

ANNUAL REPORT

**2014**

## Financial Key Figures

|   | IFRS consolidated, in CHF thousands | 2014    | 2013   |
|---|-------------------------------------|---------|--------|
| Net sales                                 |                                     | 2,591   | 1,319  |
| Operating expenses                        |                                     | -10,442 | -8,744 |
| Operating result                          |                                     | -7,517  | -7,309 |
| Net result                                |                                     | -7,534  | -5,755 |
| Basic and diluted loss per share (in CHF) |                                     | -1.60   | -1.55  |
| Cash and cash equivalents at December 31  |                                     | 17,435  | 5,044  |
| Net change in cash and cash equivalents   |                                     | 12,391  | -7,239 |

## Share Price Development in 2014



– Santhera (closing prices)

– Swiss Performance Index (adjusted)

|                                   |                                |
|-----------------------------------|--------------------------------|
| High                              | CHF 104.90 (September 9, 2014) |
| Low                               | CHF 3.46 (April 16, 2014)      |
| Price change <sup>1</sup>         | 2,186%                         |
| Share price at year-end           | CHF 85.05                      |
| Market capitalization at year-end | CHF 423.1 million              |
| Average volume                    | 80,830 shares/day              |

<sup>1</sup> Global top performer in biotech shares in 2014 (Source: BioCentury)

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# Letter to Our Shareholders

Dear Shareholders,

We are pleased to report that the confidence you placed in us to turn Santhera around has paid off to this day. In 2014 we achieved clinical and regulatory milestones that advanced Santhera from a company with late-stage clinical projects towards a company with products and sustainable income streams.

The patients we serve suffer from rare diseases with little or no therapeutic relief. Our lead product, Raxone®/Catena®, demonstrated efficacy in two orphan mitochondrial indications: Leber's Hereditary Optic Neuropathy (**LHON**) and Duchenne Muscular Dystrophy (**DMD**).

In LHON, clinical data indicate that Raxone both prevents further vision loss in patients with residual vision and promotes clinically relevant recovery of already-lost vision. Based on these results, Raxone received a temporary approval in France, where it is now a fully-reimbursed treatment for LHON patients. Subsequently, we re-filed the Raxone Marketing Authorization Application (**MAA**) in the EU, where we expect a decision shortly. In the meantime we prepare for the launch of Raxone in major European markets.

In May last year, our pivotal Phase III trial in Duchenne Muscular Dystrophy (DELLOS) reported a clinically-relevant and statistically significant benefit in preserving respiratory function, irrespective of the patients' mutation or disease status. In fact, our Phase III trial is the first with a positive outcome in DMD. We have started to prepare a New Drug Application (**NDA**) for submission to the Food and Drug Administration in the US and a MAA for submission to the EMA in the EU.

On the operations side, we placed shares with new investors and secured additional funds to finance expansions necessitated by our anticipated growth. We recently appointed senior staff members Dr. Nicholas Coppard, Dr. Günther Metz, and Oliver Strub to the Executive Management team. Additionally, Giovanni Stropoli, an experienced marketing and sales specialist, well-versed in orphan indications, joined our team as Chief Commercial Officer for Europe. In preparation of our first product launch we have started building our own sales organization for the main European markets and are currently evaluating this option for North America.

Looking forward, we anticipate investing in additional indications and promising new compounds to broaden the clinical development pipeline. In cooperation with the US National Institutes of Health, we are advancing two programs with Catena/Raxone and with omigapil, our second compound, in Primary Progressive Multiple Sclerosis and Congenital Muscular Dystrophies, respectively. In addition, we seek in-licensing opportunities in orphan neuromuscular or mitochondrial indications, preferably in products that have already shown proof-of-concept in man.

We thank our employees for their loyalty and commitment and you, our shareholders, for your continued support and trust. We would like to emphasize the dedication and determination of everyone at Santhera to meet upcoming development, regulatory and commercial milestones. Together, we can achieve success with lasting benefits to patients, employees and investors.



Martin Gertsch  
Chairman



Thomas Meier  
Chief Executive Officer

# Santhera Reports Significant Progress in All Programs

## Financial highlights in 2014

- Financing and income from Raxone sales increased cash position: As of December 31, 2014, Santhera had cash and cash equivalents of CHF 17.4 million (2013: CHF 5.0 million) which corresponds to a net year-on-year increase of CHF 12.4 million (2013: CHF –7.2 million). The Company realized an aggregate gross amount of CHF 15.7 million through private share placements, sale of treasury shares and sale of shares under the Standby Equity Distribution Agreement, which together with increasing income from product sales contributed to the strong cash position.
- Top-line growth driven by increasing sales of Raxone: Mainly due to increasing top-line growth in the second half year, net sales 2014 climbed to CHF 2.6 million (2013: CHF 1.3 million). Increasing sales were generated with Raxone for Leber's Hereditary Optic Neuropathy (**LHON**) under the French temporary authorization for use (**cATU**) and with international Named Patient Programs for patients with Duchenne Muscular Dystrophy (**DMD**) and LHON.
- Operating and net result at previous year's level: Development expenses increased to CHF 5.7 million (2013: CHF 4.7 million). Preparations for market entry contributed to higher general and administrative expenses of CHF 4.2 million (2013: CHF 3.1 million). Overall, the operating result of CHF –7.5 million was comparable to 2013 (CHF –7.3 million).  
For the full-year 2014, Santhera reports a net result of CHF –7.5 million (2013: CHF –5.8 million including extraordinary financial income of CHF 1.5 million from the settlement of finance lease liabilities).

## Product and pipeline highlights

- Received temporary approval in France for Raxone as first treatment for LHON: In January 2014, the French National Agency for Medicines and Health Products Safety granted a temporary approval (cATU) for Raxone to treat patients with LHON. This cATU was renewed for 2015 and allows patients in France to receive reimbursed treatment with Raxone before a marketing authorization is granted in the European Union.
- Re-filed European MAA for Raxone in LHON – Regulatory review in progress: In May 2014, Santhera re-filed a Marketing Authorization Application (**MAA**) with efficacy data from the pivotal RHODOS study and additional clinical efficacy data from an Expanded Access Program. An opinion from the Committee for Medicinal Products for Human Use (**CHMP**) of the European Medicines Agency is expected in H1 this year. Subject to approval, Santhera plans to launch Raxone as the first product authorized in Europe for the treatment of LHON.
- Reported positive results of the DELOS phase III trial with Raxone/Catena in DMD: In May 2014, Santhera announced the positive outcome of the placebo-controlled phase III trial with Raxone in DMD. The study met its primary endpoint and demonstrated that Raxone can delay the loss of res-

piratory function in patients not using glucocorticoid steroids. The preservation of respiratory function is considered of major clinical importance for Duchenne patients.

- Initiated collaboration with Parent Project Muscular Dystrophy (**PPMD**): In November 2014, Santhera announced a collaboration agreement with the US patient advocacy organization PPMD for a survey-based benefit/risk evaluation in DMD. The survey will focus specifically on patient and caregiver preferences regarding pulmonary therapies and will be used in support of the Company's NDA filing.
- Continued collaborative phase II trial with the US National Institutes of Health (**NIH**) on Raxone/Catena in primary progressive Multiple Sclerosis (**ppMS**): Santhera continues its collaboration with the NIH in a double-blind, placebo-controlled phase II clinical trial investigating the efficacy of Raxone/Catena in patients with ppMS, the compound's third indication. The trial which combines a 1-year observational run-in phase followed by a 2-year randomized, placebo-controlled treatment period is now fully enrolled.
- Initiated a clinical development program with omigapil in Congenital Muscular Dystrophies (**CMD**) with support from private-public partnership: In July 2014, Santhera announced a public-private partnership with the NIH, EndoStem, an EU 7th Framework Program, and two patient organizations, Cure CMD and the Swiss Foundation for Research on Muscle Diseases (FSRMM), to evaluate the pharmacokinetic profile, safety and tolerability of orally administered omigapil. The clinical phase I study in pediatric CMD patients will also identify clinical parameters suitable for future efficacy studies.
- Started development of novel formulation for Raxone (idebenone): Santhera is developing a transmucosal formulation for idebenone as part of its future life cycle management efforts. This novel formulation, for which patent applications have been filed, is aimed at offering improved bioavailability and better convenience for certain patient populations.

## Outlook

Santhera's main priorities in the near term are the marketing authorizations of Raxone/Catena for the indications LHON and DMD. In Europe, the regulatory review of the MAA for LHON is ongoing and an opinion from the CHMP is expected in H1 2015. Subject to a positive decision, Raxone will become the first product authorized for the treatment of LHON. Santhera currently prepares to file for regulatory approvals for Raxone/Catena in DMD in the US and EU. Recently the Company received FDA Fast Track Designation for Raxone/Catena for the treatment of DMD.

Santhera expanded its Executive Management and started building a commercial team to prepare the anticipated launch of Raxone in Europe. Marketing efforts will focus on major European markets to be supplemented by national and/or regional distribution agreements. The Company is also evaluating opportunities to commercialize its products in North America.

Santhera believes that, with cash of CHF 14.0 million (March 31, 2015) and the potential to use conditional and authorized capital, it has sufficient financial flexibility to support the development and commercialization of the current pipeline.

## Santhera's Lead Compound Raxone®/Catena® Close to Market in Orphan Indications

Santhera's current pipeline of drug candidates focuses on Raxone/Catena (INN: *idebenone*). *Idebenone*, a synthetic short-chain benzoquinone and a cofactor for the enzyme NAD(P)H:quinone oxidoreductase (NQO1), has a dual mode of action: it enhances mitochondrial function and acts as a cell-protecting antioxidant. Numerous mitochondrial indications exist in which a defect in the mitochondrial electron transport chain is considered to be the primary cause of the disease. *Idebenone's* pharmacological properties make it a treatment of choice for such diseases.

Santhera is exploring Raxone/Catena's full clinical and commercial potential by evaluating the compound in multiple mitochondrial and neuromuscular indications with the goal of building a broad franchise in these orphan indications. Competition is scarce, if any, in these diseases, and regulators worldwide grant incentives to spur drug development in these neglected areas.

### Raxone could be the first product authorized for the treatment of LHON

Leber's Hereditary Optic Neuropathy (LHON) is a rare inherited mitochondrial disease that untreated invariably leads to permanent vision loss and blindness. Clinical evidence suggests that Raxone can prevent from further vision loss in patients with residual vision and can restore vision in blind patients. Approximately 50% of patients enrolled in an expanded access program achieved clinically relevant improvement in their vision. Over 60% were protected from further vision loss following Raxone treatment.

#### Raxone-treated patients show recovery in visual acuity

In May 2014, Santhera submitted a Marketing Authorization Application (MAA) to the European Medicines Agency for Raxone in the treatment of LHON. An opinion is expected in the first half of 2015. The Company currently plans a market launch in the first European countries in the second half of this year.

*Idebenone* has been granted orphan drug designations for LHON, which allows for market exclusivity upon approval. Raxone would become the first therapy authorized by health authorities to treat LHON.

