Santhera Pharmaceuticals Holding AG
Hammerstrasse 47
CH-4410 Liestal / Switzerland
Phone +41 (0)61 906 89 50
Fax +41 (0)61 906 89 51
www.santhera.com

Santhera Reports Solid 2009 Interim Financial Results; Well Funded into H2 2011

Liestal, Switzerland, September 4, 2009 – Santhera Pharmaceuticals (SIX: SANN), a Swiss specialty pharmaceutical company focused on orphan neuromuscular diseases, announced today the results for the first half year ending June 30, 2009. During the reporting period, Catena® achieved net sales of CHF 0.5 million in Canada, slightly better than anticipated. Net cash burn in the first six months of 2009 was CHF 21.6 million compared to CHF 25.5 million in the first half of 2008. As of June 30, 2009, Santhera had cash and cash equivalents of CHF 53.4 million. Considering milestone (EUR 5.0 million from Takeda) and upfront payments (USD 8.0 million from new partner Biovail), which Santhera received after the close of the books for the 2009 Interim Report, the pro forma cash position amounts to CHF 69.8 million.

Major events of 2009 to date include

- Catena® in Canada: Continued success with commercialization of first product**,** now approximately 40% of the expected patient population on prescription and 50 patients on drug;
- Regional partnering of JP-1730/fipamezole for Dyskinesia in Parkinson's Disease: License signed with Biovail for development and commercialization in North America;
- Juvantia acquisition: All rights to JP-1730/fipamezole secured through exercise of call option;
- FJORD Phase IIb study with JP-1730/fipamezole: Safety and efficacy confirmed in reduction of levodopa-induced dyskinesia and additional clinically meaningful benefits observed;
- DELOS Phase III study with Catena®/Sovrima®: First patient randomized in Duchenne Muscular Dystrophy triggering Takeda milestone payment;
- IONIA Phase III study with Catena®/Sovrima®: Disappointing results from first pivotal trial in Friedreich's Ataxia;
- Catena® Named-Patient Program: Extension into Europe signed with Takeda;
- Restructuring: Resources aligned to safeguard strategic flexibility until after approvals of Catena®/Sovrima® in Friedreich's Ataxia.

Financial key data

(IFRS, consolidated, for half year ended June 30, in CHF thousands)	**2009**	2008	Changes
Cash and cash equivalents	**53,442**	75,006[1]	nm
Pro forma cash and cash equivalents*	**69,752**	n/a	nm
Net change in cash and cash equivalents	**–21,564**	–25,540	–16%
Net sales	**463**	0	nm
Gross profit	**365**	0	nm
Total operating expenses	**–24,893**	–22,620	10%
whereof R&D	**–16,876**	–15,725	7%
Net loss	**–23,407**	–23,255	1%

[1] As of December 31, 2008 * Pro forma adjusted by milestone and upfront payments subsequent to June 30, 2009

Commenting on the operational results, Klaus Schollmeier, Chief Executive Officer of Santhera, said: “The positive FJORD results and the subsequent licensing of JP-1730/fipamezole to Biovail in North America mark the highlights of the first months of this year. The successful partnering of our second compound is a significant milestone in the development of our Company as it moves Santhera a big step towards our goal of becoming a neuromuscular specialty pharmaceutical company with a sustainable revenue stream from our products and pipeline. Importantly, this success allows us to build Santhera on several product franchises”.

Commenting on the financial results, Barbara Heller, Chief Financial Officer of Santhera, said: “The results of the first half of 2009 are in line with our expectations. We continue our strict cash management and initiated a restructuring program while focusing on the key assets on the market and in development. Our sales in Canada together with income from our partnerships ensure that the Company is financed well into the second half of 2011”.

Solid balance sheet with a cash position of CHF 53.4 million (pro forma CHF 69.8 million) at mid-year 2009

As of June 30, 2009, Santhera had cash and cash equivalents of CHF 53.4 million, reflecting a net change of CHF 21.6 million in the first six months of 2009 compared to CHF 25.5 million in the same reporting period of 2008, primarily as a result of strict cost control. Total equity at mid-year 2009 amounted to CHF 82.6 million compared to CHF 104.5 million as of December 31, 2008. In line with the focus on its core activities, Santhera is targeting the spending of its funds primarily on the continuous marketing efforts in Canada, its core assets in development Catena®/Sovrima® and JP-1730/fipamezole.

Santhera’s share capital was increased by the exercise of employee stock options. As of June 30, 2009, the share capital consisted of 3,522,715 registered shares with a nominal value of CHF 1 each.

Efficient cash management; 68% of total operating expenses allocated to R&D

In the first six months of 2009, Santhera generated net sales of CHF 0.5 million from the sale of Catena® in Canada and a gross profit of CHF 0.4 million. Subsequently to the half-year closing and before the publication of this half-year report, Santhera recognized income from milestone and upfront payments of CHF 16.3 million.

