



## Media Release

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18 February 2010

### **Actelion announces Full year 2009 financial results**

**2009 Total net revenues of CHF 1,772.6 million, up 23 percent in local currencies – Tracleer® sales of CHF 1,508.0 million, up 19 percent in local currencies – Non-GAAP (cash) EBIT of CHF 567.9 million, up 25 percent in local currencies – Positive outlook for existing business Focus on innovation creates additional growth opportunities – 11 compounds in development – Two Phase III studies to report in 2010**

**ALLSCHWIL/BASEL, SWITZERLAND – 18 February 2010** – Actelion Ltd (SIX: ATLN) today announced its financial results for the full year 2009. With total net revenues CHF1,772.6 million (FY 2008: CHF 1,473.5 m) and operating expenses of CHF 1,433.2 million (FY 2008: CHF 1,102.2 m), the company reported a full year 2009 operating profit of CHF 339.4 million (FY 2008: CHF 371.4 m).

For the full year 2009, Actelion reported a non-GAAP (cash) EBIT of CHF 567.9 million, an increase of 19 percent compared to 2008. In local currencies, non-GAAP (cash) EBIT increased by 25 percent. Adjusted (non-GAAP) diluted earnings per share for the 2009 were CHF 4.38, compared to CHF 3.38 during the same period last year.

The non-GAAP (cash) EBIT and adjusted non-GAAP diluted earnings per share exclude charges such as In-Process R&D, charges related to employee stock options under ASC 718, non-cash depreciation and amortization charges as well as other one-off items which would distort comparative analysis.

On a US GAAP basis, net profit for the full year 2009 was CHF 311.3 million (FY 2008: CHF 306.1 m). Fully diluted earnings per share (EPS) on a US GAAP basis for the same period were CHF 2.53, compared to CHF 2.48 for 2008.

Jean-Paul Clozel, M.D. and Chief Executive Officer commented: “Actelion has become a stronger company in 2009. The sales of our products continued to grow in an increasingly competitive environment. Our clinical pipeline continues to mature, with five compounds in advanced development stage. By focusing on innovation, we have created a wide range of growth opportunities. Our marketing and sales infrastructure in all key pharmaceutical markets worldwide, will allow us to generate best value for our existing and future products.”

Jean-Paul Clozel continued: “In 2009, we have demonstrated our commitment to improve the quality of patients’ lives. By introducing a new special pediatric formulation of Tracleer® in the EU, we are helping to treat children with Pulmonary Arterial Hypertension (PAH). In addition, we have introduced Zavesca® in the EU for the treatment of the very rare orphan disease Niemann-Pick type C.”

Jean-Paul Clozel concluded: “I view the outlook for 2010 positively. I expect our existing business to continue to grow. I am looking forward to the results of our two pivotal Phase III programs reporting this year.

Andrew J. Oakley, Chief Financial Officer commented: “In 2009, Actelion delivered on its promise to drive growth, in terms of product sales as well as in terms of cash generation, with non-GAAP (cash) EBIT up 25 percent in local currencies. We have continued building a leveragable platform for future growth through ongoing investment in research and development and ongoing investment in infrastructure. Going forward, we will operate from an even stronger base.”

Andrew J. Oakley concluded: “We will continue in 2010 to leverage the growth platforms developed over the last few years. Unforeseen events excluded, we believe that total net revenue growth in local currencies will be above 10 percent and non-GAAP (cash) EBIT growth, again in local currencies, will be close to 20 percent.”

#### **Financial result overview – Table FY 2009 vs. FY 2008**

In CHF thousands	Result FY 2009	Result FY 2008	Variance	%
Net Revenues	1,772,564	1,473,508	299,056	20
Operating Expenses	1,433,158	1,102,151	331,007	30
Operating Income	339,406	371,357	(31,951)	(9)
Non-GAAP (cash) EBIT	567,935	476,833	91,102	19
Net Income*	311,270	306,073	5,197	2
Diluted EPS in CHF*	2.53	2.48	0.05	2
No of shares in calculation	122.880m	123.418m	-	-

\* 2006 convertible bond reclassification according to adoption of ASC 470-20 – comparative period adjusted.