### Raxone/Catena reduces respiratory function loss in DMD

Clinical results published in spring 2014 show that Raxone/Catena delays the loss of respiratory function in Duchenne Muscular Dystrophy (DMD), one of the most common and devastating types of inherited muscle weakness. The pivotal DELOS trial randomized and treated 64 patients not using concomitant corticosteroids. The study investigated the difference between orally-administered Catena/Raxone and placebo in the change in peak expiratory flow, a measure of respiratory muscle strength, as well as other respiratory function markers, the decline of which are major contributing factors to early morbidity and mortality in Duchenne patients. The study met its primary endpoint. Additionally, over the one-year period of the study, Catena/Raxone significantly reduced the annual decline in peak expiratory flow by ~70%, compared to patients taking placebo. Results of additional respiratory function

endpoints from the DELOS trial corroborate this positive outcome. These data provide supportive evidence of a treatment benefit for Catena/Raxone in the preservation of respiratory function.

Raxone/Catena is the first and only treatment for Duchenne patients not using steroids. Additionally, it can be used in patients with any mutational or disease status. In the EU, Santhera plans to file a MAA for DMD as a variation to the LHON label in the second half of 2015. In the United States of America, Santhera intends to submit a New Drug Application to the Food and Drug Administration by mid-2015. The Company has recently initiated a partnership with Parent Project Muscular Dystrophy, the leading US patient advocacy organization, and is collaborating on a benefit/risk study which will be used in the regulatory procedure.

**Raxone/Catena slows  
the loss of respiratory  
function in patients not  
using steroids**

### **Santhera is expanding its Raxone/Catena franchise and explores efficacy in ppMS**

Primary progressive Multiple Sclerosis (**ppMS**) is a subtype of MS in which patients suffer from a slow, but steady, functional decline without any distinct episodes of regeneration or acute relapses that characterize more common forms of MS. ppMS is Catena/Raxone's third indication. Lead by the National Institute of Neurological Disorders and Stroke (**NINDS**), Santhera is collaborating with the US National Institutes of Health (**NIH**) to investigate the efficacy of Raxone/Catena in a phase I/III trial with a 12-month pre-treatment baseline period. This will be followed by a double-blind, placebo-controlled treatment of 24 months duration in total. Patients who complete the study will be offered the chance to enrol in an open label extension study of one-year duration. Final study results are expected in 2017. The Company and NIH are exploring the possibility of conducting an interim analysis.

### **Santhera develops omigapil in CMD**

The second compound in Santhera's pipeline is *omigapil*, which is in a phase I trial for the treatment of Congenital Muscular Dystrophies (**CMD**), a group of inherited neuromuscular diseases characterized by different forms of progressive loss of muscle tissue, frequently affecting young children. The clinical development is supported by a public-private partnership, including the NINDS, EndoStem, an EU 7th Framework Programme, and two patient organizations. The study investigates the safety, tolerability and the pharmacokinetic profile of a new liquid formulation of *omigapil* in pediatric and adolescent patients with CMD.

# Consolidated Financial Statements

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## Consolidated Balance Sheet

|                                     | In CHF thousands | Notes | 31.12.2014    | 31.12.2013   |
|-------------------------------------|------------------|-------|---------------|--------------|
| <b>Assets</b>                       |                  |       |               |              |
| Tangible assets                     |                  | 5     | 132           | 39           |
| Intangible assets                   |                  | 6     | 4,197         | 4,225        |
| Financial assets long-term          |                  |       | 85            | 85           |
| Deferred tax assets                 |                  | 12    | 0             | 0            |
| <b>Noncurrent assets</b>            |                  |       | <b>4,414</b>  | <b>4,349</b> |
| Prepaid expenses and accrued income |                  |       | 376           | 301          |
| Inventories                         |                  | 8     | 0             | 0            |
| Trade and other receivables         |                  | 9     | 720           | 42           |
| Cash and cash equivalents           |                  | 10    | 17,435        | 5,044        |
| <b>Current assets</b>               |                  |       | <b>18,531</b> | <b>5,387</b> |
| <b>Total assets</b>                 |                  |       | <b>22,945</b> | <b>9,736</b> |
| <b>Equity and liabilities</b>       |                  |       |               |              |
| Share capital                       |                  | 11    | 4,974         | 3,934        |
| Capital reserves and share premium  |                  |       | 293,232       | 274,896      |
| Retained earnings                   |                  |       | -272,838      | -265,304     |
| Employee benefit reserve            |                  | 20    | -1,287        | 405          |
| Treasury shares                     |                  | 11    | -177          | -221         |
| Other components of equity          |                  |       | -6,666        | -6,604       |
| <b>Total equity</b>                 |                  |       | <b>17,238</b> | <b>7,106</b> |
| Pension liabilities                 |                  | 20    | 2,680         | 997          |
| <b>Total noncurrent liabilities</b> |                  |       | <b>2,680</b>  | <b>997</b>   |
| Trade and other payables            |                  | 13    | 2,166         | 597          |
| Accrued expenses                    |                  | 14    | 861           | 1,036        |
| <b>Total current liabilities</b>    |                  |       | <b>3,027</b>  | <b>1,633</b> |
| <b>Total liabilities</b>            |                  |       | <b>5,707</b>  | <b>2,630</b> |
| <b>Total equity and liabilities</b> |                  |       | <b>22,945</b> | <b>9,736</b> |

## Consolidated Income Statement

| For the year ended December 31, in CHF thousands | Notes     | 2014           | 2013          |
|--|-----------|----------------|---------------|
| Net sales  | 17        | 2,591          | 1,319         |
| <b>Revenue</b>                                   |           | <b>2,591</b>   | <b>1,319</b>  |
| Cost of goods sold                               |           | -199           | -140          |
| <b>Gross profit</b>                              |           | <b>2,392</b>   | <b>1,179</b>  |
| Other operating income                           | 18        | 533            | 256           |
| Development                                      | 19        | -5,695         | -4,709        |
| Marketing and sales                              | 19        | -574           | -926          |
| General and administrative                       | 19        | -4,164         | -3,109        |
| Other operating expenses                         | 19        | -9             | 0             |
| <b>Operating expenses</b>                        | <b>19</b> | <b>-10,442</b> | <b>-8,744</b> |
| <b>Operating result</b>                          |           | <b>-7,517</b>  | <b>-7,309</b> |
| Financial income                                 | 21        | 54             | 1,731         |
| Financial expenses                               | 21        | -69            | -182          |
| <b>Result before taxes</b>                       |           | <b>-7,532</b>  | <b>-5,760</b> |
| Income taxes                                     | 23        | -2             | 5             |
| <b>Net result</b>                                |           | <b>-7,534</b>  | <b>-5,755</b> |
| <b>Basic and diluted loss per share (in CHF)</b> | <b>24</b> | <b>-1.60</b>   | <b>-1.55</b>  |

## Consolidated Statement of Comprehensive Income

| For the year ended December 31, in CHF thousands                           | Notes | 2014          | 2013          |
|--|-------|---------------|---------------|
| <b>Net result</b>  |       | <b>-7,534</b> | <b>-5,755</b> |
| <i>Items never to be reclassified to net income in subsequent periods:</i> |       |               |               |
| Actuarial gains/(losses) on defined benefit plans                          | 20    | -1,692        | 773           |
| <i>Items to be reclassified to net income in subsequent periods:</i>       |       |               |               |
| Currency translation differences   | 22    | -62           | 55            |
| <b>Other comprehensive result</b>  |       | <b>-1,754</b> | <b>828</b>    |
| <b>Total comprehensive result</b>  |       | <b>-9,288</b> | <b>-4,927</b> |

## Consolidated Cash Flow Statement

| For the year ended December 31, in CHF thousands              | Notes  | 2014          | 2013          |
|---|--------|---------------|---------------|
| Result before taxes   |        | <b>-7,532</b> | <b>-5,760</b> |
| Depreciation of tangible assets                               | 5      | 66            | 47            |
| Amortisation and impairment of intangible assets              | 6      | 9             | 551           |
| Expenses for share options                                    | 16, 19 | 759           | 290           |
| Change in pension liabilities                                 | 20     | -9            | -51           |
| Taxes paid  |        | -2            | -6            |
| Change in net working capital                                 |        | 634           | -482          |
| Total financial result  | 21     | 15            | -1,549        |
| Interest received   | 21     | 4             | 5             |
| Interest paid   | 21     | -7            | -21           |
| <b>Cash flow from operating activities</b>                    |        | <b>-6,063</b> | <b>-6,976</b> |
| Investments in tangible assets                                | 5      | -160          | -4            |
| Investments in intangible assets                              | 6      | -47           | 0             |
| Proceeds from/investment in other financial assets            |        | 0             | 276           |
| <b>Cash flow from investing activities</b>                    |        | <b>-207</b>   | <b>272</b>    |
| Capital increases from options exercised                      | 11     | 3,247         | 12            |
| Proceeds from sale of treasury shares SEDA <sup>1</sup>       | 11     | 1,444         | 416           |
| Capital increase private placement                            | 11     | 1,000         | 0             |
| Capital increase  | 11     | 13,294        | 0             |
| Cost of issuance of share capital                             |        | -324          | -50           |
| Amortization of finance lease                                 |        | 0             | -9            |
| Settlement of finance lease liabilities                       |        | 0             | -900          |
| <b>Cash flow from financing activities</b>                    |        | <b>18,661</b> | <b>-531</b>   |
| Effects of exchange rate changes on cash and cash equivalents |        | 0             | -4            |
| <b>Net increase/(decrease) in cash and cash equivalents</b>   |        | <b>12,391</b> | <b>-7,239</b> |
| Cash and cash equivalents at January 1                        |        | 5,044         | 12,283        |
| <b>Cash and cash equivalents at December 31</b>               |        | <b>17,435</b> | <b>5,044</b>  |

<sup>1</sup> Standby Equity Distribution Agreement, see note 11 "Share Capital".

