of CHF 1.5 million, charge on the Convertible Bond of CHF 7.8 million, other financial expense of CHF 11.3 million and an income tax expense of CHF 1.2 million.

In Q4 2005, the net profit was CHF 24.3 million compared to CHF 35.3 million in the previous quarter.

In 2005, Actelion generated net cash flow from operations of CHF 138.4 million (FY 2004: CHF 91.7 m). Cash and cash equivalents at 31 December 2005 were CHF 382.9 million (30 September 2005: CHF 344.0 m).

Review of Research and Development programs

- The EARLY study, a double-blind, placebo-controlled clinical trial evaluating the safety and efficacy of bosentan in PAH patients, is currently enrolling 170 patients worldwide. Study results are expected by year-end 2006.
- The pediatric Phase III study FUTURE-1 is evaluating the safety and bioequivalency of a special pediatric formulation of bosentan. Study results are expected in Q3 2006, with patients then rolled over in the open-label study FUTURE-2.
- The COMPASS program evaluates the safety and efficacy of bosentan in PAH patients in combination with sildenafil. The study includes both hemodynamic benefits (COMPASS-1) as well as effects on mortality/ morbidity of the combination (COMPASS-2). Study results are expected in Q2 2007.
- The BENEFIT study, a double-blind, placebo-controlled Phase III trial to evaluate the safety and efficacy of bosentan in combination with sildenafil from chronic thrombo-embolic pulmonary hypertension (CTEPH). CTEPH is caused by blockage of the pulmonary arteries by thrombotic material. Study results are expected in Q2 2007.
- The ASSET Program with two trials, ASSET-1 and ASSET-2, has been initiated to evaluate the safety and efficacy of bosentan in combination with sildenafil in PAH patients.

secondary to sickle cell disease. The program also explores the potential of Tracleer[®] to reduce the frequency of hospitalizations, which is believed to play a central role. Results are expected in Q3 2007.

- A placebo-controlled randomized trial is currently enrolling patients to evaluate the safety and efficacy of ipilimumab in patients with melanoma. An earlier open-label trial in end-stage patients with metastatic melanoma at five centers is well tolerated. Results of the new event-driven study are expected in 2007.
- Following encouraging findings in the BUILD-1 study evaluating the safety and efficacy of bosentan in idiopathic pulmonary fibrosis, Actelion is currently finalizing the design for a mortality-morbidity driven Phase III study, BUILD-3, for discussions with regulatory authorities.
- The MAINTENANCE program, evaluating the long-term safety and efficacy of miglustat (Zavesca[®]) as replacement therapy (ERT) in adult type 1 Gaucher patients with stable disease, has been initiated in late 2006 and is expected to be completed by year-end 2007.
- Analyses have been recently completed for three clinical programs, with a total of 100 adult and pediatric patients, evaluating the safety and efficacy of high-dose miglustat (Zavesca[®]) in lysosomal storage disorders with predominant neurological manifestations: Gaucher type 3 (GD3) and Late onset Tay-Sachs (LOTS). In NP-C, encouraging results have been seen, including improvement or stabilization of key features of the disease such as saccadic eye movements, swallowing, and quality of life. The ability of miglustat to work in the brain. After consultation with regulatory authorities, Actelion has decided that these studies should continue. The NP-C study is continuing as planned for 24 months, as is the GD3 study, where the 12-month results in a group of severe, heterogeneous and advanced patients showed no change. In the LOTS study, the 24-month results in a group of severe, heterogeneous and advanced patients showed no change. In all studies, the safety profile was consistent with earlier observations in patients with type 1 Gaucher disease.
- CONSCIOUS-1, a multi-center, international, double-blind, randomized, placebo-controlled, parallel group study evaluating the efficacy and safety of clazosentan in preventing the occurrence of cerebral vasospasm following aneurysmal subarachnoid hemorrhage, was initiated in late November 2005. CONSCIOUS-1 has recruited over 400 patients in 52 centers in 11 countries worldwide. The study should provide the necessary information (dose, number of patients) for a mortality-morbidity-driven Phase III study.
- Actelion-1, an undisclosed compound is currently in a Phase IIa program to evaluate its potential in cancer.
- The single-dose Phase I study evaluating Actelion's Orexin Receptor Antagonist was successfully completed. The study demonstrated quick absorption and disposition as well as other necessary features required for a sleep agent. The study was initiated in late 2005. The primary target indication, insomnia, is expected to commence enrollment in Q1 2006. First results are expected in Q2 2006.

- Entry-into-man for the S₁P₁ agonist is expected in the coming months. S₁P₁ agonism might have therapies such as multiple sclerosis or rheumatoid arthritis. Initial Phase I findings are expected by year-end 2006.
- In 2005, a second milestone in the Global Actelion Merck Renin Inhibitor Alliance project was achieved, selected for full preclinical development, which is currently ongoing. Entry into man is planned before mid-2006.
- A broad research program in the field of antibacterials focusing on fighting resistant bacterial pathogens is ongoing.
- An additional number of unnamed projects are in various phases of drug discovery. These projects target cancer, infectious diseases and central nervous system disorders.

For documentation purposes – table Q4 2005 vs. Q3 2005

In CHF thousands	Results Q4 2005	Results Q3 2005	Variance	in %
Net Revenues	186'533	180'832	5'701	+3
Operating Expenses	160'317	133'595*	26'722	+20
Operating Profit	26'216	47'237	-21'021	-45
Net Profit	24'286	35'328	-11'042	-31
Basic EPS in CHF	1.08	1.58	-0.50	-32
Net cash from operations	48'161	41'176	6'985	+17

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NOTE TO THE EDITOR:

Actelion Ltd will hold a Media & Analyst conference today to further comment on its financial performance and approved indication, PAH. On the same day, the company will also provide a full update on its major current developments.

Location: Unique Conference Center, Airport Zurich

Media Conference: 23 February 2005, 09.30 am CET

Analyst Conference: 23 February 2005, 12.30 pm CET

NOTE TO THE SHAREHOLDERS:

The Annual General Meeting of Shareholders approving the Business Report of the year ending 31 December 2005 will be held on 23 February 2006.

Shareholders holding more than 1 million CHF nominal value of shares (i.e. 400'000 shares at nominal value of CHF 2.50) are invited to send in proposals, if any, for the annual general meeting of shareholders, to arrive no later than 3 March 2006. Any proposals received after this date will be disregarded.

In order to attend and vote at the Annual General Meeting of Shareholders, shareholders must be registered in the share register of Actelion Ltd as of 23 February 2006 at the latest.

Please note that the annual report 2005 will be available in March 2006, both in hard copy as well as on the company website.

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