The full financial statements can be found on <http://www.actelion.com>.

### **Continued growth of total net revenues**

During the full year 2009, Actelion's total net revenues increased by 20 percent to CHF 1,772.6 million (FY 2008: CHF 1,473.5 m). In local currencies, total net revenues increased by 23 percent compared to 2008.

Contract revenues for 2009 amounted to CHF 74.6 million (FY 2008: CHF 44.6 m).

### **Product sales**

During the full year 2009, Tracleer® (bosentan) sales were CHF 1,508.0 million (FY 2008: CHF 1,294.1 m). In local currencies, this represents an increase of 19 percent compared to the same period last year.

At the end of December 2009, Tracleer® was commercially available in over 55 countries worldwide, including all major pharmaceutical markets.

In August 2009, Tracleer® received a label extension in US for the treatment of patients with mildly symptomatic WHO Functional Class II pulmonary arterial hypertension. This label extension follows the EMEA FC II label approval in 2008 and was based on the EARLY (Endothelin Antagonist tRial in miLdly symptomatic PAH patients) study, published in the Lancet in June 2008. EARLY, the first study exclusively performed in patients with mildly symptomatic WHO Functional Class II, demonstrated the relentlessly progressive nature of PAH, even in its early stages. It also highlighted the need for earlier treatment and intervention in PAH management. In the EARLY study, although the improvement of 6MWT had not reached statistical significance, Tracleer® had demonstrated a highly significant reduction of disease progression as assessed by clinical worsening events as compared to placebo.

Additionally, 2009 saw the approval of a pediatric formulation of Tracleer® in Europe. This indication makes Tracleer® the first oral PAH treatment with an approved pediatric formulation in children aged from two years.

Otto Schwarz, President Business Operations, commented: "The strong growth momentum of Tracleer® sales is remarkable, reflecting strong demand for innovative treatments in PAH as well as – in the EU – for the prevention of Digital Ulcerations in patients suffering from systemic scleroderma. Sales growth is also the result of our commercial efforts based on strong product labeling, strong relationships with key stakeholders, and excellence in execution on our competitive and market-building strategies."

Ventavis® (iloprost) sales amounted to CHF 136.9 million for the full year 2009 (FY 2008: CHF 94.6 m). This represents an increase of 44 percent in US Dollars.

In early August 2009, the FDA approved a new 20 microgram per milliliter (mcg/ml) formulation of Ventavis® as a therapy for New York Heart Association Class III and IV PAH. This increased-strength formulation delivers the same dose in half the volume, which is expected to both reduce inhalation time and improve convenience for patients. A clinical program to evaluate the use of a higher-powered disk for the delivery device has recently concluded and Actelion is currently reviewing further development options.

Efforts are ongoing to further strengthen our PAH franchise with the forthcoming market introduction of an improved formulation of epoprostenol sodium for the intravenous treatment of primary and scleroderma related PAH. This medication was acquired from privately-held GeneraMedix Inc. in the first half of 2009.

The drug was approved in June 2008 in the United States for the long-term intravenous treatment of primary pulmonary hypertension and pulmonary hypertension associated with the scleroderma spectrum of disease in NYHA Class III and Class IV patients who do not respond adequately to conventional therapy. In France, Actelion has initiated regulatory activities for this product. Further regulatory filings are in preparation in other markets worldwide. Actelion is also starting a dedicated program to generate clinical experience data with this product.

In 2009, sales of Zavesca® (miglustat) grew to CHF 53.1 million – an increase of 38 percent in local currencies (32 percent in CHF). This increase was mainly due to the approval of the new indication Niemann-Pick type C disease (NP-C) by the European Commission in January 2009, with first reimbursements granted by mid-2009. Sales in the type 1 Gaucher disease indication also continued to grow.

Zavesca® is commercially available in over 35 countries including the United States and most European markets for the treatment of adult patients with mild to moderate type 1 Gaucher disease for whom enzyme replacement therapy (ERT) is not a therapeutic option.

