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Santhera Reports Financial Results 2008 and Successful First Product Launch

Liestal, Switzerland, February 27, 2009 – Santhera Pharmaceuticals (SIX: SANN), a Swiss specialty pharmaceutical company focused on neuromuscular diseases, today announced its financial and operational results for the year 2008 with first revenues from product sales. The results reflect the significant progress in clinical development and the transition to a product company with a first marketed drug. During the period, expenses for research and development (R&D) amounted to CHF 31.5 million, an increase of 35% over 2007, reflecting the advancements in its clinical pipeline. Net cash burn in 2008 was CHF 31.6 million compared to CHF 19.0 million in 2007. For the 2008 year-end, Santhera reported cash and cash equivalents of CHF 75.0 million.

Major events of 2008 include:

- **First product successfully launched in first regional market:** Santhera launched Catena® as first approved treatment for Friedreich’s Ataxia in Canada in late 2008. After only four months, Catena® has been prescribed for approximately 20% of the estimated patients.
- **Early approval in Europe refused:** The European Medicines Agency (EMA) issued a negative opinion on Catena® to treat Friedreich’s Ataxia, citing the still limited set of clinical data and the potential for additional near-term clinical data as primary reasons for its decision.
- **Full recruitment of pivotal trials in Friedreich’s Ataxia:** Both the US and the European Phase III trials were fully recruited by October and December 2008, respectively, keeping the programs on track for regulatory filings in 2009.
- **Additional financing:** In November, Santhera raised CHF 15.9 million in a private placement with Ares Life Sciences, strengthening the Company’s financial flexibility and supporting its cash position beyond the expected launch of Catena® in the United States and well into 2011.
- **In-place commercial operations:** Subsidiaries were incorporated in Boston and in Montréal. Senior professionals joined Santhera to coordinate and launch Catena® in Canada and later in the United States.

Key financial figures

(IFRS, consolidated, in CHF thousands)	2008	2007	Changes
Cash and cash equivalents	75,006	106,618	nm
Net increase in cash and cash equivalents	-31,612	-19,044	66%
Net sales	48	0	nm
Gross profit	25	9,226	nm
Other operating income	26	2,439	nm
Total operating expenses	-45,642	-42,792	7%
whereof R&D	-31,467	-23,335	35%
whereof noncash-relevant share-based payments	-1,680	-10,154	-84%
Net loss	-44,656	-27,871	60%

Today’s presentation to analysts (Zurich, 11:00 CET) will be available as webcast or teleconference. See page 7 for details on how to access.

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Commenting on the year-end results, Klaus Schollmeier, Chief Executive Officer of Santhera, said: "2008 was another successful year for Santhera. The activities surrounding the launch of our first product in Canada were quite productive and marked our transition to a product company. After only a few weeks, a substantial number of Friedreich's Ataxia patients had access to Catena®. Importantly, this validated our business model in orphan diseases. First, meeting an unmet medical need can translate into a high and instant awareness from prescribers and patients. Secondly, since the majority of patients are treated by few physicians and centers, we demonstrated that a small specialized team could address a significant regional market. And finally, insurers will and already have accepted our price for Catena®." He continued: "Meanwhile, our two pivotal Phase III trials are completely recruited with the first top-line data expected this coming summer and subsequent filings for marketing approval in the United States and Europe remaining on track for later in 2009. Everyone at Santhera remains fully committed to make this important drug available to patients in these regions as soon as possible."

Barbara Heller, Chief Financial Officer of Santhera, commented: "The increase in cash burn is in line with our expectations reflecting focused expenses for clinical development, costs associated with our first product launch and building of inventory of drug substance. Additionally, the first revenues from own product sales in Canada were generated in a short period of time." She added: "We continue to move forward as a lean organization with resources allocated on our key value drivers and, simultaneously, the North American markets for Catena®. The new funds raised in November provide us with additional financial flexibility and secure our cash position well beyond the planned launch in the United States. Together with the expected revenues from product sales and partnering income, Santhera could be able to independently finance its operations into 2011."

Solid balance sheet with cash reserves of CHF 75.0 million at year-end 2008

As of December 31, 2008, Santhera had cash and cash equivalents of CHF 75.0 million. Net cash burn in 2008 was CHF 31.6 million compared to CHF 19.0 million in the preceding year. Total equity at year-end 2008 amounted to CHF 104.5 million compared to CHF 135.5 million as of December 31, 2007. The Company is targeting the spending of its funds primarily at the expansion of the pipeline and the specialty sales organization in North America.

The Company's share capital was increased by 395,038 shares through a private placement with Ares Life Sciences and the exercise of employee stock options as well as warrants held by the investors of Juvantia Pharma. As of December 31, 2008, the share capital consisted of 3,513,899 registered shares with a nominal value of CHF 1 each. With the recent capital increase, Santhera remains financed through equity only.