## Consolidated Statement of Changes in Equity

| In CHF thousands                                     | Notes  | Share<br>capi-<br>tal | Capital<br>reserves<br>and<br>share<br>premium | Retained<br>earnings | Em-<br>ployee<br>benefit<br>reserve | Treas-<br>ury<br>shares | Transla-<br>tion<br>differ-<br>ences | Total         |
|--|--------|-----------------------|--|----------------------|-------------------------------------|-------------------------|--------------------------------------|---------------|
| <b>Balance at January 1, 2013</b>                    |        | <b>3,677</b>          | <b>274,441</b>                                 | <b>-259,549</b>      | <b>-368</b>                         | <b>-177</b>             | <b>-6,659</b>                        | <b>11,365</b> |
| Net result   |        | 0                     | 0  | -5,755               | 0                                   | 0                       | 0                                    | -5,755        |
| Other comprehensive result                           | 20, 22 | 0                     | 0  | 0                    | 773                                 | 0                       | 55                                   | 828           |
| <b>Total comprehensive result for<br/>the period</b> |        | <b>0</b>              | <b>0</b>                                       | <b>-5,755</b>        | <b>773</b>                          | <b>0</b>                | <b>55</b>                            | <b>-4,927</b> |
| Share-based payment transactions                     | 16     | 0                     | 290  | 0                    | 0                                   | 0                       | 0                                    | 290           |
| Capital increase from options<br>exercise            | 11     | 12                    | 0  | 0                    | 0                                   | 0                       | 0                                    | 12            |
| Capital increase SEDA <sup>1</sup>                   | 11     | 160                   | 300  | 0                    | 0                                   | -44                     | 0                                    | 416           |
| Commitment fee SEDA <sup>1</sup>                     | 11     | 85                    | -85  | 0                    | 0                                   | 0                       | 0                                    | 0             |
| Cost of issuance of share capital                    |        | 0                     | -50  | 0                    | 0                                   | 0                       | 0                                    | -50           |
| <b>Balance at December 31, 2013</b>                  |        | <b>3,934</b>          | <b>274,896</b>                                 | <b>-265,304</b>      | <b>405</b>                          | <b>-221</b>             | <b>-6,604</b>                        | <b>7,106</b>  |
| <b>Balance at January 1, 2014</b>                    |        | <b>3,934</b>          | <b>274,896</b>                                 | <b>-265,304</b>      | <b>405</b>                          | <b>-221</b>             | <b>-6,604</b>                        | <b>7,106</b>  |
| Net result   |        | 0                     | 0  | -7,534               | 0                                   | 0                       | 0                                    | -7,534        |
| Other comprehensive result                           | 20, 22 | 0                     | 0  | 0                    | -1,692                              | 0                       | -62                                  | -1,754        |
| <b>Total comprehensive result for<br/>the period</b> |        | <b>0</b>              | <b>0</b>                                       | <b>-7,534</b>        | <b>-1,692</b>                       | <b>0</b>                | <b>-62</b>                           | <b>-9,288</b> |
| Share-based payment transactions                     | 16     | 0                     | 759  | 0                    | 0                                   | 0                       | 0                                    | 759           |
| Capital increase from options<br>exercise            | 11     | 197                   | 3,050  | 0                    | 0                                   | 0                       | 0                                    | 3,247         |
| Capital increase SEDA <sup>1</sup>                   | 11     | 355                   | 1,045  | 0                    | 0                                   | 44                      | 0                                    | 1,444         |
| Capital increase private placement                   | 11     | 288                   | 712  | 0                    | 0                                   | 0                       | 0                                    | 1,000         |
| Capital increase                                     | 11     | 200                   | 13,094   | 0                    | 0                                   | 0                       | 0                                    | 13,294        |
| Cost of issuance of share capital                    |        | 0                     | -324   | 0                    | 0                                   | 0                       | 0                                    | -324          |
| <b>Balance at December 31, 2014</b>                  |        | <b>4,974</b>          | <b>293,232</b>                                 | <b>-272,838</b>      | <b>-1,287</b>                       | <b>-177</b>             | <b>-6,666</b>                        | <b>17,238</b> |

<sup>1</sup> Standby Equity Distribution Agreement, see note 11 "Share Capital".

## Notes to the Consolidated Financial Statements

### 1 General Information

Santhera Pharmaceuticals Holding AG (the **Company**, together with its subsidiaries **Santhera** or **Group**) is a specialty pharmaceutical company focused on the development and commercialization of products for the treatment of mitochondrial and neuromuscular diseases, an area which includes many orphan and niche indications with no current therapy.

The Company, having its primary listing of its registered shares (**Shares**) on the SIX Swiss Exchange (**SIX**), is a Swiss stock corporation and the parent company of the Group. Its purpose is to acquire, dispose and manage investments. The Company has its registered offices at Hammerstrasse 49 in 4410 Liestal, Switzerland.

The consolidated financial statements were approved for publication by the Board of Directors (**Board**) on April 13, 2015. They are subject to approval by the Annual Shareholders' Meeting (**ASM**) on May 19, 2015.

### 2 Summary of Significant Accounting Policies

The principal accounting policies applied in the preparation of these financial statements are set out below. These policies have been consistently applied to all the years presented, unless otherwise stated.

#### Basis of preparation

The consolidated financial statements of Santhera have been prepared in accordance with International Financial Reporting Standards (**IFRS**).

The consolidated financial statements are based on the financial statements of the individual Santhera companies prepared for the same reporting period using consistent accounting policies. The consolidated financial statements are prepared using the historical cost convention except for the revaluation to fair value of certain financial assets and financial liabilities.

The presentation currency is Swiss francs (**CHF**). All figures included in these financial statements and notes to the financial statements are rounded to the nearest CHF 1,000 except where otherwise indicated.

## **Uncertainties and ability to continue operations**

Santhera is sufficiently funded to progress its two main development programs up to the regulatory decision point of the respective Marketing Authorisation Application (**MAA**).

Santhera filed an MAA with the European Medicines Agency (**EMA**) in Leber's Hereditary Optic Neuropathy (**LHON**) in June 2014. The Company expects a regulatory decision in the first half year 2015. Subject to a positive outcome, Raxone would be launched in the European markets and would provide positive cash flow. A negative decision, however, would have a major impact on the plans of the Company including but not limited to the time of achieving positive cash flow, questions regarding the regulatory pathway in other indications, and the necessity of additional clinical trials and funding thereof

The positive outcome of a phase III trial in Duchenne Muscular Dystrophy (**DMD**) reported in May 2014 forms the basis for regulatory filings in the European Union (**EU**) and the United States of America (**US**). Depending on the outcome of the MAA in LHON, the potential regulatory filing in DMD and the related commercialization strategy of Raxone in these indications, Santhera will require additional funding in order to finance its activities until revenues reach a level to sustain positive operating cash flows.

Under the above-described circumstances, the Board believes in the Company's chances to get sufficient funding to execute the current development and commercial strategy.

## **Consolidation**

Subsidiaries in which the Company has a direct or indirect controlling interest are consolidated. Control exists when the investor is exposed, or has rights, to variable returns from its investment with the investee and has the ability to affect those returns through its power over the investee. Control is normally evidenced when the Company owns, either directly or indirectly, more than 50% of the voting rights or potential voting rights of a company's share capital that are currently exercisable.

The consolidated financial statements of Santhera include the accounts of Santhera Pharmaceuticals Holding AG, Liestal, Switzerland, and its wholly owned subsidiaries Santhera Pharmaceuticals (Schweiz) AG, Liestal, Switzerland; Santhera Pharmaceuticals (USA), Inc., Charlestown, US; Santhera Pharmaceuticals (Canada), Inc., Montréal, Canada; Santhera Pharmaceuticals (Deutschland) GmbH, Lörrach, Germany; and Oy Santhera Pharmaceuticals (Finland) Ltd, Helsinki, Finland.

The acquisition method is used to account for the acquisition of subsidiaries by the Company. The consideration transferred is measured at the fair value of the assets given, equity instruments issued and liabilities incurred or assumed at the date of exchange. Identifiable assets acquired and liabilities and contingent liabilities assumed in a business combination are measured initially at their fair value at the acquisition date, irrespective of the extent of any noncontrolling interest. The excess of the consideration transferred over the fair value of the Group's share of the identifiable net assets acquired is recorded as goodwill. If the consideration transferred is less than the fair value of the net assets of the subsidiary acquired, the difference is recognized directly in the income statement.

The consolidation commences from the date on which control is transferred to the Company, and subsidiaries are no longer consolidated from the date that control ceases. Intercompany balances and transactions between Group companies are eliminated. Intercompany transactions solely result from providing services, financing and selling goods to other Group companies.

The Group had no business combinations in the periods reported.

## Changes in accounting policies

The adopted accounting policies are consistent with the previous year except for those described below.

The following changes in standards had neither an effect on accounting policies nor on reported amounts or disclosures in these financial statements:

- Amendments to IAS 32 ("*Offsetting financial instruments*")
- Amendments to IAS 36 ("*Recoverable Amount Disclosures for Non-Financial Assets*")
- IFRIC 21 ("*Levies*")

The IASB has issued a number of amendments to existing standards as well as new standards and interpretations which will become effective in future periods. Many of these changes are not relevant for Santhera or are currently not expected to have a material impact on Santhera's accounting policies or financial performance but may lead to additional disclosures. The most important change relates to IFRS 15 Revenue from contracts with Customers (effective for annual period beginning on or after January 1, 2017). Santhera has not yet assessed the impact of this standard.

## Segment reporting

Santhera has one operating segment, namely the development and commercialization of products for the treatment of mitochondrial and neuromuscular diseases. The Board, the Executive Management and senior managers, being the Chief Operating Decision Makers (**CODM**), assess the reporting data and allocate resources as one segment on an aggregated consolidated level according to operating expenses by function. Santhera generates revenue from sales of Raxone® and Catena® (for the treatment of LHON and DMD). Geographic revenue information is based on location of the customer or licensee.

## Foreign currency translations

The consolidated financial statements are presented in CHF. The functional currency of each of Santhera's companies is the currency of the primary economic environment in which the local entity operates. Transactions in foreign currencies are accounted for at the rates prevailing at the dates of the transaction. Translation differences from financial transactions are included in the financial result.

Gains and losses resulting from the translation of foreign currency transactions and from the adjustment of foreign currency monetary assets and liabilities at the reporting date are recognized in the income statement.

Assets and liabilities of foreign entities are translated into CHF using the balance-sheet exchange rates at year-end. Income and expenses are translated into CHF at average exchange rates. The exchange differences arising on the retranslation are accounted for in other comprehensive income/equity.

**Intangible assets**

Patents, licenses, trademarks and other intangible assets are capitalized as intangible assets when it is probable that future economic benefits will be generated. Such assets are in general amortized on a straight-line basis over their useful lives. Estimated useful life is the lower of legal duration and economic useful life. The estimated useful life of the intangible assets is regularly reviewed and if necessary the future amortization charge is accelerated. For pharmaceutical products, the estimated useful life normally corresponds to the remaining lifetime of their patent or orphan drug protection (up to 20 years).

**Patents**

Patents not yet available for use are not amortized, but tested for impairment annually. Once useful life can be determined, amortization starts on a straight-line basis (2 to 20 years).

**IT software**

Acquired IT software licenses are capitalized on the basis of the costs incurred to acquire and implement the specific software. These costs are amortized on a straight-line basis over their estimated useful lives (2 to 5 years).

**Tangible assets**

Tangible assets are stated at cost less accumulated depreciation and any impairment losses. Depreciation is calculated on a straight-line basis over the estimated useful life of the asset or the shorter lease term, as follows:

|             | Useful life   |
|-------------|---------------|
| Equipment   | 4 to 10 years |
| IT hardware | 2 to 5 years  |

**Impairment of assets**

Assets include intangible assets not yet available for use, intangible assets with finite useful lives and tangible assets. In general and in accordance with the terms of IFRS, assets not in use are capitalized at cost in the balance sheet and reviewed for impairment at least annually. This impairment test is performed at the same time every year or upon any reporting date if deemed necessary. A change to finite useful life is accounted for as a change in an accounting estimate for the respective asset. Testing for indicators of impairment is done at the end of each reporting period.

**Trade and other receivables**

Receivables which generally have 30 days payment terms are stated at their nominal value less an allowance for any uncollectible amount if required. An allowance for doubtful debts is made when collection of the full amount is no longer probable.