In January 2009, Zavesca® received approval in the European Union for the treatment of progressive neurological manifestations in adult and pediatric patients with NP-C. Zavesca® is the first treatment to be approved for patients with NP-C, a very rare and devastating neurodegenerative genetic disorder affecting both children and adults.

At the end of 2009, Zavesca® was also approved for the treatment of patients with NP-C in Brazil, South Korea and Russia, with applications under evaluation in Australia, Canada, Colombia, Switzerland and Thailand.

In November 2009, Actelion announced that the FDA had granted a priority review for a supplemental new drug application (sNDA) concerning an extended indication for Zavesca® – for the treatment of progressive neurological manifestations in adult and

pediatric patients with NP-C. The Endocrine and Metabolic Drug Advisory Committee (EMDAC) reviewed the sNDA in early January 2010 and voted that the benefit/risk profile of Zavesca® (miglustat) supports its approval for the treatment of progressive neurological manifestations in adult patients and pediatric patients with Niemann-Pick type C disease. A response from the FDA is expected later in 2010.

Otto Schwarz concluded: "At the end of 2009, our global commercial presence included 28 operational affiliates in all key pharmaceutical markets, including Japan where our efforts to expand the PAH market further generated significant return on investment. With our strong data-driven approach, I am confident that in 2010, we will continue to grow Tracleer® sales in PAH globally and the indication digital ulceration in Europe. In Europe, as well as in other markets where we obtain approval for NP-C, we will accompany market introductions with increased educational efforts to facilitate disease awareness. In the United States, we are fully prepared for the recent change in the competitive landscape, with another inhaled therapeutic option for PAH launched Q3 2009 by a competitor."

In February 2010, the existing collaboration with Nippon Shinyaku and Actelion's position in Japan was further strengthened. The two companies decided that in Japan, they will co-develop and co-commercialize the highly potent endothelin receptor antagonist macitentan, currently in clinical development. Such an option was part of the initial agreement for the oral, non-prostanoid IP receptor agonist.

### **Operating expenses**

During the full year 2009, operating expenses were CHF 1,433.2 million (FY 2008: CHF 1,102.2 m).

During the same period, research and development expenses increased by 24 percent to CHF 464.1 million (FY 2008: CHF 374.5 m). Full year 2008 operating expenses included milestone payments related to the IP receptor agonist in-licensed from Nippon Shinyaku. A third payment related to the commencement of the Phase III study was made in December 2009.

Selling, general and administrative expenses for 2009 amounted to CHF 645.5 million (FY 2008: CHF 550.0 m), an increase of 17 percent.

### **Research and Development**

At the end of 2009, Actelion's pipeline had 11 compounds in clinical development as well as around 25 active projects in drug discovery.

Actelion is currently pursuing five ongoing Phase III programs:

*Almorexant in primary insomnia:* Almorexant is investigated in the Phase III program RESTORA (REstore physiological Sleep with The Orexin Receptor antagonist Almorexant). The first Phase III study, RESTORA 1 met its primary endpoint, superiority of the dual orexin receptor antagonist almorexant compared to placebo on objective and subjective wake after sleep onset (WASO). The finding was highly significant ( $p < 0.001$ ). In addition, several secondary endpoints of the study were met with statistical significance.

In RESTORA 1, the use of almorexant was well-tolerated. However, in this study as well as in the ongoing non-pivotal program, certain safety observations were made that will require further evaluation and assessment in longer-term Phase III studies. The Phase III studies are currently in preparation - in both adults and elderly patients suffering from insomnia - and will evaluate long-term efficacy and safety.

*Bosentan (Tracleer®) in IPF:* This multicenter, double-blind, randomized, placebo-controlled, parallel group, event-driven morbidity/mortality study (BUILD-3) is evaluating the safety and efficacy of bosentan 125mg b.i.d. in patients diagnosed with idiopathic pulmonary fibrosis (IPF). BUILD-3 enrollment was completed in October 2008 with 616 patients.

Upon reaching 202 confirmed events, Actelion started closing procedures at the end of 2009. Top-line results are expected in the first quarter of 2010.