Continued efficient cash management, expenses focused on clinical development

In 2008, Santhera generated cash income of CHF 0.1 million compared to CHF 11.7 million in 2007, representing upfront and milestone payments from Takeda and the sale of noncore intellectual property rights.

Operating expenses in 2008 amounted to CHF 45.6 million, a 7% increase from CHF 42.8 million in 2007. This increase was in line with expectations and is mainly due to the advancement of the clinical development programs.

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R&D expenses, mainly driven by the advanced clinical and regulatory status of the pipeline, amounted to CHF 31.5 million (2007: CHF 23.3 million) representing 69% of total operating expenses. Marketing and sales (M&S) amounted to CHF 3.5 million (2007: CHF 1.2 million) reflecting the build up of the North American commercial organization and expenses for the launch of Catena® in Canada. General and administration (G&A) expenses decreased to CHF 10.6 million (2007: CHF 18.2 million) due to less share-based payments.

For the year 2008, Santhera reported a net loss of CHF 44.7 million (2007: CHF 27.9 million), in line with expectations. The gross operating and investing cash flow amounted to CHF –46.5 million (2007: CHF –29.6 million), reflecting costs associated with the late-stage clinical trials and related extension studies.

Continued focus on core activities and outlook

Santhera continues to focus all resources on its key value drivers namely on SNT-MC17/idebenone in its three indications as well as JP-1730/fipamezole. Simultaneously, the Company is planning to strengthen its commercial operations in North America in anticipation of prelaunch activities in the United States to be initiated in the second half of 2009. Company-wide additional costs and new hirings are tied to the achievement of development and regulatory milestones of the pivotal Phase III trial in Friedreich's Ataxia in the United States.

According to its current financial planning, Santhera is financed well into the year 2011. The Company expects its average monthly gross cash burn to remain fairly stable. Taking into account estimated product sales in Canada as well as the US from mid-2010 onwards and potential revenues from partnering activities, the average monthly net cash burn is expected to amount to approximately CHF 2.5 to 3.0 million.

Update on products and pipeline: Focusing on key value drivers

1. Catena® in Friedreich's Ataxia

In July 2008, Health Canada approved Catena® under conditions for the treatment of Friedreich's Ataxia. The product was launched on the Canadian market in October. Four months after launch, almost 20% of the expected patient population of 300 individuals in Canada have received a prescription from their treating physicians and are being enrolled into the Catena® Support Program. Roughly half of them are privately insured. Santhera is working on national and provincial levels to apply for reimbursement for publicly insured patients.

2. SNT-MC17/idebenone in Friedreich's Ataxia

Both pivotal Phase III clinical trials are fully recruited and well advanced. In the United States, the IONIA (Idebenone effects On Neurological ICARS Assessments) trial enrolled a total of 70 patients by the end of October 2008. Top-line data are expected for summer 2009. Subject to positive outcome, the New Drug Application and the Marketing Authorization Application in the United States and in the European Union, respectively, will be filed towards the end of 2009. In Europe, the MICONOS (Mitochondrial Protection With Idebenone In Cardiac Or Neurological Outcome Study) trial enrolled a total of 232 patients by early December 2008. Top-line data from this study with predominantly adult patients are expected in the first half of 2010 and are planned to be used for regulatory purposes if required.

3. SNT-MC17/idebenone in Duchenne Muscular Dystrophy

The design of the Phase III program including the selection of primary and secondary endpoints was recently discussed with EMEA's Scientific Advise Working Party as well as the US Food and Drug Administration (FDA) during a pre-IND meeting. Santhera currently plans for one single, placebo controlled pivotal Phase III trial with study centers in Europe, in the United States and Canada. Subject to finalization, the study protocol calls for a twelve-month treatment period with approximately 200 ambulatory and nonambulatory patients at the age of 10 to 18 years. Key objectives of the trial are to investigate the effects on respiratory and muscle strength parameters. Patient recruitment is anticipated to begin in summer of 2009. The randomization of the first patient will trigger a milestone payment from European marketing partner Takeda Pharmaceutical.

4. SNT-MC17/idebenone in Leber's Hereditary Optic Neuropathy

The six-month Phase II RHODOS (Rescue Of Hereditary Optic Disease Outpatient Study) trial assesses the efficacy of one dose of SNT-MC17/idebenone against placebo in the treatment and prevention of vision loss associated with this genetically determined eye disease. Patient recruiting is well advanced and all three study centers in Munich, Germany, Newcastle, United Kingdom, and Montréal, Canada, are enrolling study participants.

