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## **Santhera's 2007 Interim Results Reflect Increased Investment in Advanced Development Pipeline**

Santhera Pharmaceuticals (SWX: SANN), a Swiss specialty pharmaceutical company with a focus on neuromuscular diseases, announced today its report for the first half of 2007, ending June 30, 2007. The report highlights the progress that the Company has made, particularly with regard to its advanced development pipeline. During the period, expenses for research and development amounted to CHF 10.7 million, an increase of 40% over 2006 reflecting the advancement of the clinical development pipeline. Gross cash burn in the first six months was CHF 15.3 million. As of June 30, 2007, Santhera had cash and cash equivalents of CHF 110.3 million.

### **Highlights of 2007 to date include**

- **First ever product filing:** In August, the European Medicines Agency (EMA) accepted the Company's filing of the Marketing Authorization Application (MAA) for its lead product SNT-MC17 (INN: idebenone) in Friedreich's Ataxia (FRDA);
- **Further expansion of the clinical pipeline:** In June, Santhera concluded an inlicensing agreement with Novartis for omigapil to develop the compound (SNT-317) for Congenital Muscular Dystrophy (CMD) and other neuromuscular indications;
- **Extension of marketing partnership:** In August, Santhera granted Takeda exclusive European marketing rights for SNT-MC17 in its second indication, Duchenne Muscular Dystrophy (DMD).

Commenting on the half-year results, Dr. Klaus Schollmeier, CEO of Santhera, said: "During the first half of 2007, we have continued to make good progress across all areas of our business. I am particularly pleased that the EMA has accepted our first ever product filing. This is a key milestone for Santhera and means we could see our first product reach the market before the end of 2008. We also completed an extended European marketing agreement with Takeda for SNT-MC17 in DMD and added a new compound to our clinical pipeline via our deal with Novartis. The financial and operational results announced today are also in line with our expectations. We anticipated a very busy 2007 and have already delivered upon a number of important milestones. Santhera continues to make rapid progress towards realizing the goal of becoming a leading specialty pharmaceutical company within the field of orphan neuromuscular diseases."

### **Solid balance sheet with cash reserves of CHF 110 million**

As of June 30, 2007, Santhera had cash and cash equivalents of CHF 110.3 million, reflecting a net cash burn in the first six months of CHF 15.3 million. Total equity at June 30, 2007, amounted to CHF 139.6 million compared to CHF 152.0 million as of December 31, 2006.

During the period, Santhera has continued to repay loans from tbG Technologiebeteiligungsgesellschaft mbH (tbG). In the first half of 2007, a further CHF 0.5 million was repaid thus reducing the Company's interest expenses. The remaining loans outstanding to tbG amount to a total of CHF 1.0 million.

### **Controlled increase in expenses, focused on research and development**

Santhera generated no revenues in the first half of 2007. In the six-month period ending June 30, 2006, Santhera recognized pro rata revenues of CHF 0.8 million from the outlicensing of its DPP-IV program to Biovitrum.

Operating expenses in the first six months of 2007 amounted to CHF 20.7 million, a 67% increase from the CHF 12.3 million spent in the same period in 2006. This increase was in line with expectations and is mainly due to CHF 5.6 million noncash-relevant expenses resulting from unvested stock options (CHF 0.7 million in first half of 2006).

Research and development (R&D) expenses amounted to CHF 10.7 million, including CHF 0.4 million noncash-relevant expenses for share-based payments, in the first six months of 2007. In the same period in 2006, R&D expenses amounted to CHF 7.6 million, including CHF 0.3 million for share-based payments. The 40% increase was mainly driven by higher costs for clinical and preclinical studies which were conducted to advance the Company's development pipeline. Other costs which contributed to this increase related to technical development and personnel expenses.

Expenses for marketing and sales (M&S) amounted to CHF 0.5 million (CHF 0 in first half of 2006) while general and administrative (G&A) expenses rose to CHF 9.4 million (CHF 5.0 million in same period in 2006). Taking into consideration that CHF 5.1 million of this amount were due to noncash-relevant expenses relating to share-based payments (CHF 0.4 million in first half of 2006), actual G&A expenses were in fact CHF 0.2 million lower in the first half of 2007 when compared to the corresponding period in 2006.

Santhera reported an operating result (EBIT) of CHF -20.7 million for the first six months of 2007 (CHF -11.6 million for the first half of 2006). The financial result during the period increased to CHF 1.6 million due to interest income from the Company's higher cash reserves and unrealized gains from currency hedging activities. The net loss that Santhera reported for the first half of 2007 increased to CHF 19.0 million compared to the net loss of CHF 11.7 million for the same period in 2006.