*Clazosentan in aSAH:* Clazosentan is investigated in the pivotal Phase III study CONSCIOUS-2 (Clazosentan to Overcome Neurological iSchemia and Infarct Occurring after Subarachnoid hemorrhage) in 1,100 patients with aSAH and treated with aneurysmal surgical clipping. The study will measure the clinical benefits of clazosentan through the primary endpoint of vasospasm-related morbidity and all-cause mortality.

CONSCIOUS-2 results are expected to become available in the second half of 2010. If successful, Actelion will approach health authorities for filing.

A second Phase III study with Clazosentan, CONSCIOUS-3, has commenced enrollment, this time evaluating efficacy and safety clazosentan in patients post-aSAH treated by endovascular coiling.

*Macitentan in PAH:* Macitentan is investigated in the Phase III study SERAPHIN (Study with an Endothelin Receptor Antagonist in Pulmonary arterial Hypertension to Improve cliNical outcome). This study is designed to evaluate the safety and efficacy of this highly potent, tissue-targeting, endothelin receptor antagonist through the primary endpoint of morbidity and all-cause mortality in patients with symptomatic PAH.

Global enrollment was completed in December 2009 with a total of 742 patients. Study results could become available earlier than initially foreseen - which was the end of 2012.

*Selexipag (proposed INN) in PAH:* At the end of 2009, Actelion has progressed its first-in-class, orally active, non-prostanoid IP receptor agonist, selexipag, into a Phase III morbidity/mortality study in pulmonary arterial hypertension.

In a 43-patient Phase IIa study concluded in mid-2009, the primary endpoint of pulmonary vascular resistance (PVR) change from baseline was met with high statistical significance.

Guy Braunstein, M.D. and head of clinical development at Actelion commented. "In 2009, we have made significant progress in advancing a growing number of our projects. Despite the growing complexity of conducting clinical trials on a global scale, we were able to complete our studies in the timeframe foreseen and with the required quality. In 2010, we will have even more clinical studies ongoing. Naturally, we are also fully prepared for regulatory filings, if warranted, for our two upcoming Phase III studies that will report this year."

The earlier-stage clinical development programs include:

*CRTH2 receptor antagonist in asthma:* Positive data was obtained in 2009 in a proof-of-mechanism study with Actelion's orally active CRTH2 receptor antagonist in mild asthma.

Plans for initiating a Phase II dose-finding study in asthma are ongoing with further clinical studies in this and other indications planned for 2010, once additional preclinical studies have concluded.

*Macitentan in IPF:* A pilot clinical development study with this highly potent, tissue-targeting, endothelin receptor antagonist in idiopathic pulmonary fibrosis has commenced enrollment in H1 2009.

*Miglustat in Cystic Fibrosis:* A first Phase IIa study with miglustat in cystic fibrosis was concluded in mid-2009. Following further preclinical and clinical analysis, a newly designed proof-of-concept study will be initiated in 2010.

*Selective S1P<sub>1</sub> receptor agonist in multiple sclerosis:* Following a successful Phase I program, Actelion's first-in-class selective S1P<sub>1</sub> receptor agonist started enrolling patients with multiple sclerosis in a Phase IIb dose-finding study.

*Selective S1P<sub>1</sub> receptor agonist in psoriasis:* Actelion has advanced its selective S1P<sub>1</sub> receptor agonist for the treatment of psoriasis based on a Phase IIa proof-of-concept study. While this short term study did not reach statistical significance, sufficient information was obtained to proceed with a first pivotal study in psoriasis.

In 2009, Actelion also commenced Phase I studies for a novel antibiotic and a novel cardiovascular agent.

Martine Clozel, MD and Chief Scientific Officer at Actelion commented: "Actelion's platform approach, combined with our technological capabilities and in-house expertise, has resulted in two novel compounds progressing into clinical development in 2009. Several compounds are currently in full preclinical development."

