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# Focus on Growth and Bottom-Line Results



**Andrew J. Oakley**  
Chief Financial Officer

Dear Shareholders,

The year 2003 was one of tremendous progress and transition for Actelion. Our company demonstrated growing maturity as an organization, as we continued to build underlying profitability as well as substantially investing in our extensive research and development efforts. Our R&D pipeline, one of the industry's strongest, is expected to yield multiple growth opportunities in the years ahead.

#### Well-considered investments in the future

The year was highlighted by a number of corporate decisions, which will ensure the future growth of Actelion.

With the acquisition of Axovan in October 2003, Actelion strengthened its late-stage development pipeline and early drug discovery efforts. For an actual consideration of only CHF 53 million, Actelion gained access to the development compound clazosentan, which has major promise in a specific form of stroke (subarachnoid hemorrhage) as well as bolstering our early stage research capacity and pipeline. The total acquisition price of CHF 245 million is only payable upon achievement of important development, regulatory and marketing milestones, thereby minimizing the risk profile of the transaction.

In December 2003, Actelion formed an alliance with Merck to discover, develop and market new classes of renin inhibitors. Actelion received an upfront payment of USD 10 million from Merck and will be eligible to receive research, development and approval milestone payments of up to USD 262 million for the successful commercialization of the first collaboration product. This alliance is expected to generate revenues for Actelion in the short to medium term while allowing us to benefit from the success of the product in the marketplace – not only through substantial royalties, but also in the form of a paid-for sales force that can be utilized for other Actelion products intended for general practitioners.

#### Sale of Hesperion changes cost balance

In early 2004, Actelion announced that it had sold its clinical services subsidiary, Hesperion, to CEREP. Hesperion had been an important factor in the early-stage development of the company, giving Actelion access to sufficient operational capacity to rapidly complete clinical trials with bosentan and tezosentan. With the company now a well-recognized leader in the biopharmaceutical industry, our requirement for an in-house clinical research organization (CRO)

has diminished. The decision to sell Hesperion allows us to change the clinical trial cost balance between fixed and variable costs, effectively variabilizing the majority of our operational development costs.

#### Increasing transparency – US GAAP

In the autumn of 2003, Actelion decided to adopt US GAAP for its financial reporting as of the year under review. This decision was designed to make Actelion's financial reporting more comparable to our peer group of successful biotechnology companies, who are predominantly US based and accordingly apply US GAAP. The decision, we believe, also provides us with a more stable accounting platform for the future, given the ongoing evolution of IFRS.

#### Strong financial performance in 2003

The year 2003 was a very successful one for Actelion. Our revenues were derived predominantly from Tracleer® sales, which totaled CHF 307.5 million, up 132% compared to 2002. Total expenses, excluding the in-process R&D charge for the acquisition of Axovan, grew to CHF 262.5 million, an increase of only 59% from the year 2002. This clearly highlights that our result at an operational level has improved substantially, with the company generating cash from operations in the three last quarters of 2003 and for the year as a whole.

The operating loss for the year of CHF 1.7 million is after taking a one-time accounting charge of CHF 47 million for costs related to the acquisition of Axovan and the treatment of the CHF 7.5 million loss in Hesperion as a discontinued operation.

#### Net revenues of CHF 307.5 million driven by strong performance of Tracleer®

Net revenue for the year 2003 totaled CHF 307.5 million, an increase of 132% over 2002. This good result is almost exclusively due to the very strong sales growth of Tracleer® in all markets where the drug is commercially available. Total Tracleer® sales in 2003 were CHF 299.7 million, an increase of 146% over 2002. Total Zavesca® sales were CHF 0.7 million, in line with its limited availability in only a few European markets and its restricted labeling as second-line therapy for type 1 Gaucher's disease.

Contract revenues of CHF 7.2 million for 2003 included three components: the contract revenues from the continuing recognition under US GAAP of revenue from the collaboration agreements entered into with Genentech for both bosentan (Tracleer®) and

tezosentan (Veletri™), the recognition of milestone payments received from Merck, and other miscellaneous revenues. Contract revenue recognized under the two Genentech contracts amounted to CHF 6.3 million in 2003, the same as in 2002. Actelion also recognized in 2003 CHF 0.3 million from the USD 10 million sign-up fee received from Merck & Co for our worldwide alliance on renin inhibition. The 2002 contract revenue number also included some revenues from the Johnson & Johnson collaboration.