**Inventories**

Inventories are stated at the lower of cost and net realizable value using the weighted average cost formula.

## **Financial assets**

Generally, Santhera classifies its financial assets in the following categories:

### *Financial assets at fair value through profit or loss*

This category has two subcategories: financial assets held for trading and those designated at fair value through profit or loss upon initial recognition. A financial asset is classified in this category if acquired principally for the purpose of selling in the short term. Derivatives are also categorized as held for trading unless they are designated as hedges. Assets in this category are classified as current assets if they are either held for trading or are expected to be realized within 12 months of the reporting date. Valuation is at fair value through profit and loss. Financial assets at fair value through profit or loss are subsequently carried at fair value. Realized and unrealized gains and losses arising from changes in the fair value are included in the income statement in the period in which they arise.

### *Loans and receivables*

Loans and receivables are nonderivative financial assets with fixed or determinable payments that are not quoted in an active market. They arise when Santhera provides money, goods or services directly to a debtor with no intention of trading the receivable. They are included in current assets, except for maturities longer than 12 months after the balance sheet date. These are classified as non-current assets. Loans and receivables are measured at amortized cost using the effective interest method.

Purchases and sales of financial assets are recognized on their trade date. This is the date on which Santhera commits to purchase or sell the asset. Financial assets are initially recognized at fair value plus transaction costs for all financial assets not carried at fair value through profit or loss. Financial assets are de-recognized when the rights to receive cash flows from the financial assets have expired or have been transferred and Santhera has transferred substantially all risks and rewards of ownership.

## **Leases**

Leases of assets under which Santhera essentially assumes all the rewards and risks of ownership are classified as finance leases. Finance leases are capitalized as assets and liabilities at the commencement of the lease at the fair value of the leased item or, if lower, at the present value of the minimum lease payments. The assets acquired under these contracts are depreciated over the shorter of the estimated useful life of the asset or the lease term.

Leases of assets under which the risks and rewards of ownership are effectively retained by the lessor are classified as operating leases, and payments made are charged to the income statement on a straight-line basis.

## **Cash and cash equivalents**

This item includes cash on hand and at banks, deposits held at call with banks and other short-term highly liquid investments with original maturities of three months or less.

## **Share capital**

Common shares are classified as equity. Incremental costs directly attributable to the issue of new common shares or options are shown in equity as a deduction, net of tax, from the proceeds.

## **Financial liabilities**

Santhera classifies its financial liabilities into two categories:

### *Financial liabilities at fair value through profit or loss*

This category includes derivatives with negative replacement values. They are initially recognized at their fair value. Any subsequent change in fair value is recognized in the income statement in the period they occur.

### *Other liabilities measured at amortized costs*

This category principally covers debt instruments and trade and other payables. They are initially recognized at fair value and subsequently measured at amortized costs using the effective interest method. Any difference between the net proceeds received and the principal value due on redemption is amortized over the duration of the debt instrument and is recognized as part of interest expense in the income statement.

## **Income taxes**

The income tax charge is based on profit for the year and includes deferred taxes. Deferred taxes are calculated using the liability method. Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Deferred tax assets and liabilities are measured using the tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled based on enacted or substantially enacted tax rates as of the balance sheet date.

The amount of deferred tax liabilities and deferred tax assets reflects the tax consequences on the balance sheet date of the Company's expectation of recovery or settlement of such carrying amount of its assets and liabilities.

Deferred tax assets and liabilities are not discounted and are classified as noncurrent assets (liabilities) in the balance sheet. They are offset against each other if they relate to the same taxable entity and tax authority.

Deferred tax assets are recognized when it is probable that sufficient taxable profits will be available against which the deferred tax assets can be utilized. At each balance sheet date, the Company reassesses unrecognized deferred tax assets and the carrying amount of deferred tax assets. The Company recognizes a previously unrecognized deferred tax asset to the extent that it has become probable that future taxable profit will allow the deferred tax asset to be recovered. The Company conversely reduces the carrying amount of a deferred tax asset to the extent that it is no longer probable that sufficient taxable profit will be available to allow the benefit of part or the entire deferred tax asset to be utilized. Deferred tax is provided on temporary differences arising on investments in subsidiaries, associates and joint ventures, except where the timing of the reversal of the temporary difference can be controlled and it is probable that the difference will not reverse in the foreseeable future.

## Employee benefits

### *Post-retirement benefits*

Santhera operates both defined benefit and defined contribution pension schemes.

- Defined benefit scheme:

Santhera's pension plan in Switzerland is classified as a defined benefit plan. Payments under this scheme are made directly to the pension fund for the account of each insured person. Typically, on retirement, an employee will receive an amount of the accumulated defined benefit obligation depending on several factors such as the total individual amount paid in, age and implied life expectancy. The compensation will be in the form of a lifelong pension or a lump sum payment. The scheme also covers disability as a consequence of illness and death-in-service.

The liability recognized in the balance sheet in respect of defined benefit pension plans is the present value of the defined benefit obligation at the balance sheet date less the fair value of plan assets, adjusted for the effects of the asset ceiling, when relevant.

The defined benefit obligation is calculated annually by independent actuaries using the projected unit credit method. The present value of the defined benefit obligation is determined by discounting the estimated future cash outflows using interest rates of high-quality corporate bonds that are denominated in the currency in which the benefits will be paid and that have terms to maturity approximating the terms of the related pension liability.

- Defined contribution schemes:

Defined contribution schemes are also funded through direct payments for the account of each insured person. Upon retirement, an employee will receive an amount of the accumulated contributions in the form of a lifelong pension or a lump sum payment. No further obligations arise from these schemes other than the fixed periodic contributions to the plan.

### *Share-based compensation*

Santhera has established five stock option plans, the Employee Stock Option Plan 2004 (**ESOP 2004**), the Executive Incentive Plan (**EIP**), the Employee Stock Option Plan 2008 (**ESOP 2008**), the Employee Stock Option Plan 2010 (**ESOP 2010**) and the Board Stock Option Plan 2011 (**BSOP 2011**) to align the long-term interests of the members of the Board, the Executive Management, employees and selected consultants who are eligible to participate in the ESOP 2004, 2008, 2010 and BSOP 2011 (only Board members). Only members of the Executive Management were eligible to participate in the EIP following the Company's listing on the SIX in November 2006. Options granted under all plans are equity-settled. The fair value of granted employee stock options is recognized as personnel expense and accounted for over the relevant vesting periods of each grant in accordance with IFRS 2. Stock option plan modifications can be made and the expenses are at least recognized such, as if no terms were modified; modifications which increase the fair value of options are expensed additionally. Unless determined otherwise by the Board, terminations of employment by the employer are treated as forfeiture and any previously accumulated share-based payment expenses for unvested awards are reversed.

## **Provisions**

Provisions are recognized when Santhera has a present obligation (legal or constructive) as a result of a past event, where it is more probable than not that a cash outflow will be required to fulfill the obligation and where a reliable estimate can be made of the amount of the obligation.

If the effect of the time value of money is material, provisions are determined by discounting the expected future outflows.

## **Revenue recognition**

Revenue comprises the fair value of the sale of goods and services, net of value-added tax, rebates, discounts, returns and after eliminating intercompany sales. Revenue is recognized when title, risks and rewards of the products are transferred to customers.

### *Revenue from out-licensing*

Out-licensing agreements are concluded with third parties, where the counterparty has to pay license fees. In situations where no further performance commitment exists, revenues are recognized on the earlier of when payments are received or collection is assured. Where continuous involvement for a certain period is required in the form of technology transfer or technical support, revenues are recognized over the period in question.

### *Revenue associated with up-front payments or performance milestones*

Such revenue is recognized in accordance with respective agreements.

### *Revenue from royalties*

Royalty payments are recognized on an accrual basis in accordance with the respective agreements.

### *Interest income*

Interest income is recognized on a pro rata temporis basis using the effective interest method.

## **Development / intangible assets**

Development expenses are charged to the income statement as incurred. They are capitalized as intangible assets when it is probable that future economic benefits will flow to Santhera. Such intangible assets are amortized on a straight-line basis over the period of the expected benefit when the asset becomes available for use, and are reviewed for impairment at each balance sheet date. Assets not available for use are tested annually.

### 3 Critical Accounting Estimates, Assumptions and Judgments

The preparation of financial statements in conformity with IFRS requires the use of certain critical accounting estimates. It also requires management to exercise its judgment in the process of applying Santhera's accounting policies. Santhera makes estimates and assumptions concerning the future. The resulting accounting will not necessarily equal the related actual outcome. The following areas involve assumptions and estimates that can have a significant impact on the consolidated financial statements:

- For general information see section "*Uncertainties and ability to continue operations*" in note 2 "*Summary of Significant Accounting Policies*".
- Measurement and impairment testing of intangible assets, see note 7 "*Impairment Test for Intangible Assets*".
- Measurement and impairment testing of inventory, see note 8 "*Inventories*".
- Personnel expenses from share-based payments in accordance with IFRS 2, i.e. estimates regarding the valuation of employee stock options when granted or modified, see note 16 "*Stock Option Plans*".
- Actuarial valuations in the context of defined benefit pension plans where various assumptions on e.g. discount rates, salary increase rates and mortality rates, etc. bear significant uncertainties due to the long-term nature of the plans, see note 20 "*Employee Expenses and Benefits*".

### 4 Exchange Rates of Principal Currencies

|                         | Income statement in CHF<br>average rates |        | Balance sheet in CHF<br>year-end rates |        |
|-------------------------|--|--------|--|--------|
|                         | 2014                                     | 2013   | 2014                                   | 2013   |
| 1 euro (EUR)            | 1.2146                                   | 1.2307 | 1.2028                                 | 1.2257 |
| 1 US dollar (USD)       | 0.9152                                   | 0.9270 | 0.9895                                 | 0.8904 |
| 1 Canadian dollar (CAD) | 0.8287                                   | 0.9004 | 0.8510                                 | 0.8325 |

## 5 Tangible Assets

| In CHF thousands                                      | Equipment  | IT hard-<br>ware | Leasehold<br>improvements<br>– finance lease | Leasehold<br>improvements | 2014       |
|---|------------|------------------|--|---------------------------|------------|
| <b>Cost</b>   |            |                  |  |                           |            |
| At January 1  | 184        | 633              | 0  | 540                       | 1,357      |
| Additions   | 1          | 158              | 0  | 0                         | 159        |
| Disposals   | -5         | -458             | 0  | -493                      | -956       |
| Exchange differences                                  | 0          | 1                | 0  | 0                         | 1          |
| Reclassification                                      | 5          | 0                | 0  | -5                        | 0          |
| <b>At December 31</b>                                 | <b>185</b> | <b>334</b>       | <b>0</b>                                     | <b>42</b>                 | <b>561</b> |
| <b>Accumulated depreciation and impairment losses</b> |            |                  |  |                           |            |
| At January 1  | 170        | 617              | 0  | 531                       | 1,318      |
| Additions   | 7          | 51               | 0  | 8                         | 66         |
| Disposals   | -5         | -458             | 0  | -493                      | -956       |
| Exchange differences                                  | 0          | 1                | 0  | 0                         | 1          |
| Reclassification                                      | 5          | 0                | 0  | -5                        | 0          |
| <b>At December 31</b>                                 | <b>177</b> | <b>211</b>       | <b>0</b>                                     | <b>41</b>                 | <b>429</b> |
| <b>Net book value</b>                                 | <b>8</b>   | <b>123</b>       | <b>0</b>                                     | <b>1</b>                  | <b>132</b> |