Operating expenses in the first half of 2009 amounted to CHF 24.9 million, a 10% increase over the same period in 2008. This change is in line with expectations and mainly due to the advancement of the clinical development programs and the North American commercial operations. The expenses in Research and Development (R&D) of CHF 16.9 million (2008: CHF 15.7 million) reflect higher costs associated with fully recruited clinical trials and extension studies. In the first six months of 2009, R&D represented 68% of total operating expenses. Marketing and Sales (M&S) increased to CHF 2.0 million or 8% of total operating expenses (2008: CHF 1.5 million) reflecting the costs of a fully operational, yet small commercial organization. General and administrative expenses amounted to CHF 6.0 million or 24% of total operating expenses, including expenses for corporate finance and business development activities (2008: CHF 5.4 million).

For the first half of 2009, Santhera reported a net loss of CHF 23.4 million, almost on the same level as in 2008 (CHF 23.3 million) and in line with expectations.

Focus continues on core activities; outlook

Since the beginning of the second half of 2009, Santhera has received a total of CHF 16.3 million as milestone and upfront payments. The randomization of the first patient into the DELOS Phase III study with Catena®/Sovrima® in Duchenne Muscular Dystrophy triggered a milestone payment of EUR 5.0 million from Takeda Pharmaceutical Company, marketing partner in the European Union and Switzerland. Santhera also received USD 8.0 million from Biovail Corporation as upfront fee for partnering its JP-1730/fipamezole program in North America. As a consequence, the pro forma adjusted cash position of Santhera as of June 30, 2009, amounts to CHF 69.8 million. A further milestone payment of USD 4.0 million will be due from new partner Biovail upon the closing of the acquisition of Juvantia.

In connection with its partnering activities for JP-1730/fipamezole, Santhera exercised its option to acquire Oy Juvantia Pharma Ltd, the owner of the compound, and will issue up to 105,973 previously reserved shares from its authorized capital to the shareholders of Juvantia.

In July, Santhera announced plans to align its resources and to continue the focus of its financial and human resources on the Company's key value drivers, namely on Catena®/Sovrima® as well as JP-1730/fipamezole. The restructuring effectively results in a reduction in headcount primarily in drug discovery by 23 persons. Santhera's core pharmacology and medicinal chemistry know-how in neuromuscular diseases, however, is maintained and fully operational. The Company expects total restructuring costs in the amount of CHF 1.3 million, whereof CHF 0.5 million will be cash relevant.

For the second half of 2009, Santhera anticipates to be close to cash break even with an expected net cash burn of approximately CHF 3.0 million for the period. An average net cash burn of CHF 2.0 to 2.5 million per month is expected over the planning period until end of 2010. According to this current financial planning, the Company is well funded into the second half of 2011, i.e. beyond the potential marketing approvals for Catena®/Sovrima® in Friedreich's Ataxia in the US and Europe.

Update on products and pipeline: Focusing on key value drivers

1. Catena®/Sovrima® in Friedreich's Ataxia

Sales of Catena® in Canada continue on a steady hike. By the end of August, approximately 120 patients or 40% of the expected patient population of 300 individuals in Canada have received a prescription from their treating physician with an even split of private and public insurance coverage. Catena® has been shipped to 50 sufferers, among them a growing number of patients with public insurers. Santhera is in ongoing negotiations with public and private payors to secure reimbursement on both national and provincial levels.

In response to requests from patients and physicians, Santhera extended its Named-Patient Program (NPP) into Europe to make Catena® available on an individual basis and to bridge the time until regulatory approval is received. The Catena® NPP is managed by Idis, a global leader in the development and implementation of such programs.

The twelve-month MICONOS study with 232 patients enrolled is well advanced and data from this pivotal study are expected in the first half of 2010. Subject to positive outcome, Santhera intends to file a New Drug Application for Catena® in the United States and a Marketing Authorization Application for Sovrima® (Takeda's brand name for the drug in Europe) in the European Union in the second half of 2010.

2. Catena®/Sovrima® in Duchenne Muscular Dystrophy

The first patient was recently enrolled into the pivotal DELOS study. The primary endpoint of this twelve-month, double-blind, placebo-controlled Phase III study is the change in respiratory function measured by peak expiratory flow. The study is expected to enroll up to 240 ambulatory and nonambulatory patients and involve up to 25 centers in Europe and North America. Both the US Food and Drug Administration (FDA) and the European Medicines Agency agreed that a single pivotal study could suffice for approval.

3. Catena® in Leber's Hereditary Optic Neuropathy

At the end of July, the last of 85 patients was enrolled into the six-month Phase II RHODOS study. The Phase II study investigates the efficacy of Catena® in improving visual function in this disease causing rapid and complete vision loss. Data of the RHODOS study are expected in the first half of 2010.

4. Catena® in MELAS syndrome

The first patients are being randomized into the one-month MELTIMI study. The double-blind, placebo-controlled Phase II study is being performed in collaboration with the Columbia University, New York. Data of this proof-of-concept study are expected in the first half of 2010. Meanwhile, the FDA granted orphan drug designation to the program.

5. Catena® in Primary Progressive Multiple Sclerosis

The US National Institutes of Health have enrolled the first patient into the natural history phase of the IPPoMS study. The Phase I/II study is conducted in collaboration with Santhera and consists of a one-year observational and a two-year interventional period.