The cash-relevant operational key figure, the gross operating and investing cash flow, amounted to CHF -15.0 million in the first six months of 2007 compared to CHF -12.4 million in the same period in 2006. This 21% increase in operational cash burn for the first six months of 2007 is largely due to expenses for R&D activities as outlined above. This figure is based on the operating result, excluding noncash charges such as expenses for stock options, amortization and depreciation, also excluding cash flows from financing activities and net of gross profit.

#### **Outlook for the second half of 2007**

Since the beginning of the second half-year 2007, Santhera generated revenues of EUR 5.0 million from Takeda of these EUR 2.0 million was an upfront payment for the marketing rights for SNT-MC17 in DMD in Europe and EUR 3.0 million were triggered by the acceptance of the MAA filing of the by the EMEA for SNT-MC17 in FRDA.

In the coming months, Santhera intends to start two major clinical studies in the US, a Phase III trial with SNT-MC17 in FRDA and a Phase IIb trial with JP-1730 (INN: fipamezole) in Dyskinesia in Parkinson's Disease (DPD). Preparations for the new clinical program in CMD with SNT-317, a compound in-licensed from Novartis, are ongoing. As a result, the Company expects a further increase of its cash burn.

#### **Update on Santhera's clinical development portfolio**

**1. SNT-MC17 in FRDA:** On August 15, 2007, the EMEA accepted Santhera's MAA filing for SNT-MC17 for FRDA. In anticipation of the expected market launch in the second half of 2008, the Company is currently preparing prelaunch activities together with its marketing partner Takeda, who will sell the product in the European Union (EU) and Switzerland.

Although the MAA is accepted, Santhera continues its ongoing Phase III trial in Europe under an amended protocol to collect additional safety and efficacy data in a wider population of FRDA patients particularly at higher doses of SNT-MC17.

In the United States, Santhera is in advanced stages with the Food and Drug Administration (FDA) under a Special Protocol Assessment (SPA) procedure regarding the planned Phase III clinical trial. Based on the positive outcome of the collaborative study with the US National Institutes of Health, Santhera submitted a new protocol at the end of June reflecting its discussions with the FDA. The Company is expecting an agreement on the protocol under SPA in due course.

**2. SNT-MC17 in DMD:** On August 1, 2007, Santhera and Takeda signed an extension of their existing marketing partnership in the EU and Switzerland to cover the compound's second potential indication DMD. Santhera received an upfront payment of EUR 2.0 million and is entitled to milestone payments of up to EUR 18.0 million prior to the product's market launch for this indication. Under the agreement, Santhera will deliver finished goods to its partner and is entitled to ongoing royalties on product sales by Takeda on terms which are identical to those of the earlier agreement covering SNT-MC17 in FRDA.

Results of a Phase II clinical trial, that is currently ongoing at the University of Leuven, Belgium, are expected later in 2007.

**3. SNT-MC17 in Leber's Hereditary Optic Neuropathy (LHON):** The Phase IIa trial is ongoing at two centers in the UK and in Germany. In order to facilitate recruitment, Santhera recently amended the study protocol to not only allow the enrollment of acute patients but also of patients with progressive disease. Under the revised protocol, patients experiencing vision loss for up to 5 years are now eligible. The study revision will allow the assessment of the efficacy of SNT-MC17 in the treatment as well as the prevention of vision loss in such LHON patients. The study duration is reduced to 6 months of treatment and 84 patients are now planned to be enrolled. Originally, the study was designed to recruit up to 60 acute patients for a treatment period of 9 months.

**4. JP-1730 in DPD:** Preparatory work for the Phase IIb trial in the US is well advanced and almost complete. The start of recruitment for this one-month, multicenter study is planned for fall 2007. The protocol under the open US IND (Investigational New Drug) is designed to confirm the positive results of a previous Phase IIa proof-of-concept trial in a larger cohort of patients. Meanwhile, Juvantia, the compound's owner and Santhera's collaboration partner, has been granted EU patent protection for the intended formulation of JP-1730 until 2023.