#### Cost of sales in line with sales growth

Cost of sales for the full year amounted to CHF 31.8 million, or 10.6% of product sales. Historically, Costs of Goods Sold (COGS) had included the cost of providing clinical services. With Hesperion now accounted for as a discontinued operation, our gross margin has increased quite markedly. Removing the effect of Hesperion, the gross margin is approximately the same on a percentage basis in 2003 and 2002.

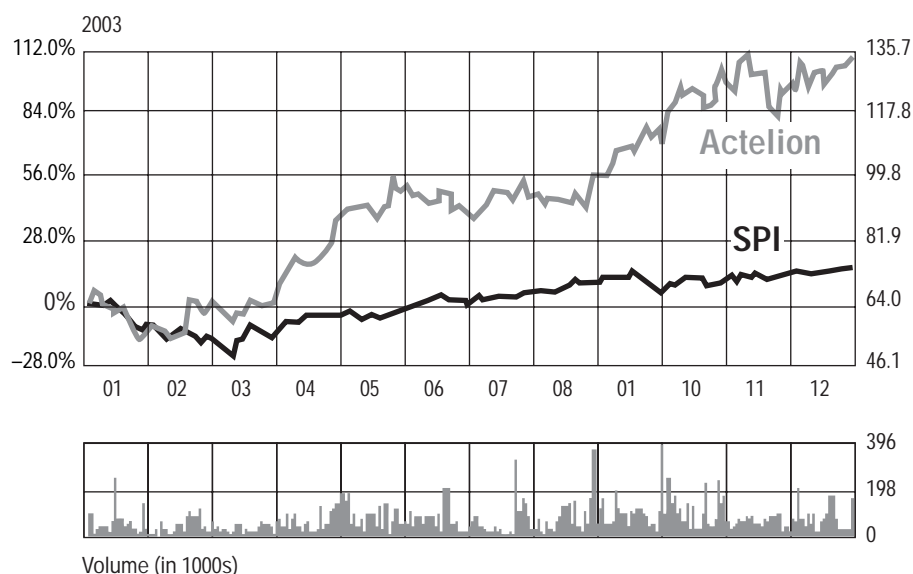
#### Operating expenses in line with investment in expanding R & D pipeline

In 2003, operating expenses continued to increase in line with the ongoing expansion of the company, both in terms of further establishing Tracleer® in the marketplace as well as building one of the industry's most promising research and development pipelines.

Total operating expenses for 2003 were CHF 230.4 million (excluding IPRD charges), an increase of CHF 79 million or 52% over 2002. This compares to an increase in total net revenue for the same period of CHF 175 million. Also adding to operating expenses in 2003 was the launch of our second product, Zavesca®, in a few European Union member states as well as the preparation of the launch in the United States in early January 2004.

Research and development expenses amounted to CHF 79.2 million for the year, an increase of 57% over 2002. Strategically, Actelion is committed to a substantial yet controlled increase in both research and development expenditure as we continue to seek out new drug candidates and move them through the increasingly more expensive development process. In line with our promising portfolio of development projects, development expenditure was significantly higher in 2003 compared to 2002. The company, following the acquisition of Axovan in October 2003, now has a total of 11 projects in Phase II and III. Marketing and advertising expenses for the year amounted to CHF 79.8 million. This represented an increase of 41% over 2002. Included in this cost are

Actelion's share price development 2003



the advertising and general promotional programs for Tracleer® and Zavesca®, participation in medical congresses, and our proprietary post-marketing surveillance systems. Obviously, as Tracleer® was launched in new markets throughout 2003, our expenses in this area rose accordingly. Additionally, Zavesca® was launched in a number of European countries throughout 2003 and in the United States in early 2004, further adding slightly to this expense line in 2003.

Selling, general and administration expenses reached CHF 69.6 million in 2003 compared to CHF 43 million in 2002. These costs include increasing the size and outreach of our sales forces as well as maintaining affiliate operations and general management. Especially noteworthy were the investments made into a fully staffed Actelion affiliate in Japan, which is poised to be operational upon approval of Tracleer®, expected in 2004. On March 1 2004, the Australian affiliate became operational, having been granted reimbursement status in late 2003.

#### The conversion to US GAAP results in three major changes compared to IFRS

The adoption of US GAAP has resulted in one major recurring and two one-time differences impacting the operating expenses of Actelion. The recurring item is the expensing of the intrinsic value of employee stock options. The two one-time differ-

ences refer to the acquisition of Axovan and the disposal of Hesperion.

