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Santhera’s 2008 Interim Results Reflect Advances in Clinical Development and Preparation for First Product Launch

Liestal, Switzerland, August 22, 2008 – Santhera Pharmaceuticals (SWX: SANN), a Swiss specialty pharmaceutical company with a focus on neuromuscular diseases, announced today its results for the first half year, ending June 30, 2008. The interim results highlight the progress in the Company’s development programs and preparations for the launch of Santhera’s first product. During the reporting period, research and development (R&D) amounted to CHF 15.7 million, reflecting expenses associated with the advanced stages of the ongoing studies as well as additional clinical trials. Net cash burn in the first six months of 2008 was CHF 25.6 million compared to CHF 15.3 million in the first half of 2007. As of June 30, 2008, Santhera had cash reserves of CHF 81.1 million. The Company continues to focus its resources on the launch preparation of CATENA® in Canada and its core development programs.

Major events of 2008 to date include

- **First product approval:** In July, Health Canada approved under conditions Catena for symptomatic treatment of Friedreich’s Ataxia. Product launch is scheduled for late October 2008.
- **Pivotal Phase III trials in Friedreich’s Ataxia well-advanced:** Recruitment for the two trials with SNT-MC17/idebenone in Europe and in the United States is close to complete.
- **Regulatory delay in Europe:** In its July meeting, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) issued a negative opinion on SNT-MC17/idebenone to treat Friedreich’s Ataxia.
- **Commercial operations on track:** Two subsidiaries in North America set up to coordinate and launch Catena in Canada and later in the United States.

Financial key data

(IFRS, consolidated, for half-year ended June 30, in CHF thousands)

	2008	2007	Changes
Cash and cash equivalents	81,078	110,338	nm
Net cash burn	25,563	15,324	67%
Total operating expenses	22,620	20,662	10%
whereof R&D	15,725	10,685	47%
Net loss	23,255	19,036	22%

Conference call / Webcast: At 15:00 CET / 14:00 UKT / 9:00 EST today August 22, 2008, Santhera will host a conference call webcasted on www.santhera.com/webcasts. Anyone interested in participating may join the conference using the dial-in +41 (0)44 580 73 80.

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Commenting on the operational results, Klaus Schollmeier, CEO of Santhera, said: "The contrasting decisions from the Canadian and European health authorities represent the high and low points of this year. The approval for Catena in Canada is Santhera's most important achievement so far since this positive news marks our transformation into a product company. For the first time, Friedreich's Ataxia patients have access to a safe, efficacious and approved therapy to treat their devastating disease. On the other hand, the surprising rejection by the CHMP is a disappointment for us and the Friedreich's Ataxia community in Europe. It means that the launch of this important drug in the EU could be postponed by up to two years. We remain committed to working with the CHMP to make SNT-MC17/idebenone available for patients in Europe, as soon as possible."

Commenting on the financial results, Barbara Heller, CFO of Santhera, said: "The increase in cash burn is in line with our expectations. It reflects primarily expenses for clinical development and the preparations for our first product launch as well as investments in inventory of active ingredient for the launch later this year. We continue to move forward as a lean organization with resources focused on our key value-drivers. Simultaneously, we are preparing our organization for the successful market launch of Catena in Canada."

Solid balance sheet with cash reserves of CHF 81 million by mid-year 2008

As of June 30, 2008, Santhera had cash and cash equivalents of CHF 81.1 million reflecting a net cash burn of CHF 25.6 million in the first six months of 2008 compared to CHF 15.3 million in the first half of 2007. Total equity by mid-year 2008 amounted to CHF 112.2 million compared to CHF 135.5 million as of December 31, 2007.

The Company's issued and outstanding share capital was increased by CHF 14,279 through the exercise of employee stock options and warrants held by the shareholders of Juvantia Pharma, equaling to 4,461 and 9,818 new shares, respectively. As of June 30, 2008, the issued nominal share capital amounted to CHF 3,133,140 divided into 3,133,140 registered shares.

During the reporting period, Santhera built up an inventory of active pharmaceutical ingredient to the amount of CHF 4.6 million for the anticipated launch of SNT-MC-17/idebenone in Friedreich's Ataxia.