5. JP-1730/fipamezole in Dyskinesia in Parkinson's Disease

Recruitment for the Phase IIb FJORD (Fipamezole From Juvantia For The Treatment Of Dyskinesia) trial is advancing according to plan. 26 study centers in the United States and 7 in India are enrolling patients. As of today, more than 100 patients have been randomized, targeted are 120 completers. FJORD investigates the capacity of JP-1730/fipamezole versus placebo to reduce levodopa-induced dyskinesia. Top-line data are expected for early second half of 2009. Santhera has initiated partnering activities for Phase III clinical development and commercialization.

6. SNT-317/omigapil in Congenital Muscular Dystrophies

Preclinical work is ongoing internally in preparation of the clinical Phase II/III development, while external clinical development work has been postponed to support Santhera's current focus on the core programs. The EMEA and FDA have both granted orphan drug designation to omigapil in the two most common subtypes of Congenital Muscular Dystrophies.

7. Melanocortin-4 (MC4) receptor antagonists in cancer cachexia

Santhera's most advanced candidates of a novel generation of MC4 receptor antagonists significantly increase food intake in healthy animals and prevent cancer-induced body weight loss in disease-relevant models. Preclinical work is expected to be completed by the end of 2009 with an anticipated entry into the clinic in 2010. Santhera is seeking to build a strategic alliance with a partner for further development and commercialization of the program.

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2008 Financial Report

The complete financial statements of Santhera Pharmaceuticals are available on the Company's Web site www.santhera.com.

Condensed Income Statements

(IFRS, consolidated, in CHF thousands)	2008	2007
Net sales	48	0
Gross profit	25	9,226
Other operating income	26	2,439
R&D	-31,467	-23,335
whereof noncash-relevant share-based payments	-401	-417
M&S	-3,484	-1,170
whereof noncash-relevant share-based payments	-261	-167
G&A	-10,624	-18,151
whereof noncash-relevant share-based payments	-1,018	-9,570
Other operating expenses	-67	-136
Operating expenses	-45,642	-42,792
whereof noncash-relevant share-based payments	-1,680	-10,154
Operating result	-45,591	-31,127
Financial result	814	2,573
Result before taxes	-44,777	-28,554
Income taxes	121	683
Net loss	-44,656	-27,871
Basic and diluted loss per share (in CHF)	-14.11	-8.99

Condensed Balance Sheets

(IFRS, consolidated, in CHF thousands)	December 31, 2008	December 31, 2007
Cash and cash equivalents	75,006	106,618
Noncurrent assets	31,641	34,588
Other current assets	6,300	2,969
Total assets	112,947	144,175
Equity	104,474	135,514
Noncurrent liabilities	263	272
Current liabilities	8,210	8,389
Total equity and liabilities	112,947	144,175

Condensed Cash Flow Statements

(IFRS, consolidated, in CHF thousands)	2008	2007
Gross operating/investing cash flow	-46,535	-29,646
Cash and cash equivalents at January 1	106,618	125,662
Cash and cash equivalents at December 31	75,006	106,618
Net change in cash and cash equivalents	-31,612	-19,044

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Share Capital

	December 31, 2008	December 31, 2007
Number of shares issued with a par value of CHF 1	3,513,899	3,118,861
Conditional capital for stock options	684,862	351,971
Conditional capital for convertible rights	490,182	230,000
whereof allocated to Juvantia investors	0	9,818
Authorized capital	429,918	561,092
whereof for the potential acquisition of Juvantia	105,973	105,973

Corporate Calendar 2009

April 27	Annual Shareholders' Meeting, Basel
September 4	Interim Report first half 2009

Webcast/Teleconference

At **11.00 CET / 10.00 UKT / 5.00 EST** on **February 27, 2009**, Santhera will host an analyst presentation in Zurich (SIX Swiss Exchange, ConventionPoint, Selnaustrasse 30, Zurich). Anyone interested in participating may join either the **webcast on www.santhera.com/webcast** or the **teleconference** using the conference **ID 87633316** and one of the following dial-ins

Germany	0221 455 3004 (local call)
Switzerland	0615 800 002 (local call)
UK	0845 146 2035 (local call)
UK	+44 (0) 1452 562 659 (standard international)
USA	1866 966 9439 (free call)

The webcast will be available for playback one hour after the analyst presentation ends.

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About Santhera

Santhera Pharmaceuticals (SIX: SANN) is a Swiss specialty pharmaceutical company focused on the discovery, development and commercialization of small-molecule pharmaceutical products for the treatment of severe neuromuscular diseases, an area of high unmet medical need which includes many orphan indications with no current therapy. Santhera's first product, Catena® has received a marketing approval from Health Canada to treat Friedreich's Ataxia. The drug is investigated in two fully recruited pivotal trials in the United States and in Europe. The same compound has also shown efficacy in a Phase II clinical trial as a potential treatment for Duchenne Muscular Dystrophy. For further information, please visit the Company's Web site www.santhera.com.

Catena® is a trademark of Santhera Pharmaceuticals, registered in Canada and the United States.

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