The accounting for employee stock options affects all operating expense lines. The total expense charged to the P&L in 2003 was CHF 4.4 million, compared to CHF 3.1 million in 2002. In order to limit further charges of this magnitude, the company has revised the nature of options granted to employees. This will minimize the P&L impact without impacting the incentive the company believes is necessary to attract and retain the best qualified and performing individuals available in the industry.

With the acquisition of Axovan, US GAAP also requires that intangible assets identified as a part of an acquisition, which meets the definition of in-process research and development, be written off. Included, therefore, in the operating result is a non-cash charge of CHF 47 million. In note 3 to the accounts, you will see the reconciliation of purchase price paid to assets acquired. It shows that the value of the assets acquired was CHF 6.6 million more than the purchase consideration.

#### Non-operating income lower in 2003

Interest income is significantly reduced for 2003 compared to 2002 as a result of lower net average cash balances and the lower yield curve in Switzer-

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land. Interest expense comprises two parts: cash expense, which increased in line with the increase in borrowing as we drew down on a credit facility in late 2002, and the non-cash amortization charge related to the convertible bond issue.

Other financial income showed a dramatic turnaround due to a change in treasury policy, resulting in the liquidation in 2002 of equity investment positions and the decision not to hold USD cash deposits. Additional gains in foreign exchange were made in 2003 compared to 2002.

Income tax expense under US GAAP only represents income tax expense in certain group entities, which were profitable for the full year. Under US GAAP, when a company has a history of losses, the value of deferred tax assets, which we had previously recognized under IFRS, cannot be appropriately reflected in either the Balance Sheet or Profit & Loss Statement. The full value of the carry forward tax losses, however, are shown in the footnotes to the accounts, and we fully expect to be able to utilize these tax losses over the next few years.

I was also very pleased to be able to report during the year that the company has received favorable tax rulings from the Swiss authorities that will ensure a tax rate in the future comparable to those enjoyed by other Swiss companies in our industry.

As a result of the above, our net loss for the year 2003 is CHF 9.9 million, which compares to a net loss for 2002 of CHF 52.1 million. The loss per share for 2003 for continuing operations is CHF 0.11 compared to CHF 1.77 for 2002.

#### **Balance sheet supporting growth**

During 2003, there were a few major changes in balance sheet positions. Debtors continued to increase in line with the expansion of the business, as did the other components of working capital such as inventories. On the liabilities side, trade payables and accrued expenses rose. Working capital management will become increasingly important during the next phase of growth in 2008–2009.

Overall total assets nearly doubled from CHF 219.0 million to CHF 402.8 million in 2003. A large proportion (78%) of this increase stems from an increase in cash resulting from positive cash generation from operations for the year as well as the net proceeds of the convertible bond issued in October, minus the CHF 40.1 million outlay for the acquisition of Axovan.

Total liabilities increased by CHF 179.8 million from CHF 168.1 million in 2002 to CHF 347.9 million by year-end. Of this increase, 81% is attributable to the financial debt arising from the convertible bond. By mid-February, our share price was trading above the initial conversion price of the bond of CHF 153.4. Deferred revenue increased marginally as we continued the non-cash revenue recognition from the Genentech milestones, but deferred the recognition of nearly all of the USD 10 million received from Merck.

There has been little change in overall net shareholder equity, the small net loss resulting from the in-process R&D charge being offset by an increase in paid-in capital resulting from the exercise of employee stock options and the expensing of these options.

#### **Strong liquidity and capital resources ensure strategic flexibility**

Cash and cash equivalents at year-end totaled CHF 258.8 million. With the company now having had three consecutive quarters of positive cash generation as well as positive cash generation for the year as a whole, I consider our cash reserves sufficient to meet the company's current plans. Other than for employee stock options, no use was made of the conditional authorized capital facilities provided by the shareholders. As a result, these remain available to the Board of Directors, should a suitable opportunity arise.

#### **Concluding remarks**

The year 2003 has been an extremely challenging and rewarding one for Actelion and all of the finance team. I would like to thank all of them for their professionalism and dedication throughout the year.

Finally, I would like to express a parting word of thanks to André J. Mueller. André has been instrumental in ensuring a smooth transition of the finance leadership in early 2003. I have and will continue to value his advice and input, as well as that of the other members of the Finance and Audit committee, all of whom have been of great assistance to me in my first year as CFO.



Andrew J. Oakley  
Chief Financial Officer