  

| In CHF thousands                                      | Laboratory<br>and other<br>equipment | IT hard-<br>ware | Leasehold<br>improvements<br>– finance lease | Leasehold<br>improvements | 2013         |
|---|--------------------------------------|------------------|--|---------------------------|--------------|
| <b>Cost</b>   |                                      |                  |  |                           |              |
| At January 1  | 333                                  | 629              | 2,314  | 540                       | 3,816        |
| Additions   | 0                                    | 4                | 0  | 0                         | 4            |
| Disposals   | -149                                 | 0                | -2,314                                       | 0                         | -2,463       |
| <b>At December 31</b>                                 | <b>184</b>                           | <b>633</b>       | <b>0</b>                                     | <b>540</b>                | <b>1,357</b> |
| <b>Accumulated depreciation and impairment losses</b> |                                      |                  |  |                           |              |
| At January 1  | 306                                  | 594              | 2,314  | 521                       | 3,735        |
| Additions   | 13                                   | 25               | 0  | 9                         | 47           |
| Disposals   | -149                                 | 0                | -2,314                                       | 0                         | -2,463       |
| Exchange differences                                  | 0                                    | -2               | 0  | 1                         | -1           |
| <b>At December 31</b>                                 | <b>170</b>                           | <b>617</b>       | <b>0</b>                                     | <b>531</b>                | <b>1,318</b> |
| <b>Net book value</b>                                 | <b>14</b>                            | <b>16</b>        | <b>0</b>                                     | <b>10</b>                 | <b>39</b>    |

The insurance value (including fire) of tangible assets amounted to CHF 3.0 million as of December 31, 2014 (December 31, 2013: CHF 3.0 million).

## 6 Intangible Assets

| In CHF thousands                                      | Raxone/<br>Catena | Capitalized<br>development<br>costs Raxone/<br>Catena | Fipamezole   | IT software/<br>patents | 2014          |
|---|-------------------|---|--------------|-------------------------|---------------|
| <b>Cost</b>   |                   |   |              |                         |               |
| At January 1  | 21,293            | 3,662   | 3,918        | 292                     | <b>29,165</b> |
| Additions   | 0                 | 0   | 0            | 47                      | <b>47</b>     |
| Disposals   | 0                 | 0   | 0            | -28                     | <b>-28</b>    |
| Exchange differences                                  | -392              | 0   | 0            | 1                       | <b>-391</b>   |
| <b>At December 31</b>                                 | <b>20,901</b>     | <b>3,662</b>  | <b>3,918</b> | <b>312</b>              | <b>28,793</b> |
| <b>Accumulated amortization and impairment losses</b> |                   |   |              |                         |               |
| At January 1  | 17,702            | 3,033   | 3,918        | 287                     | <b>24,940</b> |
| Additions   | 0                 | 0   | 0            | 9                       | <b>9</b>      |
| Disposals   | 0                 | 0   | 0            | -28                     | <b>-28</b>    |
| Exchange differences                                  | -325              | 0   | 0            | 0                       | <b>-325</b>   |
| <b>At December 31</b>                                 | <b>17,377</b>     | <b>3,033</b>  | <b>3,918</b> | <b>268</b>              | <b>24,596</b> |
| <b>Net book value</b>                                 | <b>3,524</b>      | <b>629</b>  | <b>0</b>     | <b>44</b>               | <b>4,197</b>  |
| <b>Cost</b>   |                   |   |              |                         |               |
| In CHF thousands                                      | Raxone/<br>Catena | Capitalized<br>development<br>costs Raxone/<br>Catena | Fipamezole   | IT software/<br>patents | 2013          |
| At January 1  | 20,981            | 3,662   | 3,918        | 293                     | <b>28,854</b> |
| Exchange differences                                  | 312               | 0   | 0            | -1                      | <b>311</b>    |
| <b>At December 31</b>                                 | <b>21,293</b>     | <b>3,662</b>  | <b>3,918</b> | <b>292</b>              | <b>29,165</b> |
| <b>Accumulated amortization and impairment losses</b> |                   |   |              |                         |               |
| At January 1  | 16,989            | 2,952   | 3,918        | 281                     | <b>24,140</b> |
| Additions   | 0                 | 0   | 0            | 6                       | <b>6</b>      |
| Impairment  | 464               | 81  | 0            | 0                       | <b>545</b>    |
| Exchange differences                                  | 249               | 0   | 0            | 0                       | <b>249</b>    |
| <b>At December 31</b>                                 | <b>17,702</b>     | <b>3,033</b>  | <b>3,918</b> | <b>287</b>              | <b>24,940</b> |
| <b>Net book value</b>                                 | <b>3,591</b>      | <b>629</b>  | <b>0</b>     | <b>5</b>                | <b>4,225</b>  |

## 7 Impairment Test for Intangible Assets

IAS 36 requires intangible assets not available for use to be tested for impairment on an annual basis by comparing the carrying value to its recoverable amount. The recoverable amount is the higher of fair value less costs of disposal and value in use.

An entity should also consider the relationship between market capitalization and book values, among other factors, when reviewing for indicators of impairment. As of December 31, 2014 the market capitalization of Santhera was above the book value of its equity and therefore not indicating a potential impairment of the intangible assets.

### **Raxone/Catena (INN: idebenone) and capitalized development costs Raxone/Catena**

Raxone/Catena and the capitalized development costs Raxone/Catena amounting to a net book value of CHF 4.2 million at year-end 2014 (2013: CHF 4.2 million) are the primary intangible assets of Santhera and form the basis of the Raxone/Catena development projects. Movements are related to foreign exchange valuations in the amount of CHF 0.1 million (2013: CHF 0.5 million).

Santhera's main intangible asset not yet available for use does not generate cash flows on a stand-alone basis and was allocated to the Company which is considered to be the smallest identifiable group of assets that generates cash flows that are largely independent.

Management used the risk-adjusted Net Present Value (**rNPV**) model taking into consideration the expected cumulative probability of reaching the market to calculate recoverable amount. This is a customary model for the valuation of pharmaceutical intangibles.

The rNPV model considers the net cash flows over the expected lifetime of the products based on the lifetime of the underlying intellectual property or the market exclusivity granted through orphan drug protection. For the purpose of estimating these cash flows, Santhera made estimates about the expected revenues based on estimated market size and patient numbers, expected market penetration rates, product pricing and project- or product-related costs.

Santhera's strategic focus is on LHON and DMD. Since LHON is the most advanced program with an ongoing filing for an MAA, the impairment test for 2014 is entirely based on project cash flows derived from this program in Europe.

The key assumptions for the tests were as follows:

|                                     | <b>2014</b> | 2013    |
|-------------------------------------|-------------|---------|
| Discount rate (WACC)                | 15%         | 15%     |
| Market growth rate (terminal value) | 0%          | 0%      |
| Probability of reaching market      | > 50%       | > 50%   |
| Period of projected cash flows      | 5 years     | 5 years |

The impairment test of the recoverable amount of the intangible assets performed as explained above does not result in the requirement to recognize an impairment of the carrying value of "Raxone/Catena" and "Capitalized development costs Raxone/Catena".

## Sensitivity to changes in assumptions

An uncertainty remains as to whether a final and successful market registration can be achieved for LHON and DMD. A risk of future adjustments to the carrying amount of the Raxone/Catena projects remains should the Company fail to obtain such registrations, see section "*Uncertainties and ability to continue operations*" in note 2 "*Summary of Significant Accounting Policies*".

## 8 Inventories

Inventories have technically a carrying amount of nil at the end of 2014 (December 31, 2013: TCHF 0 of finished goods). Inventories mainly represent the value of active pharmaceutical ingredients (API) for Raxone/ Catena which are kept by Santhera as stock for market supply, potential launch/ commercialization and inventory risk management purposes (security stock). Under the uncertainties following Santhera's withdrawal of its original MAA in January 2013, the API was fully impaired.

## 9 Trade and Other Receivables

|                             | In CHF thousands | 2014       | 2013      |
|-----------------------------|------------------|------------|-----------|
| Trade receivables           |                  | 610        | 0         |
| Other receivables           |                  | 110        | 42        |
| <b>Total at December 31</b> |                  | <b>720</b> | <b>42</b> |

Trade receivables in 2014 mainly result from sales in the EU, see note 17 "*Segment and Geographic Information*". Other receivables consist mainly of amounts due from the government for tax reimbursements (VAT) and other positions (prepayments). They are due within 30 to 120 days and bear no interest. No allowance for doubtful debts was recognized on the receivables as management estimates that no allowance is necessary as of December 31, 2014, and 2013.

## 10 Cash and Cash Equivalents

|                             | In CHF thousands | 2014          | 2013         |
|-----------------------------|------------------|---------------|--------------|
| Cash at banks and on hand   |                  |               |              |
| In CHF                      |                  | 16,416        | 4,347        |
| In EUR                      |                  | 724           | 331          |
| In USD                      |                  | 267           | 279          |
| In CAD                      |                  | 28            | 87           |
| <b>Total at December 31</b> |                  | <b>17,435</b> | <b>5,044</b> |

Short-term money market deposits

|        |        |   |
|--------|--------|---|
| In CHF | 10,002 | 0 |
|--------|--------|---|

Cash at banks earns interests at floating rates based on bank deposit rates. The fair value of the entirety of these positions at year-end amounted to CHF 17.4 million (2013: CHF 5.0 million).

## 11 Share Capital

### Ordinary share capital

As of January 1, 2013, the share capital amounted to CHF 3,677,538, divided into 3,677,538 Shares at a nominal value of CHF 1 each. During 2013, 11,511 Shares were issued from conditional capital upon the exercise of stock options under the EIP and ESOP 2004. 245,000 additional Shares were issued from conditional capital under the Standby Equity Distribution Agreement (**SEDA**) (see below). As a result, as of December 31, 2013, the share capital amounted to CHF 3,934,049, divided into 3,934,049 Shares at a nominal value of CHF 1 each.

During 2014, 197,126 Shares were issued from conditional capital upon the exercise of stock options under the EIP, BSOP 2011, ESOP 2004, ESOP 2008 and ESOP 2011. 355,000 Shares were issued from conditional capital for the SEDA (see below). 288,317 Shares were issued from authorized capital for a private placement and 200,000 Shares were issued from conditional capital for sale by an independent broker. As a result, as of December 31, 2014, the share capital amounted to CHF 4,974,492, divided into 4,974,492 Shares at a nominal value of CHF 1 each.

