Actelion announces Full Year 2003 financial results

Net revenue up 132% to CHF 307.5 million - Sales of Tracleer® continue to grow - Controlled increase of operating expenses by 88% to CHF 309.2 m - One-time impact of CHF 47 million In-Process R&D charge responsible for small operating loss of CHF 1.7 million - Pipeline with multiple late phase projects should support long-term growth

ALLSCHWIL/BASEL, SWITZERLAND - 2 March 2004 - Actelion Ltd (SWX: ATLN) today announced its financial results for the year 2003. With net revenues of CHF 307.5 million (FY 2002: CHF 132.4 m) and operating expenses of CHF 309.2 million (FY 2002: 164.5 m), the company reported an operating loss of CHF 1.7 million (FY 2002 loss: 32.0 m), mainly the result of a one-time In-Process R&D charge, related to the acquisition of Axovan in late 2003.

The net loss was CHF 9.9 million (FY 2002 loss: CHF 52.1 m), which included the loss from discontinued operations (Hesperion) of CHF 7.5 m. Accordingly the loss per share (EPS) for 2003 improved to CHF (0.46), compared to 2002 with a loss per share of CHF (2.45).

On 31 December 2003, the company reported a gross cash position of CHF 258.8 million (31 December 2003: CHF 116.2 million). In addition to generating a positive cash flow from operations in 2003 of CHF 38.3 million, the company also benefited from net proceeds of CHF 140.9 million from the issuance of a senior unsecured zero coupon convertible bond in October 2003.

Jean-Paul Clozel, M.D and Chief Executive Officer commented: "Indeed, the year 2003 has been a banner year for Actelion. Continued growth of Tracleer® sales has resulted in an important improvement in our operational performance, with substantial positive cash flow generated from operations."

Jean-Paul Clozel added: "In the year 2003, we also improved our strategic position. We entered into an alliance with Merck in the area of renin inhibition, one of the most promising avenues in cardiovascular research, targeting high blood pressure. With the sale of the clinical services subsidiary, Hesperion, we are also completely focusing our efforts on our core business: the discovery, development and marketing of innovative, first-in-class

medicines. Additionally, with the acquisition of Axovan, we not only added another late-stage development project, but also welcomed 50 highly qualified research professionals to Actelion."

Andrew J. Oakley, Chief Financial Officer commented: "With Tracleer® sales expected to grow further, I expect our operational performance will continue to improve throughout 2004. We will continue to invest substantially in R&D to further advance our promising clinical and pre-clinical pipeline."

Financial result 2004 - US GAAP-compliant and Hesperion discontinued

In CHF thousands	Results FY 2003	Results FY 2002	Variance	in %
Net Revenues	307□544	132□448	175□096	+132
Operating Expenses	309□208	164□487	144□721	+88
Operating Loss	(1□664)	(32□039)	n/a	n/a
Net Loss	(9□916)	(52□057)	n/a	n/a
Basic and diluted EPS in CHF	(0.46)	(2.45)	n/a	n/a
Cash & cash equivalents	258□770	116□201	142□569	n/a

The Actelion Ltd consolidated financial statements for December 2003 can be found on **http://www.actelion.com**.

In 2003, net revenues increased to CHF 307.5 million (2002: 132.5 million), including Tracleer® sales revenues of CHF 299.7 million (2002: 121.8 million), Zavesca® sales revenues of CHF 0.7 million (2002: not marketed yet) and contract revenues of CHF 7.2 million (2002: 10.6 million).

Operating expenses in line with business expansion

Operating expenses increased to CHF 309.2 million (2002: 164.5 million), with marketing and advertising expenses at CHF 79.8 million (2002: 56.6 million), research and development costs at CHF 79.2 million (2002: 50.6 million) and selling, general and administration expenses at CHF 69.6 million (2002: 43.0 million). Cost of goods sold of CHF 31.8 million (2002: 13.1 million) and amortization of intangible assets of CHF 1.8 million (2002: 1.2 million) are also recognized as part of operating expenses, as well as the one time In-Process R&D charge of CHF 47.0 million related to the acquisition of Axovan in October 2003.

Going forward, both marketing and advertising, as well as selling, general and administration expenses, will increase to further strengthen the Tracleer® brand in the marketplace as well as preparing for the introduction of new indications and new innovative medicines. R&D expenditures are expected to increase in line with further enrollments into ongoing clinical trials and the initiation of

new clinical programs and pre-clinical projects.

The operating loss in 2003 amounted to CHF 1.7 million (2002 loss: 32.0 million).

Strengthened financial income through risk management

The net loss of CHF 9.9 million (2002 loss: 52.1 million) includes interest income of CHF 0.9 million, interest expense of CHF 0.9 million, a non cash charge of CHF 1.5 m related to the issue of Actelion□s convertible bond, foreign currency gains of CHF 2.6 m and income tax expense of CHF 0.8 m as well as the loss from discontinued operations (Hesperion) of CHF 7.5 m.

On 31 December 2003, the company held cash, cash equivalents of CHF 258.8 million. In the fourth quarter, Actelion issued a convertible bond raising net CHF 140.9 m.

Tracleer® marketing ensuring long-term business growth

At the end of 2003, Tracleer® was marketed in 18 countries worldwide, including all major pharmaceutical markets except Japan. In Australia, Tracleer® became commercially available on 1 March 2004. In Japan and Taiwan, the regulatory review is ongoing.

