Annual Report 2008

In Detail

ACTELION

Introduction

Progress in 2008

In 2008, strong financial performance – with a keen eye on the bottom line – enabled Actelion to continue its unprecedented growth in the biopharmaceutical sector. Once again, this was largely driven by sales of our flagship product Tracleer® (bosentan), the undisputed cornerstone therapy for pulmonary arterial hypertension (PAH).

In an effort to optimize geographic reach, Actelion has expanded and enhanced its commercial infrastructure. At the end of 2008, the company had 26 sales and marketing organizations, including the expansion to Mexico, and 25 other countries serviced through partners. This global reach – with future expansion to markets such as Russia, as well as realignment in the key Japanese market – means that Actelion is equipped to shape markets for future launches.

We have also been putting processes and infrastructure in place to transform novel chemical entities, currently in late-stage development, into innovative medicines for patients. Our global headcount expanded by more than 300 employees in 2008 taking Actelion over 1900 professionals. With higher levels of growth expected in the future, office and laboratory space, IT infrastructure and the coordination of corporate services will be key efficiency factors. Actelion's business center, founded at the end of 2007, has already made great progress in addressing these future needs, and we have started work on our second R&D building.

With a broad dataset and experience in over 60,000 patients, Tracleer® is the best described treatment for PAH. In 2008 Tracleer® saw the successful market introduction for digital ulcers in systemic sclerosis and WHO Functional Class II patients added to the label in the EU. Having secured the expanded label, Actelion intends to continue its commitment to patients with PAH by building a product franchise led by the global availability of Tracleer® and our commercialization of Ventavis® (iloprost) in the US. In addition, our Phase III compound macitentan is continuing to progress rapidly through development. Thanks to Actelion's partnership with Nippon Shinyaku, announced in the first quarter of 2008, an orally active non-prostanoid PGI_2 receptor agonist has also been added to the development pipeline.

We also continued our commitment to Zavesca® in 2008, not only in the market place but also with clinical support resulting in the CHMP positive opinion in December to extend the use of this treatment to include patients with a very rare neurodegenerative genetic disease, Niemann-Pick type C.

The Zavesca® sales force is now making the necessary preparations to immediately bring this product to patients after obtaining approval in the EU in January 2009.

Our clinical development pipeline holds great promise for patients with many other unmet medical needs. Results from the current Phase III study with bosentan (Tracleer®) as a treatment for idiopathic pulmonary fibrosis are expected to become available toward the end of 2009. A positive outcome would allow patients to benefit from this compound's antifibrotic properties. Also expected for the second half of 2009 are results from two other Phase III projects, investigating clazosentan in the prevention of vasospasm as a consequence of aneurysmal subarachnoid hemorrhage and almorexant in primary insomnia.

Almorexant shows potential in the treatment of insomnia and beyond. To optimize the value of this discovery, Actelion sought a partner who understood this potential. The partnership with GlaxoSmithKline, announced in July 2008, has proved to be a good choice, with rapid and committed implementation. The two companies' combined knowledge, capabilities and experience will allow us to realize the transformational potential of almorexant and other orexin receptor antagonists, creating value above and beyond what each company could achieve alone. The alliance also allows Actelion to potentially build a primary care presence in key pharmaceutical markets, driving almorexant's value creation and helping to maximize leverage for our substantial pipeline.

As data is reported from our early-stage development programs, we will learn more about the potential of our CRTH2 receptor antagonist in allergic asthma and the initiation of Phase II studies for the $S1P_1$ receptor agonist (in partnership with Roche). We also hope to benefit from a drug discovery approach in which compound identification is followed by a patient-oriented search for therapeutic applications.

Our corporate culture – combining the innovation, entrepreneurial spirit and flexibility of biotech with the risk management and regulatory and commercial discipline of big pharma – will continue to drive our success in 2009. By focusing on our values and fostering an enthusiastic, stimulating environment for employee development and company growth, we will attract and retain the best people in the industry.

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