Foreign currency developments increased the fair value of the short-term financial liabilities consisting of forward contracts to CHF 1.1 million.

Expenses focused on clinical development

Operating expenses amounted to CHF 22.6 million including CHF 0.9 million noncash-relevant expenses for share-based payments, compared to CHF 20.7 million and CHF 5.6 million noncash-relevant expenses for share-based payments in the same period 2007. This 10% increase was in line with expectations and is mainly due to the advancement of the clinical development programs. No revenues were generated in both the first half of 2008 as well as in 2007.

Expenses for R&D amounted to CHF 15.7 million including CHF 0.2 million noncash-relevant expenses for share-based payments for the first half of 2008. In the preceding year, R&D accounted for CHF 10.7 million including CHF 0.4 million noncash-relevant expenses for share-based payments. The increase of 47% reflects the advancements of the clinical programs, in particular the

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three additional studies, namely the MICONOS (Mitochondrial Protection With Idebenone In Cardiological Or Neurological Outcome Study) extension study in Europe, the IONIA (Idebenone Effects On Neurological ICARS Assessments) Phase III trial in the United States, both in Friedreich's Ataxia, and the FJORD (Fipamezole from Juvantia fOR treatment of Dyskinesia) Phase IIb trial in Dyskinesia in Parkinson's Disease.

Preparing for the commercialization of the first products, expenses for marketing and sales (M&S) increased to CHF 1.5 million including CHF 0.1 million noncash-relevant expenses for share-based payments compared to CHF 0.5 million and CHF 0.1 million in the first half of 2007.

Expenses for general and administration (G&A) decreased from CHF 9.4 million in the first six months of 2007 to CHF 5.4 million in the reporting period due to a reduction of noncash-relevant expenses for share-based payments from CHF 5.1 million in 2007 to CHF 0.5 million in 2008. Actual cash-relevant G&A expenses slightly increased by CHF 0.6 million due to higher personnel expenses and costs incurred in connection with the incorporation of the two North American subsidiaries, in the United States in Boston, Massachusetts, and in Canada in Montréal, Québec.

For the first half of 2008, the operating result of Santhera amounted to CHF –22.6 million compared to CHF –20.7 million. The financial result fell to CHF –0.6 million compared to CHF 1.6 million in 2007 due to fair value valuation of currency hedging contracts and currency losses of the Swiss franc against the US dollar and the euro. As a consequence, for the first half of 2008, the Company reported a net loss of CHF 23.3 million, an increase of 22% over CHF 19.0 million for the same period in 2007.

The cash-relevant operating key figure, the gross operating and investing cash flow, increased by 70% to CHF –25.5 million (CHF –15.0 million in first half of 2007). The figure primarily reflects the higher expenses in clinical development, in regulatory activities surrounding the Canadian and EU approval processes and the one-time build up of inventory. As a result, the net burn rate for the first six months 2008 amounted to CHF 25.6 million or CHF 4.3 million per month compared to CHF 15.3 million or CHF 2.6 million in the corresponding period of the preceding year.

Continuing focused cash spending and outlook

Santhera is building its commercial operations in North America in preparation of the launch of its first product in Canada. Simultaneously, the Company continues to focus financial and human resources on its key value drivers namely on SNT-MC17/idebenone and JP-1730/fipamezole. Santhera expects cash burn to remain at the same level as reported for the first six months of 2008. The Company is convinced that the tight focus of its resources preserves cash while maximizing the value of its two core franchises.

Update on products and pipeline: Focusing on key value-drivers

1. **CATENA[®] (idebenone) in Friedreich's Ataxia:** Shipment of the drug is on track for the launch in Canada in late October 2008. The drug will be marketed by Santhera's own specialized marketing team. Canada has granted use patent protection until 2019.

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- 2. SNT-MC17/idebenone in Friedreich's Ataxia:** Santhera requested reexamination of the original negative opinion adopted by the CHMP in its July meeting. A final decision could be reached within the forthcoming months. Despite this appeal, Santhera is focused on completing its two well-advanced Phase III trials in order to apply for marketing authorizations in Europe and in the United States during the second half of 2009.