#### *Standby Equity Distribution Agreement*

In October 2013, Santhera entered into a SEDA with Yorkville Advisors Global Master SPV Ltd., New York, US (**YA Global**). Under the terms of the agreement, YA Global has committed to provide up to CHF 10 million in equity financing during a period of three years. The SEDA has been established in order to support the funding of Santhera's operations. It remains at the sole discretion of the Company to determine the timing of the funding. During 2014, Santhera has drawn a total of TCHF 1,444 from YA Global for which 399,425 Shares were delivered. During 2013, Santhera has drawn a total of TCHF 416 from YA Global for which 115,505 Shares were delivered. The remaining amount for equity financing with YA Global amounts to CHF 8.1 million.

#### *Treasury shares*

As of January 1, 2014, Santhera held 44,425 treasury shares which were not delivered to YA Global for draws in 2013. They were entirely delivered to YA Global for draws in 2014 (see above).

In connection with the liquidation of Oy Juvantia Pharma, Turku, Finland (**Juvantia**), a company acquired in 2009, Santhera received 8,028 Shares from former Juvantia shareholders. These treasury shares serve as pledge from the former owners of Juvantia for compensation of a potential tax claim related to pre-acquisition activities of Juvantia. Final tax assessment by the Finnish authorities is expected to be obtained mid to end 2015.

In total, Santhera holds 8,028 treasury shares as of December 31, 2014 (2013: 52,453).

### Authorized share capital

On the occasion of the ASM on May 20, 2014, the shareholders approved an extension of the authorized share capital of the Company. The Board is authorized to increase the share capital at any time until May 21, 2016, through the issuance of up to 1,500,000 Shares with a nominal value of CHF 1 each. An increase in partial amounts is permitted. For each such increase, the Board has to determine the issue price, the type of payment, the date of issuance of new Shares, the conditions for the exercise of pre-emptive rights and the beginning date for dividend entitlement.

## Conditional share capital

At the ASM the shareholders additionally approved a maximum increase of the share capital by an aggregate amount of CHF 800,000 (2013: CHF 700,000) through the issuance of a maximum of 800,000 (2013: 700,000) Shares with a nominal value of CHF 1 each. The Shares can be issued through the exercise of option rights which are granted according to respective regulations of the Board. The exercise price of each option to be granted shall, at the full discretion of the Board, either equal (i) the weighted average share price during the three months preceding the grant for employees outside the US and Canada, or (ii) the closing price of the Share at the grant date for employees in the US and Canada.

As of December 31, 2014, the Company had a conditional share capital, pursuant to the above provisions, whereby the share capital may be increased by

- a maximum amount of CHF 604,029 (2013: CHF 684,414) through the issuance of up to 604,029 (2013: 684,414) Shares, under the exclusion of shareholders' pre-emptive rights, for option rights being exercised under the Company's stock option plans, see note 16 "*Stock Option Plans*", and
- a maximum amount of CHF 600,000 (2013: CHF 355,000) by issuing up to 600,000 (2013: 355,000) Shares, through the exercise of warrants/options and/or notes granted in connection with bonds or similar debt instruments linked with option and/or conversion rights granted by the Company.

## 12 Deferred Taxes

### Net deferred taxes recorded

|  | In CHF thousands | <b>2014</b>    | <b>2013</b>    |
|--|------------------|----------------|----------------|
| Temporary differences on intangible assets     |                  | 831            | 844            |
| Tax loss carryforwards                         |                  | -831           | -844           |
| <b>Deferred tax liabilities recognized</b>     |                  | <b>0</b>       | <b>0</b>       |
| <hr/>  |                  |                |                |
| Tax loss carryforwards                         |                  | 317,170        | 338,649        |
| Of which recorded                              |                  | -4,153         | -4,220         |
| <b>Of which unrecorded</b>                     |                  | <b>313,017</b> | <b>334,429</b> |
| <hr/>  |                  |                |                |
| Expiring in                                    |                  |                |                |
| 1 year   |                  | 47,276         | 21,958         |
| 2 years  |                  | 9,738          | 47,276         |
| 3 years  |                  | 5,832          | 9,738          |
| 4 years  |                  | 22,671         | 5,832          |
| 5 years  |                  | 188,257        | 22,671         |
| More than 5 years                              |                  | 11,265         | 198,433        |
| Without expiration                             |                  | 27,978         | 28,521         |
| <b>Total unrecorded tax loss carryforwards</b> |                  | <b>313,017</b> | <b>334,429</b> |

Due to the uncertainty surrounding the future results of operations and the uncertainty as to whether Santhera can use the loss carryforwards for tax purposes, deferred tax assets on tax loss carryforwards were only considered to the extent that they offset taxable temporary differences within the same taxable entity. As there are no temporary differences associated with investments in subsidiaries, no deferred tax liability has to be recognized. No deferred tax assets are calculated on temporary differences related to pension obligations from IAS 19 (TCHF 2,680 per December 31, 2014 and TCHF 997 per December 31, 2013, respectively). Furthermore, there are no income tax consequences for Santhera of paying a dividend to its shareholders.

### 13 Trade and Other Payables

|                               | In CHF thousands | <b>2014</b>  | <b>2013</b> |
|-------------------------------|------------------|--------------|-------------|
| Trade payables                |                  | 1,654        | 597         |
| Other payables (nonfinancial) |                  | 512          | 0           |
| <b>Total at December 31</b>   |                  | <b>2,166</b> | <b>597</b>  |

All positions are noninterest-bearing and usually settled within 30 to 60 days.

### 14 Accrued Expenses

|  | In CHF thousands | <b>2014</b> | <b>2013</b>  |
|--|------------------|-------------|--------------|
| Development programs                     |                  | 422         | 785          |
| Liabilities to employees                 |                  | 137         | 53           |
| Accrued marketing and sales expenses     |                  | 38          | 27           |
| Expenses for audit, consulting and other |                  | 264         | 171          |
| <b>Total at December 31</b>              |                  | <b>861</b>  | <b>1,036</b> |

### 15 Commitments and Contingent Liabilities

#### Commitments

##### *Commitment for operating lease: buildings*

Santhera has lease contracts for its facilities in Liestal (Switzerland), Charlestown (US), Montréal (Canada) and Lörrach (Germany).

|                             | In CHF thousands | <b>2014</b> | <b>2013</b> |
|-----------------------------|------------------|-------------|-------------|
| Within 1 year               |                  | 125         | 125         |
| 1 year through 5 years      |                  | 0           | 0           |
| <b>Total at December 31</b> |                  | <b>125</b>  | <b>125</b>  |

## Contingent liabilities

### *License agreement with Institut National de la Santé et de la Recherche Médicale*

Based on a license agreement between Santhera and the Institut National de la Santé et de la Recherche Médicale, Paris, France (**INSERM**), Santhera has an obligation to make a milestone payment (TEUR 150) after approval of the first New Drug Application for Catena in Friedreich's Ataxia (**FA**) filed with the US Food and Drug Administration (**FDA**). In addition, Santhera has an obligation to pay to INSERM a running royalty equal to 3% of net sales, not to exceed EUR 0.5 million per year and Santhera has to pay 25% of any non-royalty sublicense income received in the US and Canada. As of December 31, 2014, Santhera had no ongoing development activities for Catena in FA.

### *Collaboration and license agreement with Takeda*

In September 2013, Santhera announced an agreement with Takeda Pharmaceutical Company Ltd, Osaka, Japan (**Takeda**) to license back all previously granted rights in DMD and FA in order to increase its strategic flexibility. In return, Takeda is eligible to obtain a percentage from future licensing and/or sales income generated by Santhera in DMD of up to EUR 7.0 million. In addition, Santhera has obtained the right to cross-reference Takeda's *idebenone* data for regulatory use in any indication and in any territory. If Santhera makes use of such cross-reference right, Takeda is eligible to obtain a percentage from future licensing and/or sales income generated by Santhera in such indications of up to EUR 3.0 million. Lastly, both companies agreed to terminate a similar agreement for FA signed in 2005 and Santhera's contingent liability of EUR 1.0 million payable to Takeda has been waived. Takeda is eligible to receive up to EUR 1.0 million as a percentage from future income generated by Santhera to offset this waiver.

### *Agreement with the University of Leuven*

In March 2005, Santhera entered into an agreement with Katholieke Universiteit Leuven, Leuven, Belgium (**KU Leuven**), under which K.U. Leuven assigned to Santhera its patents and patent applications relating to the use of Raxone/Catena to treat various forms of muscular-dystrophy-related disorders, particularly DMD. Based on this agreement, Santhera has filed patent applications in major territories covering the use of Raxone/Catena for the treatment of DMD.

KU Leuven is entitled to a success fee of up to EUR 0.4 million if and when Santhera commercializes any product in a major market, which includes the EU, the US or Japan and certain countries within the EU. In addition, in the event Santhera commercializes the product itself, KU Leuven is entitled to receive 5% royalties on net sales. In the event Santhera grants commercialization rights to a third party, KU Leuven will receive 15% of all the consideration received by Santhera from such third party.

### *License agreement with Novartis*

On June 30, 2007, Santhera entered into an agreement with Novartis Pharma AG, Basel, Switzerland (**Novartis**), under which it in-licensed *omigapil*. Santhera intends to develop *omigapil* for the treatment of Congenital Muscular Dystrophies (**CMD**). Additional payments will be due to Novartis a) upon start of a pivotal clinical trial, b) upon regulatory approval in a major market country, and c) after reaching certain commercialization milestones. Santhera will also have to pay royalties to Novartis calculated on net sales.

#### *Funding agreement with Association Française contre les Myopathies*

In October 2009, Santhera entered into an agreement with Association Française contre les Myopathies (**AFM**), under which Santhera received a funding of EUR 0.7 million to conduct certain preclinical studies in *omigapil*. In case Santhera launches *omigapil* for the treatment of CMD, it has to refund the grant. Two years after such launch, Santhera has to make an additional, final payment of EUR 1.5 million to AFM.

#### *Capital loans from Finnish Funding Agency for Technology and Innovation*

In connection with the acquisition of Juvantia in 2009, the title of capital loans from the Finnish Funding Agency for Technology and Innovation, Helsinki, Finland (**TeKes**), were passed on to Santhera. The loans were granted by Tekes in order to develop new medicines for movement disorders in Parkinson's disease (*fipamezole*). Upon grant of a first marketing authorization for *fipamezole* in a major country as specified by the contract, EUR 2.4 million plus accrued interests would become due and payable. Another EUR 2.4 million plus accrued interests would become due and payable one year after such first marketing authorization. Should no marketing authorization be granted, no payments will be due to Tekes under these capital loans. As of December 31, 2014, Santhera had no ongoing development activities with *fipamezole* in movement disorders.

#### *Capital loans from Finnish National Fund for Research and Development*

In connection with the acquisition of Juvantia in 2009, the title of capital loans from the Finnish National Fund for Research and Development, Helsinki, Finland (**Sitra**), were passed on to Santhera. The loans were granted by Sitra in order to develop new medicines for movement disorders in Parkinson's disease (*fipamezole*). Upon grant of a first marketing authorization for *fipamezole* in a major country as specified by the contract before December 31, 2014, EUR 0.2 million will be due. Another EUR 0.2 million would become due and payable one year after such first marketing authorization. Should no marketing authorization be granted, no payments will be due to Sitra under these capital loans and the respective contingent liabilities would lapse. As of December 31, 2014, Santhera had no ongoing development activities with *fipamezole* in movement disorders.