**5. SNT-317 in CMD:** On June 30, 2007, Santhera signed an inlicensing agreement with Novartis under which Santhera will develop SNT-317 as a potential treatment for CMD and possibly other neuromuscular indications. A Phase II trial is expected to start by the end of 2008. Santhera paid Novartis an upfront fee of USD 500,000. Further milestone payments are due upon the start of a pivotal clinical trial and market approval. In return, Santhera has the right to use all preclinical and clinical data generated with omigapil and receives the remaining drug substance on stock at Novartis. Novartis retained a one-time buyback right for the program which is exercisable once the data from the pivotal clinical trial is available.

#### **Key Financial Information (Unaudited)**

<b>Balance Sheets</b>		
(IFRS, consolidated, in CHF thousands)	<b>June 30, 2007</b>	December 31, 2006
Cash and cash equivalents	110,338	125,662
Noncurrent assets	34,495	34,260
Other current assets	2,856	2,472
<b>Total assets</b>	<b>147,689</b>	<b>162,394</b>
Equity	139,593	152,048
Noncurrent liabilities	1,252	1,758
Current liabilities	6,844	8,588
<b>Total equity &amp; liabilities</b>	<b>147,689</b>	<b>162,394</b>

<b>Income Statements</b>		
(IFRS, consolidated, for half-year ended June 30, in CHF thousands)	<b>2007</b>	2006
Gross profit	0	781
R&D expenses	-10,685	-7,644
M&S expenses	-505	0
G&A expenses	-9,432	-4,971
Other operating result	-40	275
<b>Operating result (EBIT)</b>	<b>-20,662</b>	<b>-11,559</b>
Financial result	1,572	-51
<b>Result before taxes</b>	<b>-19,090</b>	<b>-11,610</b>
Income taxes	54	-97
<b>Net loss</b>	<b>-19,036</b>	<b>-11,707</b>

<b>Cash Flow Statements</b>		
(IFRS, consolidated, for half-year ended June 30, in CHF thousands)	<b>2007</b>	2006
<b>Gross operating/investing cash flow</b>	<b>-15,005</b>	<b>-12,401</b>
<b>Net increase in cash and cash equivalents</b>	<b>-15,324</b>	<b>-19</b>
Cash and cash equivalents at January 1	125,662	31,268
<b>Cash and cash equivalents at June 30</b>	<b>110,338</b>	<b>31,249</b>

#### Interim report January to June 2007

The consolidated financial statements of Santhera Pharmaceuticals Holding AG for the first half-year 2007 are available on the Company's Web site at [www.santhera.com](http://www.santhera.com).

### Conference call

At 15.00 CET / 14.00 UKT / 09:00 EST today August 17, 2007, Santhera will host a conference call. People interested in participating may join the teleconference facility using the following dial-in in **Switzerland +41 52 267 07 31 (no PIN code needed)**. Slides are available from the Company's Web site [www.santhera.com](http://www.santhera.com). The conference call will be recorded for playback and is available one hour after the conference call ends and for 10 days under +41 52 267 07 00 under reference 534941#.

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### About Santhera

Santhera Pharmaceuticals (SWX: SANN) is a Swiss specialty pharmaceutical company focusing on the discovery, development and marketing of small-molecule pharmaceutical products for the treatment of severe neuromuscular diseases. Santhera's vision is to become a leading specialty pharmaceutical company offering therapies for a number of indications in this area of high unmet medical need which includes many orphan indications with no current therapy.

Santhera currently has five clinical-stage development programs, three of which are investigating its lead compound, SNT-MC17 (INN: idebenone), for the treatment of Friedreich's Ataxia (FRDA), Duchenne Muscular Dystrophy (DMD) and Leber's Hereditary Optic Neuropathy (LHON). Another clinical program is investigating JP-1730 (INN: fipamezole) for the treatment of Dyskinesia in Parkinson's Disease (DPD) in cooperation with Juvantia, the compound's owner. The fifth program comprises SNT-317 (INN: omigapil) in Congenital Muscular Dystrophies (CMD), a compound in-licensed from Novartis. The most advanced program, SNT-MC17 for FRDA, is currently in Marketing Authorization Application process in Europe and in Phase III clinical development in the US while the other clinical programs are in Phase II. For further information, please visit [www.santhera.com](http://www.santhera.com).

### Corporate schedule

February 29, 2008	Publication of Annual Results 2007
April 21, 2008	Annual Shareholders' Meeting
August 22, 2008	Publication of Interim Results 2008
tbd	R&D Day

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Company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing and other political pressures. Santhera Pharmaceuticals Holding AG is providing the information in this new release as of the date of the publication, and does not undertake any obligation to update any forward-looking statements contained herein as a result of new information, future events or otherwise.