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Santhera Reports Increase in Product Sales, Positive Net Result for 2015 and Progress in All Programs

Liestal, Switzerland, April 12, 2016 – Santhera Pharmaceuticals (SIX: SANN) announces increasing income from product sales, a positive net result for 2015 and significant progress in all development programs. Net revenues grew by 67% to CHF 4.3 million in sales of the lead product Raxone[®] for the treatment of Leber’s hereditary optic neuropathy (LHON). For 2015, the Company reported a positive net result of CHF 5.9 million influenced by a revaluation of intangible assets and inventory. Cash and cash equivalents by year-end amounted to CHF 76.9 million. Commercial rollout for Raxone for the treatment of LHON in the EU and filing preparations for Duchenne muscular dystrophy (DMD) in the EU and the US are on track.

2015 Annual Results and a Company update will be presented today by Thomas Meier, PhD, Chief Executive Officer of Santhera, during the “Investor & Analyst Track” sessions (at 13.30 hrs) at the Swiss Biotech Day in Basel.

“We are very excited about Santhera’s progress last year,” commented **Thomas Meier**, PhD, Chief Executive Officer of Santhera. “Our first product approval and launch in the EU marked a transforming milestone towards a fully-integrated specialty pharmaceutical company. The pan-European roll-out of Raxone for the treatment of LHON is ongoing and we are preparing for regulatory filings and market entry for DMD, the product’s second indication.”

“The successful financing transactions in 2015 demonstrated the enthusiasm of shareholders and investors about the progress and prospects of Santhera,” added **Christoph Rentsch**, Chief Financial Officer of Santhera. “Our Company is well financed and we have adequate resources to execute our current commercial and development plans.”

Corporate and Pipeline Highlights:

- **Strong top-line growth**

Net revenue from product sales in 2015 rose to CHF 4.3 million, a 67% increase compared to the previous year (2014: CHF 2.6 million). Net revenues in Q4 2015, the first full quarter post approval, were CHF 1.9 million. In Q1 2016 sales reached CHF 3.3 million, corresponding to a 75% increase compared to Q4 2015.

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- **Successful commercialization of Raxone drives strong sales development**

On September 9, 2015, Santhera received marketing authorization for Raxone for the treatment of LHON in all EU member states, Norway, Iceland and Liechtenstein. By end of Q1 2016, sales were reported primarily for Germany and France with additional sales also reported for several other countries. Based on the number of packs sold, it is estimated that as of end of March 2016, there were approximately 220 patients receiving Raxone for the treatment of LHON in Europe.

- **Positive operating result for 2015**

Development expenses increased to CHF 10.5 million (2014: CHF 5.9 million) due to costs associated with regulatory filings and study preparation. The launch preparations and market entry for LHON in Europe resulted in marketing and sales expenses of CHF 8.4 million (2014: CHF 0.6 million) and general and administrative expenses of CHF 8.2 million (2014: CHF 4.4 million). Approval of Raxone for LHON allowed for the reversal of a previous impairment charge of CHF 27.1 million (related to LHON development costs) and inventory and led to an improvement of the operating result from CHF –23.9 to CHF 3.2 million (2014: CHF –7.9 million).

- **Positive net result of CHF 5.9 million**

For the full-year 2015, Santhera reported a net result of CHF 5.9 million (2014: CHF –8.0 million).

- **Successful financing, CHF 82.4 million raised**

The Company realized an aggregate gross amount of CHF 82.4 million (net: CHF 80.5 million) through the issuance of newly created shares and private share placements which, together with increasing income from product sales, substantially improved the financial flexibility and cash reach.

- **Strong cash position secures development and commercialization plans**

As of December 31, 2015, Santhera had cash and cash equivalents of CHF 76.9 million (2014: CHF 17.4 million), which corresponds to a net year-on-year increase of CHF 59.4 million (2014: CHF 12.4 million). The cash position as of March 31, 2016, was CHF 69.4 million.

- **Strengthening the organization**

By year-end 2015, Santhera had 59 employees. By end of March 2016, the number of employees further increased to 65 (representing 59.4 full-time equivalents), predominantly in marketing and sales as well as clinical development functions.