#### *Agreement with Orion*

In connection with the acquisition of Juvantia in 2009, Santhera was assigned the license agreement with Orion Corporation Orion Pharma, Espoo, Finland (**Orion**), on certain US patent rights on *fipamezole*. Under this license agreement, Santhera has to pay to Orion 1% on the US net sales and a limited royalty of up to USD 4.4 million based on future development and sales milestones received. As of December 31, 2014, Santhera had no ongoing development activities with *fipamezole* in movement disorders.

#### *Final tax assessment of Juvantia*

In connection with the liquidation of Juvantia and the transfer of intellectual property into Switzerland, the Company faces an uncertain tax position in Finland in the maximum amount of TEUR 250. An initial tax assessment in 2010 confirmed no such tax liability would become due and payable in line with the filed tax declaration. Final tax assessment by the Finnish authorities is expected to be obtained towards the mid to end 2015.

#### *Agreement with the National Institutes of Health*

In June 2013, Santhera has obtained an exclusive license from the National Institutes of Health, Bethesda/Maryland, US (**NIH**), to its rights on a patent granted in the US for the use of *idebenone* for the treatment of primary progressive Multiple Sclerosis. Under the terms of the agreement, Santhera would have to make certain milestone payments to the NIH not exceeding USD 1.4 million in total. Furthermore, the NIH is eligible to a royalty fee of 3% on net sales and 15% of considerations received in case Santhera sublicenses the program.

#### *Agreement with Piper Jaffray*

Santhera and Piper Jaffray Ltd, London, UK (**PJ**), are engaged in an agreement which ends on December 12, 2015. Under the terms of the agreement PJ, would be paid fees up to 5% of the aggregate consideration in case of a merger and acquisition transaction, a licensing transaction or an option agreement.

#### *Contracts for clinical development and other*

As part of its ordinary course of business, Santhera has entered into several contracts for e.g. clinical development services. Commitments are within current market prices and can be terminated at the Company's discretion. In order to meet its requirements for market supply, potential launch and inventory risk management purposes (security stock), Santhera entered into commitments for the purchase of active pharmaceutical ingredients in the amount of up to EUR 3.2 million (to be delivered in 2015).

#### **Contingent liabilities summary**

Santhera believes that the disclosures above and accruals (see note 14 "*Accrued Expenses*") are adequate based upon currently available information. However, given the inherent difficulties in estimating liabilities relating to clinical development, regulatory, tax, possible litigation and certain other matters due to uncertainty concerning both the amount and timing of future expenditures, it cannot be guaranteed that additional costs will not be incurred materially beyond the amounts accrued.

## 16 Stock Option Plans

Santhera has established stock option plans to align the long-term interests of the members of the Board, the Executive Management, employees and consultants. Options granted under the stock option plans are equity-settled.

### Executive Incentive Plan (EIP)

In November 2006, under the EIP, the members of the Executive Management were granted stock options to acquire 101,065 Shares, as a management incentive. Each of these stock options entitles its holder to purchase one Share at an exercise price of CHF 1. The vesting period of the options was one year. At the end of the option term, i.e. after a period of ten years as from the grant date, all unexercised stock options will expire without value. The EIP is administered under the responsibility of the Board. No further grants can be made under the EIP.

#### *Options outstanding, exercised or forfeited under the EIP*

All options under the EIP were granted to the four members of the Executive Management as of November 8, 2006, and had a vesting period of 12 months, see note 25 "Related Party Transactions".

| Number of options | 2014           |                |         |                  |                |                | 2013    |                  |
|-------------------|----------------|----------------|---------|------------------|----------------|----------------|---------|------------------|
|                   | Exer-<br>cised | For-<br>feited | Expired | Out-<br>standing | Exer-<br>cised | Forfeit-<br>ed | Expired | Out-<br>standing |
| EIP               | 42,598         | 0              | 0       | 2,000            | 10,737         | 0              | 0       | 44,598           |

### Employee Stock Option Plans (ESOPs)

The Company adopted the ESOP 2004, ESOP 2008 and ESOP 2010 to provide incentives to members of the Board, the Executive Management, employees and consultants helping to ensure their commitment to Santhera over the long term. Since January 1, 2010, new grants have been allocated under the ESOP 2010. Option grants are made from time to time at the discretion of the Board or as contractually agreed with senior employees. The ESOP 2004, ESOP 2008 and ESOP 2010 contain customary provisions in respect of the adjustment or cancellation of stock options upon termination of employment, retirement, death, disability and certain corporate transactions. All stock option plans are administered under the responsibility of the Board. Each stock option entitles its holder to purchase one Share of the Company at an exercise price defined to be either a) equal to the volume-weighted average share price in the three preceding months for Swiss employees, or b) the closing share price on the SIX Swiss Exchange (SIX) at each grant date for employees in the US and Canada only. In general, 50% of the stock options vest on the second anniversary, 25% on the third anniversary and the remaining 25% on the fourth anniversary of the grant date. At the end of the option term, i.e. after a period of 10 years as from the grant date, unexercised stock options expire without value. Subject to the provisions of the ESOP 2004, vested stock options of employees leaving the Company in good faith do not lapse. Under the ESOP 2008 and ESOP 2010 vested stock options of employees leaving the Company in good faith expire six months after the termination date of the employment. Unvested stock options of employees leaving the Company are forfeited under all stock option plans.

*Options outstanding, exercised, forfeited or expired under ESOP 2004, ESOP 2008 and ESOP 2010*

| Number of options | <b>2014</b>    |                |              |              |                |
|-------------------|----------------|----------------|--------------|--------------|----------------|
|                   | Exercised      | Granted        | Forfeited    | Expired      | Outstanding    |
| ESOP 2004         | 45,834         | 0              | 0            | 4,365        | 35,136         |
| ESOP 2008         | 4,000          | 0              | 0            | 0            | 1,500          |
| ESOP 2010         | 70,694         | 332,800        | 5,800        | 850          | 409,444        |
| <b>Total</b>      | <b>120,528</b> | <b>332,800</b> | <b>5,800</b> | <b>5,215</b> | <b>446,080</b> |

| Number of options | <b>2013</b> |            |               |               |                |
|-------------------|-------------|------------|---------------|---------------|----------------|
|                   | Exercised   | Granted    | Forfeited     | Expired       | Outstanding    |
| ESOP 2004         | 774         | 0          | 0             | 6,040         | 85,335         |
| ESOP 2008         | 0           | 0          | 0             | 28,000        | 5,500          |
| ESOP 2010         | 0           | 800        | 36,176        | 22,000        | 153,988        |
| <b>Total</b>      | <b>774</b>  | <b>800</b> | <b>36,176</b> | <b>56,040</b> | <b>244,823</b> |

**Board Stock Option Plan (BSOP)**

In January 2011, the Company adopted the BSOP 2011 to provide incentives to members of the Board. Since January 1, 2011, new grants have been made under this plan. The plan contains the same customary provisions as under the ESOP plans described above. Each stock option entitles its holder to purchase one Share of the Company at an exercise price defined to be either a) equal to the volume-weighted average share price in the three preceding months for Swiss and EU Board members, or b) the closing share price on the SIX at each grant date for US or Canadian Board members. In general, 100% of the stock options vest on the first anniversary of the grant date. At the end of the option term, i.e. after a period of 10 years as from the grant date, unexercised stock options expire without value. Vested stock options of Board members leaving the Board in good faith expire six months after the termination date of them being a member of the Board. Unvested stock options of Board members leaving the Board are forfeited.

*Options outstanding, exercised, forfeited or expired under BSOP 2011*

| Number of options | <b>2014</b> |         |           |         |             |
|-------------------|-------------|---------|-----------|---------|-------------|
|                   | Exercised   | Granted | Forfeited | Expired | Outstanding |
| BSOP 2004         | 34,000      | 29,500  | 0         | 0       | 29,500      |

| Number of options | <b>2013</b> |         |           |         |             |
|-------------------|-------------|---------|-----------|---------|-------------|
|                   | Exercised   | Granted | Forfeited | Expired | Outstanding |
| BSOP 2004         | 0           | 10,500  | 0         | 9,500   | 34,000      |

As of December 31, 2014, 126,449 stock options (2013: 369,993) are available for future grants under the ESOP 2010 and/or the BSOP 2011.

### Fair value calculations for stock options granted under ESOP 2010 and BSOP 2011

The fair value of stock options is determined at each grant date by using the Hull-White option pricing model. The calculation of the option value was performed by applying the following parameters:

|  | <b>2014</b>         | <b>2013</b>            |
|--|---------------------|------------------------|
| Market price of stock                          | CHF 3.46 to 104.90  | CHF 1.09 to 6.00       |
| Exercise prices                                | CHF 4.23 to 101.00  | CHF 1.97 to 3.66       |
| Weighted average fair value of options granted | CHF 2.93            | CHF 1.47               |
| Expected volatility <sup>1</sup>               | 50% to 53%          | 65% to 73%             |
| CHF risk-free interest rate                    | 0.71% to 0.98% p.a. | 0.75% to 1.11%<br>p.a. |
| Option term <sup>2</sup>                       | 10 years            | 10 years               |
| Expected dividend yield                        | 0%                  | 0%                     |

<sup>1</sup> The expected volatility was determined on the basis of the historical volatility of the Company and selected biotech companies.

<sup>2</sup> After expiration of the vesting period, the stock options become American style options and may be exercised any time until the end of the option term. The option-pricing model takes into consideration certain assumptions about potential early exercises.

### Number of stock options outstanding and exercisable

|                                   | Number of options | <b>2014</b>    | <b>2013</b>    |
|-----------------------------------|-------------------|----------------|----------------|
| <b>Outstanding at January 1</b>   |                   | <b>323,421</b> | <b>425,348</b> |
| Granted                           |                   | 362,300        | 11,300         |
| Exercised <sup>1</sup>            |                   | -197,126       | -11,511        |
| Forfeited                         |                   | -5,800         | -45,676        |
| Expired                           |                   | -5,215         | -56,040        |
| <b>Outstanding at December 31</b> |                   | <b>477,580</b> | <b>323,421</b> |
| <b>Exercisable at December 31</b> |                   | <b>98,655</b>  | <b>263,371</b> |

<sup>1</sup> The average closing share price of options exercised during the reporting period 2014 was CHF 47.40 (2013: CHF 2.56).

The value of stock options granted is recognized as personnel expense over their vesting period. In 2014, stock option grants resulted in personnel expenses of TCHF 759 (TCHF 386 related to Development, TCHF 26 related to Marketing & Sales (M&S) and TCHF 347 to General & Administration (G&A)) and in 2013, such grants resulted in personnel expenses of TCHF 290 (TCHF 101 related to Development, TCHF 26 related to M&S and TCHF 163 to G&A).

In 2013, out of a total of TCHF 290, TCHF 41 were expensed for the accelerated vesting in the course of the option plan modification from May/June 2012.

In January 2014, a total of 352,000 options with exercise prices between CHF 3.78 and CHF 4.02 were granted. The majority of these options were exceptionally granted in order to reduce the risk of losing employees at a time when the company was in a very critical financial situation.