Martine Clozel concluded: "Actelion Drug Discovery currently works on another 15 projects in lead optimization phase, a clear sign of our high research productivity. The progressive focus on specialized therapeutic areas of cardiovascular/fibrosis, immunology/allergy/inflammation, CNS, anti-infectives and oncology, has created a mature and concentrated Drug Discovery portfolio."

### **Operating profit**

Actelion's operating profit for the full year 2009 was CHF 339.4 million (FY 2008: CHF 371.4 m) impacted by the litigation settlement of CHF 93.7 million announced in December 2009 related to an arbitration proceeding regarding a license agreement to develop Asahi Kasei's rho kinase inhibitor, fasudil. Non-GAAP (cash) EBIT (excluding this settlement) for the same period amounted to CHF 567.9 million (FY 2008: CHF 476.8 m).

### **Net Profit**

The net profit of CHF 311.3 million (FY 2008: CHF 306.1 m) for the full year 2009 includes interest income of CHF 4.4 million, predominantly non-cash interest expense of CHF 7.5 million, non-cash interest and amortization charges on the Convertible Bond of CHF 17.9 million, foreign currency gains of CHF 20.0 million and an income tax expense of CHF 27.3 million.

### **Cash and cash flow**

During 2009, Actelion generated net cash flow from operations of CHF 424.2 million (FY 2008: CHF 513.7 m). As of 31 December 2009, total liquid funds (excluding 9.8 million treasury shares) amounted to CHF 1.3 billion.

### **Strong talent growth**

At the end of 2009, Actelion employed 2,263 employees worldwide, an increase of more than 310 staff compared to the end of 2008. Of those 2,263 employees, 984 were located in Switzerland (2008: 862 employees).

In 2010, Actelion expects to increase its global work force to above 2,500 employees. In Switzerland, Actelion expects to employ by year-end 2010 more than 1,100 employees.

## Upcoming Corporate Events

Q1 2010	- BUILD-3 in IPF
Thursday, 22 April, 2010	- Q1 Results 2010
Tuesday, 4 May, 2010	- AGM 2010
Mid-2010	- CONSCIOUS-2 in clipped aSAH
Thursday, 22 July, 2010	- Half Year Results 2010
Thursday, 21 October, 2010	- Q3 Results 2010

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### Actelion Ltd

Actelion Ltd is a biopharmaceutical company with its corporate headquarters in Allschwil/Basel, Switzerland. Actelion's first drug Tracleer<sup>®</sup>, an orally available dual endothelin receptor antagonist, has been approved as a therapy for pulmonary arterial hypertension. Actelion markets Tracleer<sup>®</sup> through its own subsidiaries in key markets worldwide, including the United States (based in South San Francisco), the European Union, Japan, Canada, Australia and Switzerland. Actelion, founded in late 1997, is a leading player in innovative science related to the endothelium – the single layer of cells separating every blood vessel from the blood stream. Actelion's over 2,200 employees focus on the discovery, development and marketing of innovative drugs for significant unmet medical needs. Actelion shares are traded on the SIX Swiss Exchange (ticker symbol: ATLN) as part of the Swiss blue-chip index SMI (Swiss Market Index SMI<sup>®</sup>).

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## **Conference Call**

Actelion will host an Investor Conference Call / Webcast as follows:

### **Date/Time:**

18 February 2010	12:30 – 14:30	Basel (CEST)
	11:30 – 13:30	U.K. (BST)
	06:30 – 08:30	U.S. (EST)

### **Conference Call Connect #:**

Dial-in participants should start calling the number below 10-15 minutes before the Conference is due to start.

Dial:	Europe:	0041 44 580 73 89
	U.K.:	0044 808 238 9077
	U.S.:	001 866 931 15 72

### **Participant's mode:**

Listen-Only.

### **Webcast Access:**

Webcast participants should visit the Actelion website for further details <http://www.actelion.com/>

10-15 minutes before the conference is due to start. If you experience any access problems go directly to the URL: <http://gaia.world-television.com/actelion/20100218/trunc>

### **Webcast Replay:**

The archived Investor Webcast will be available for replay through <http://www.actelion.com/> approximately 60 minutes after the call has ended.