Outlook

Santhera's priorities for Raxone are its continued commercial rollout for the treatment of LHON across the EU and the regulatory approval and market entry to treat DMD both in the EU and the USA. Complementing its own commercialization efforts in key European countries, in January 2016 Santhera entered into a distribution and supply agreement with Ewopharma to support the launch of Raxone for the treatment of LHON in 11 countries in Eastern Europe and the Baltics.

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Following the successful outcome of the phase III DELOS clinical trial, Santhera has already held pre-submission meetings with European regulators and in the coming weeks plans to submit a Marketing Authorization Application (MAA) for the treatment of DMD patients not using glucocorticoids as a type II variation of the existing marketing authorization for LHON. In the USA, Santhera will imminently submit a meeting request and comprehensive briefing material in preparation for a pre-NDA meeting with the FDA to discuss an NDA filing for DMD.

On the development side, given the clear medical need to address respiratory function decline in all DMD patients, Santhera has initiated a new clinical trial with Raxone in patients using glucocorticoids (SIDEROS). A successful outcome of this trial will offer the potential for a future labeling extension to add the treatment of DMD patients using glucocorticoids. Clinical development programs with Raxone in primary progressive multiple sclerosis (PPMS) and omigapil in congenital muscular dystrophies (CMD) are also progressing.

Santhera believes that, with cash reserves of CHF 69.4 million (March 31, 2016) and the option to use conditional and authorized capital, it has sufficient financial flexibility to support the commercialization of Raxone in Europe and its ongoing development and regulatory projects.

Additional Information

For additional information, please visit the Company's website at www.santhera.com where the [Annual Report 2015](#) and the [Company Presentation](#) (from 15:00 hrs) given at the Swiss Biotech Day will be available.

Upcoming Events

The Annual Shareholders' Meeting of Santhera will be held on May 11, 2016, in Basel, Switzerland (shareholders will receive a separate invitation).

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2015 Full-Year Financial Information

See www.santhera.com/reports for the Santhera 2015 Annual Report.

Condensed Consolidated Income Statement (IFRS, in CHF thousands)	2015	2014 Restated ¹
Net sales	4,321	2,591
Cost of goods sold	-1,371	-199
Other operating income	188	533
Development	16,651	-5,876
Marketing and sales	-8,356	-580
General and administrative	-8,244	-4,395
Other operating expenses	-16	-9
Operating expenses	35	-10,860
Operating result	3,173	-7,935
Financial result	-239	-15
Income taxes	3,015	-2
Net result	5,949	-7,952
Basic earnings/loss per share (in CHF)	1.11	-1.69
Diluted earnings/loss per share (in CHF)	1.08	-1.69

Condensed Consolidated Balance Sheet (IFRS, in CHF thousands, as of December 31)	2015	2014 Restated ¹
Cash and cash equivalents	76,859	17,435
Noncurrent assets	33,208	4,491
Other current assets	7,085	1,096
Total assets	117,152	23,022
Equity	106,247	17,315
Noncurrent liabilities	3,957	2,680
Current liabilities	6,948	3,027
Total equity and liabilities	117,152	23,022

Condensed Consolidated Cash Flow Statement (IFRS, in CHF thousands)	2015	2014 Restated ¹
Cash flow from operating activities	-22,390	-6,063
Cash and cash equivalents at January 1	17,435	5,044
Cash and cash equivalents at December 31	76,859	17,435
Net change in cash and cash equivalents	59,424	12,391

Share Capital (number of shares with par value of CHF 1, as of December 31)	2015	2014
Shares issued	6,262,798	4,974,492
Conditional capital for stock options	401,694	604,029
Conditional capital for convertible rights	650,000	600,000
Authorized capital	910,000	1,500,000

¹ Some positions have been restated, see Annual Report 2015, note 2 "Correction of errors".

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About Santhera

Santhera Pharmaceuticals (SIX: SANN) is a Swiss specialty pharmaceutical company focused on the development and commercialization of innovative pharmaceutical products for the treatment of orphan mitochondrial and neuromuscular diseases. Santhera's lead product Raxone® is authorized in the European Union for the treatment of Leber's hereditary optic neuropathy (LHON). Santhera develops Raxone® in two additional indications, Duchenne muscular dystrophy (DMD) and primary progressive multiple sclerosis (PPMS), and omigapil for congenital muscular dystrophy (CMD), all areas of high unmet medical need. For further information, please visit the Company's website www.santhera.com.

Raxone® and Catena® are trademarks of Santhera Pharmaceuticals.

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