In Europe, the 12-month MICONOS Phase III trial is on track for full recruitment by the end of this year. Meanwhile, 48 patients have completed the study and were enrolled into the open-label extension study on the high dose.

In the United States, the minimum of 51 patients are enrolled into the IONIA Phase III trial as defined by the study protocol. Given the current prospect of additional patients, Santhera expects to complete recruitment of up to 65 patients by the forth quarter of 2008.

- 3. SNT-MC17/idebenone in Duchenne Muscular Dystrophy:** Scientific advice meetings with the EMEA and the US Food and Drug Administration (FDA) are being scheduled for later in 2008. Based on these discussions, the initiation of a European Phase III clinical trial is now planned for the first half of 2009.

In Belgium, the open-label extension study for participants of the DELPHI (Duchenne Efficacy Study In Long-Term Protocol Of High Dose Idebenone) trial, of which results were reported in 2007, is expected to start in early fall 2008.

- 4. SNT-MC17/idebenone in Leber's Hereditary Optic Neuropathy:** A third study center was recently opened in Montréal, Québec, for the RHODOS (Rescue Of Hereditary Optic Disease Outpatient Study) trial. The six-month Phase II study assesses the efficacy of SNT-MC17/idebenone against placebo in the treatment and prevention of vision loss associated with the eye disease.

- 5. JP-1730/fipamezole in Dyskinesia in Parkinson's Disease:** Study centers in the United States and India are recruiting patients for the FJORD Phase IIb trial while the first patients have already completed the study. The protocol is currently under review in order to focus on the capacity of JP-1730/fipamezole to reduce dyskinesia versus reduction of dyskinesia and extension of antiparkinsonian action of levodopa. The amendments are designed to make the study management easier and to increase recruitment speed. Santhera is evaluating partnering opportunities for advancing the program to Phase III.

- 6. SNT-317/omigapil in Congenital Muscular Dystrophy:** To support the current focus on the core programs, Santhera has postponed external development work, while internal preparation for this Phase II/III program continues. Meanwhile, the compound has been granted orphan drug designation by the EMEA and the FDA for the indication.

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Condensed Balance Sheet (unaudited)

(IFRS, consolidated, in CHF thousands)	June 30, 2008	December 31, 2007
Cash and cash equivalents	81,078	106,618
Noncurrent assets	33,939	34,588
Other current assets	6,280	2,969
Total assets	121,297	144,175
Equity	112,241	135,514
Noncurrent liabilities	274	272
Current liabilities	8,782	8,389
Total equity and liabilities	121,297	144,175

Condensed Income Statement (unaudited)

(IFRS, consolidated, for half-year ended June 30, in CHF thousands)	2008	2007
Gross profit	0	0
R&D	-15,725	-10,685
M&S	-1,464	-505
G&A	-5,406	-9,432
Other operating result	-25	-65
Operating result	-22,620	-20,662
Financial result	-635	1,572
Result before taxes	-23,255	-19,090
Income taxes	0	54
Net loss	-23,255	-19,036

Condensed Cash Flow Statement (unaudited)

(IFRS, consolidated, for half-year ended June 30, in CHF thousands)	2008	2007
Gross operating/investing cash flow	-25,491	-15,006
Net increase in cash and cash equivalents	-25,540	-15,324
Cash and cash equivalents at June 30	81,078	110,338

The full consolidated financial statements of Santhera Pharmaceuticals Holding AG for the first half-year 2008 are available on the Company's Web site at www.santhera.com/reports.

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About Santhera

Santhera Pharmaceuticals (SWX: SANN) is a Swiss specialty pharmaceutical company focused on the discovery, development and marketing 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 currently investigates three compounds in five clinical-stage development programs. The Company's first product, SNT-MC17 (INN: idebenone), has received a marketing approval with conditions from Health Canada to treat Friedreich's Ataxia and will be marketed under its brand name Catena. The product is also under review by health authorities in the EU and in Switzerland, while in the United States, a pivotal Phase III trial is recruiting patients. The 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 website www.santhera.com.

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

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