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

The recently completed FJORD Phase IIb study demonstrated that JP-1730/fipamezole reduces Dyskinesia in Parkinson's Disease without exacerbating the underlying Parkinsonian features of the disease. The study results also suggest that the drug has the potential to reduce "off time" and improve cognitive function. Furthermore, the reduction in dyskinesia was found to be strongly correlated with the investigator's clinical global impression of improvement in overall.

In August, Biovail acquired the US and Canadian rights to develop and commercialize the drug for the treatment of levodopa-induced Dyskinesia in Parkinson's Disease. Under the terms of the agreement Santhera received an upfront fee of USD 8.0 million and is entitled to another payment of USD 4.0 million upon closing the acquisition of Juvantia and to up to USD 180.0 million in development and commercialization milestones plus royalties on future sales of 8 to 15%. Santhera retains copromotion rights in the United States. The process to partner the program in other territories is ongoing.

7. SNT-317/omigapil in Congenital Muscular Dystrophies

Discussions with patient organizations to support the clinical development are well advanced. Santhera intends to reinitiate internal and external work once the funding of the program is secured.

8. Melanocortin-4 (MC4) receptor antagonists in Cancer Cachexia

A potent preclinical candidate with an impressive efficacy and oral bioavailability profile has been selected and is undergoing further preclinical studies. Activities to partner the program with an oncology specialist for further development and commercialization are ongoing.

Condensed income statement (unaudited)		
(IFRS, consolidated, for half-year ended June 30, in CHF thousands)	**2009**	2008
Net sales	463	0
Gross profit	365	0
Research and Development	–16,876	–15,725
Marketing and Sales	–1,971	–1,464
General and Administration	–6,016	–5,406
Other operating expenses	–30	–25
Total operating expenses	**–24,893**	–22,620
Operating result	**–24,528**	–22,620
Financial result	1,155	–635
Income taxes	–34	0
Net loss	**–23,407**	–23,255

Condensed balance sheet (unaudited)		
(IFRS, consolidated, in CHF thousands)	**June 30, 2009**	December 31, 2008
Cash and cash equivalents	53,442	75,006
Pro forma cash and cash equivalents*	69,752	n/a
Noncurrent assets	32,006	31,641
Other current assets	5,785	6,300
Total assets	**91,233**	**112,947**
Equity	82,550	104,474
Noncurrent liabilities	342	263
Current liabilities	8,341	8,210
Total equity and liabilities	**91,233**	**112,947**

* Pro forma adjusted by milestone and upfront payments subsequent to June 30, 2009

Condensed cash flow statement (unaudited)		
(IFRS, consolidated, for half-year ended June 30, in CHF thousands)	**2009**	2008
Gross operating/investing cash flow	**–22,013**	–25,491
Net change in cash and cash equivalents	–21,564	–25,540
Cash and cash equivalents at January 1	75,006	106,618
Cash and cash equivalents at June 30	**53,442**	81,078

The 2009 Interim Report of Santhera Pharmaceuticals including the consolidated financial statements is available on the Company's Web site under www.santhera.com/reports.

* * *

About Santhera

Santhera Pharmaceuticals (SIX: SANN) is a Swiss specialty pharmaceutical company focused on the 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® to treat Friedreich's Ataxia, is marketed in Canada and in a well-advanced Phase III development program. Recently published study results show that the Company's second compound JP-1730/ fipamezole is efficacious in reducing levodopa-induced Dyskinesia in Parkinson's Disease. For further information, please visit the Company's Web site www.santhera.com.

Catena® is a trademark of Santhera Pharmaceuticals.

Webcast / Teleconference

At **15.00 CET / 14.00 UKT / 09.00 EST** on **September 4, 2009**, Santhera's management will discuss the Interim Results. Anyone interested in participating may join either the **webcast on www.santhera.com/webcast** or the **teleconference (ID: 28750892)** using one of the following dial-ins

Switzerland	0565 800 007 (local call)
United States	1866 966 9439
Canada	1866 966 0399
Germany	0692 222 3479
United Kingdom	0844 493 3800
International	+44 (0) 1452 555 566

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

For further information, contact

Klaus Schollmeier, Chief Executive Officer
Phone: +41 (0)61 906 89 52
klaus.schollmeier@santhera.com

Barbara Heller, Chief Financial Officer
Phone: +41 (0)61 906 89 54
barbara.heller@santhera.com

Thomas Staffelbach, Head Public & Investor Relations
Phone: +41 (0)61 906 89 47
thomas.staffelbach@santhera.com

Disclaimer/Forward-looking statements

This communication does not constitute an offer or invitation to subscribe for or purchase any securities of Santhera Pharmaceuticals Holding AG. This publication may contain certain forward-looking statements concerning the Company and its business. Such statements involve certain risks, uncertainties and other factors which could cause the actual results, financial condition, performance or achievements of the Company to be materially different from those expressed or implied by such statements. Readers should therefore not place undue reliance on these statements, particularly not in connection with any contract or investment decision. The Company disclaims any obligation to update these forward-looking statements.