Christian Chavy, Actelion□s President for the EMEA region (Europe, Latin America, Middle East and Africa) commented: "The outstanding growth in Tracleer® sales is the result of very strong and broad clinical data, as well as our major educational efforts to increase disease awareness and diagnosis of Pulmonary Arterial Hypertension. Our worldwide 143 sales representatives and 22 medical liaisons serviced an increasing number of physicians in treating patients with Tracleer®, creating new clinical data, educating non-specialists and identifying patients with PAH. Our well-established post-marketing surveillance system (PMS) provides physicians and their patients with additional comfort in using Tracleer®."

Zavesca® not only launched in Europe but also in the US

In spring 2003, Actelion launched Zavesca® first in the United Kingdom and in Germany. Actelion achieved an additional milestone with the approval of the drug in the United States of America by the FDA in August 2003, following a New Drug Application (NDA) amendment filed by Actelion on 7 February 2003. The drug became commercially available in the United States in early January 2004.

As expected, Zavesca® sales continue to grow slowly as a result of prolonged enrollment and reimbursement procedures. Accordingly, Zavesca® sales for 2003 were CHF 0.7 million.

New clinical data on Tracleer® generated and presented

In May 2003, Actelion announced at the American Thoracic Society (ATS) the analysis of long-term follow-up data of primary pulmonary hypertension (PPH) patients from Tracleer® pivotal registration studies. Tracleer® has been approved for use in pulmonary arterial hypertension (PAH) in both primary forms of the disease as well as PAH related to other diseases.

In order to generate additional experience and data in specific patient populations, Actelion has initiated several post-approval Phase IV studies. In April 2003, results of the combination trial BREATHE-2 (Bosentan Randomized trial of Endothelin Antagonist THErapy for Pulmonary Hypertension-2) evaluating Tracleer® in patients with severe PPH or PAH due to scleroderma treated with intravenous epoprostenol were presented at the meeting of the International Society of Heart and Lung Transplantation (ISHLT).

In September 2003, results of a study assessing Tracleer® in the treatment of PAH related to HIV (human immunodeficiency virus) infection was announced at the annual European Society of Cardiology meeting (ESC). Analysis of the open-label study BREATHE-4 showed a statistically significant improvement in hemodynamic parameters, exercise capacity (6-minute walk test), functional status and quality of life compared to baseline after 16 weeks of treatment with Tracleer®.

Clinical development in areas of high unmet medical needs

In Clinical Development Actelion is focusing its efforts on endothelin-related diseases in a number of areas of high unmet medical need. In detail, the trials expanding the potential indications for the use of Tracleer® are:

- Tracleer® in idiopathic (BUILD-1) and scleroderma-related (BUILD-2) Pulmonary Fibrosis: Enrollment ongoing, results expected in late 2005 (BUILD-1) and early 2006 (BUILD-2)
- Tracleer® in Digital Ulcers (RAPIDS-2): Enrollment ongoing, results expected in late 2005
- Tracleer® in Class II PAH patients (EARLY): Start in Q3 2004, results expected in early 2006
- Tracleer® in Metastatic Melanoma (Proof-of-Concept study): Recruitment completed, results on schedule for Q2 2004

The trials currently evaluating VeletriTM (tezosentan) are:

- VeletriTM in Acute Heart Failure (VERITAS-1 and -2): Enrollment ongoing, first futility interim analysis expected in June 2004, results expected in early 2005
- VeletriTM in Hepatorenal Syndrome (Proof-of-Concept studies): Results expected in Q2 2004

The encouraging phase IIa results of the endothelin receptor antagonist clazosentan in the prevention of vasospasm following surgery for cerebral bleeding events (Subarachnoid Hemorrhage) are currently being discussed with regulatory agencies worldwide. If successful, a phase II/III trial could

start in Q3 2004.

Zavesca®, which has already been launched in a number of markets, is being evaluated in lipid-storage disorders other than type 1 Gaucher□s disease such as Type 3 Gaucher, Niemann-Pick type C and Late Onset of Tay-Sachs disease. The enrollment of the trials is ongoing and results will be available during 2005.

In addition, clinical testing of the first orally active urotensin-II receptor antagonist, which has a wide range of potential indications, is in progress. Two proof-of-concept trials have been initiated in Type II diabetes patients with renal failure. Results are expected in late 2004.

Approaching new therapies in drug discovery

Actelion is currently pursuing several projects in advanced stage that have the potential to satisfy important unmet medical needs in cardiovascular, central nervous system and oncology indications. After several years of chemical optimization work, the Actelion research team has now arrived at potent, orally active renin inhibitors, with high oral bioavailability. Renin is the critical enzyme at the beginning of the biochemical cascade of the renin-angiotensin system involved in many pathological processes. An alliance with Merck is currently focusing on the selection of a first clinical candidate for potential indications such as renal failure, heart failure and hypertension.

Although work was well in progress on potent orexin receptor antagonists in 2002, a major breakthrough came about during 2003, when the first orally active compounds were discovered. Substances that block the G-protein-coupled orexin receptors hold promise as novel sleep and appetite regulators. Pre-clinical development of a candidate for the therapy of sleep disorders is ongoing.

Also strong fourth quarter 2003

In CHF thousands	Results Q4 2003	Results Q3 2003	Variance	in %
Net Revenues	93□796	82□140	11□656	+14
Operating Expenses	127□623	64□171	63□452	+99
Operating Loss	(33□827)	17□969	n/a	n/a
Net Loss	(37□120)	16□163	n/a	n/a
Basic and diluted EPS in CHF	(1.71)	0.75	n/a	n/a
Cash & cash equivalents	258□770	136□639	122□131	n/a

The fourth quarter added further momentum to Actelion□s financial performance. On a quarter-to-quarter basis, net revenues increased by 14 percent to CHF 93.8 million (Q3 2003: 82.1 m).

Tracleer® revenues increased by 14 percent to CHF 91.4 million (Q3 2003: 80.3 m) while Zavesca®

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