**Terms of options outstanding at December 31**

| Exercise price range<br>for options (in CHF) | Number<br>out-<br>standing | Weighted<br>average<br>remaining<br>contractu-<br>al life<br>(years) | <b>2014<br/>Number<br/>exercisa-<br/>ble</b> | Number<br>out-<br>standing | Weighted<br>average<br>remaining<br>contractual<br>life (years) | 2013<br>Number<br>exercisa-<br>ble |
|--|----------------------------|--|--|----------------------------|---|------------------------------------|
| 1.00   | 2,000                      | 1.85   | 2,000  | 46,434                     | 2.75  | 46,434                             |
| from 3.78 to 6.34                            | 428,644                    | 8.75   | 60,019                                       | 187,988                    | 8.45  | 136,938                            |
| from 22.25 to 30.10                          | 11,800                     | 8.90   | 1,500  | 5,500                      | 2.11  | 5,500                              |
| from 59.44 to 60.25                          | 28,833                     | 1.62   | 28,833                                       | 77,196                     | 1.76  | 77,196                             |
| from 82.58 to 114.50                         | 6,303                      | 1.89   | 6,303  | 6,303                      | 2.89  | 6,303                              |
| <b>Total</b>                                 | <b>477,580</b>             | <b>8.20</b>  | <b>98,655</b>                                | <b>323,421</b>             | <b>5.74</b>   | <b>272,371</b>                     |

## 17 Segment and Geographic Information

### Segment information

Santhera operates in one operating segment, the development and commercialization of specialty niche products for the treatment of mitochondrial and neuromuscular diseases. The Board, the Executive Management and senior managers, being the CODM, assess the reporting data and allocate resources as one segment on an aggregated consolidated level according to the operating expenses by function. Santhera generates revenue from sales of Raxone/Catena for the treatment of LHON, DMD and FA. Geographic revenue information is based on location of the customer.

### Geographic information

#### *Net sales*

|                   | In CHF thousands | 2014         | 2013         |
|-------------------|------------------|--------------|--------------|
| EU                |                  | 2,548        | 467          |
| North America     |                  | 0            | 852          |
| Rest of the world |                  | 43           | 0            |
| <b>Total</b>      |                  | <b>2,591</b> | <b>1,319</b> |

#### *Noncurrent assets (excluding financial instruments and deferred taxes)*

|               | In CHF thousands | 2014         | 2013         |
|---------------|------------------|--------------|--------------|
| EU (Germany)  |                  | 3,523        | 3,590        |
| Switzerland   |                  | 803          | 674          |
| North America |                  | 3            | 0            |
| <b>Total</b>  |                  | <b>4,329</b> | <b>4,264</b> |

In 2014, net sales of Raxone/Catena under special programs (e.g. the French temporary authorization for use as well as international Named Patient Programs) amounted to CHF 2.6 million, mainly in the EU. There were no sales in Canada after the Company's voluntary withdrawal of the product from the Canadian market in April 2013. In 2013 there were sales of CHF 0.47 million in the EU and CHF 0.85 million under a conditional marketing authorization in Canada.

## 18 Other Operating Income

This position consists primarily of reimbursements from scientific programs (and income from disposal of assets in 2013).

## 19 Operating Expenses by Nature

|  | In CHF thousands | 2014           | 2013          |
|--|------------------|----------------|---------------|
| External Development expenses                                |                  | -3,168         | -1,826        |
| Patent and license expenses                                  |                  | -229           | -345          |
| Marketing expenses   |                  | -446           | -441          |
| Employee expenses  |                  | -4,747         | -3,925        |
| Of which non-cash-relevant expenses for share-based payments |                  | -759           | -290          |
| Other administrative expenses                                |                  | -1,517         | -1,314        |
| Depreciation, amortization and impairment                    |                  | -75            | -598          |
| Lease expenses   |                  | -251           | -295          |
| Other operating expenses                                     |                  | -9             | 0             |
| <b>Total operating expenses</b>                              |                  | <b>-10,442</b> | <b>-8,744</b> |

Impairment of intangible assets is recognized in development expenses. Allowances on inventory are recognized in development expenses.

## 20 Employee Expenses and Benefits

### Employee expenses

|   | In CHF thousands | 2014          | 2013          |
|---|------------------|---------------|---------------|
| Wages and salaries  |                  | -3,002        | -3,169        |
| Social security and other personnel-related expenses <sup>1</sup> |                  | -986          | -466          |
| Of which non-cash-relevant adjustments of pension fund            |                  | 9             | 51            |
| Share-based payments  |                  | -759          | -290          |
| <b>Total employee costs</b>                                       |                  | <b>-4,747</b> | <b>-3,925</b> |

|  |             |             |
|--|-------------|-------------|
| <b>Average number of full-time equivalents<sup>2</sup></b> | <b>13.8</b> | <b>16.8</b> |
|--|-------------|-------------|

|  |             |             |
|--|-------------|-------------|
| <b>Full-time equivalents at year-end</b> | <b>14.7</b> | <b>11.8</b> |
|--|-------------|-------------|

|                                    |           |           |
|------------------------------------|-----------|-----------|
| <b>Total headcount at year-end</b> | <b>18</b> | <b>14</b> |
|------------------------------------|-----------|-----------|

<sup>1</sup> Thereof TCHF 3 were expensed for defined contribution plans in North America (2013: TCHF 16).

<sup>2</sup> For the calculation of full-time equivalents, only employees with part-time and full-time permanent working contracts are taken into consideration.

### Termination benefits

In 2014 and 2013, no termination benefits were expensed.

## Pension plan

In accordance with the Swiss pension fund law "Federal Act on Occupational Old Age, Survivors' and Invalidity Pension Provision" (OPA), all employees of Santhera Pharmaceuticals Holding AG and Santhera Pharmaceuticals (Schweiz) AG, both in Liestal, Switzerland, have to be affiliated with a collective independent pension fund. These funds provide for retirement benefits, as well as risk benefits (death and disability). The plans qualify as defined benefit plans under IAS 19 and the assets cannot revert to employer. Contributions to the plans are such that the employee contributes 40% and the employer the rest. Contributions are computed as percentage of the salary, depending on age. In order to manage these risks, Santhera entered into an agreement with AXA Foundation for occupational benefits (AXA foundation). The AXA foundation is responsible for the governance of the plan; the board is composed of an equal number of representatives from the employers and employees chosen from all affiliated companies. AXA foundation has set up investment guidelines, defining in particular the strategic allocation with margins. AXA foundation has reinsured its risks (investment risk, mortality risk, etc.) with AXA Life Ltd, Winterthur, Switzerland (AXA). AXA manages the savings capital/investments on behalf of AXA foundation. The accumulated saving capital is allocated to each insured individual and consists of annual contributions, saving credits and interest credits. In certain situations, additional payments or increased periodic contributions by the employer may become due based on the pension plans funded status as measured under Swiss pension rules (OPA).

An independent actuary has performed the respective calculations as required by IAS 19:

### *Changes in defined benefit obligations*

|   | In CHF thousands | 2014         | 2013         |
|---|------------------|--------------|--------------|
| <b>Present value of obligation, January 1</b>   |                  | <b>4,176</b> | <b>7,048</b> |
| Current employer service cost                   |                  | 297          | 447          |
| Past service cost <sup>1</sup>                  |                  | -89          | 0            |
| (Gain)/loss on settlement                       |                  | 0            | -310         |
| Interest cost                                   |                  | 94           | 141          |
| Employee contributions                          |                  | 138          | 166          |
| Benefits paid / transfer payments               |                  | 1,524        | -1,180       |
| Insurance premiums                              |                  | -75          | -90          |
| Plan settlement                                 |                  | 0            | -1,247       |
| Remeasurements <sup>2</sup>                     |                  | 1,682        | -799         |
| <b>Present value of obligation, December 31</b> |                  | <b>7,747</b> | <b>4,176</b> |

<sup>1</sup> Decrease of obligation due to reduction of the conversion rates for the over-mandatory part of the retirement capital.

<sup>2</sup> Details of remeasurements:

|   | In CHF thousands | 2014         | 2013        |
|---|------------------|--------------|-------------|
| Actuarial (gain)/loss due to changes in demographic assumptions       |                  | 0            | 0           |
| Actuarial (gain)/loss due to changes in financial assumptions         |                  | 1,604        | -236        |
| Actuarial (gain)/loss due to experience adjustments                   |                  | 78           | -563        |
| <b>Subtotal (gain)/loss</b>   |                  | <b>1,682</b> | <b>-799</b> |
| (Return)/loss on plan assets (excluding interest income)              |                  | 10           | 26          |
| <b>Total remeasurements in other comprehensive income (gain)/loss</b> |                  | <b>1,692</b> | <b>-773</b> |

*Changes in plan assets*

|   | In CHF thousands | 2014         | 2013         |
|---|------------------|--------------|--------------|
| <b>Fair value of assets, January 1</b>                                    |                  | <b>3,179</b> | <b>5,227</b> |
| Interest income on assets   |                  | 77           | 108          |
| Employer contributions  |                  | 234          | 221          |
| Employee contributions  |                  | 138          | 166          |
| Benefits paid / transfer payments   |                  | 1,524        | -1,180       |
| Insurance premiums  |                  | -75          | -90          |
| Plan settlement   |                  | 0            | -1,247       |
| Remeasurements (return/(loss) on plan assets (excluding interest income)) |                  | -10          | -26          |
| <b>Fair value of assets, December 31</b>                                  |                  | <b>5,067</b> | <b>3,179</b> |

*Net defined benefit asset/(obligation)*

|  | In CHF thousands | 2014          | 2013        |
|--|------------------|---------------|-------------|
| Present value of obligation, December 31 |                  | 7,747         | 4,176       |
| Fair value of assets, December 31        |                  | 5,067         | 3,179       |
| <b>Net defined asset/(obligation)</b>    |                  | <b>-2,680</b> | <b>-997</b> |

*Asset breakdown*

Assets of the defined benefit plan are not quoted since AXA fully insures them. Therefore the entire amount of TCHF 5,067 (2013: TCHF 3,179) is treated as an insurance contract and has no quoted market price.

*The weighted-average assumptions to determine benefit obligations and defined benefit cost were as follows:*

|                                  | In % | 2014 | 2013 |
|----------------------------------|------|------|------|
| Discount rate                    |      | 1.05 | 2.30 |
| Expected future salary increases |      | 1.50 | 1.50 |

*Sensitivity analysis for 2014:*

| In CHF thousands         | Defined benefit obligation |                     | Gross service cost  |                     |
|--------------------------|----------------------------|---------------------|---------------------|---------------------|
|                          | Increase assumption        | Decrease assumption | Increase assumption | Decrease assumption |
| Discount rate +/- 0.25%  | -369                       | 397                 | -31                 | 33                  |
| Salary increase +0.25%   | 73                         | -                   | -4                  | -                   |
| Live expectancy + 1 year | 150                        | -                   | 10                  | -                   |

*Sensitivity analysis for 2013:*

| In CHF thousands        | Defined benefit obligation |                     | Gross service cost  |                     |
|-------------------------|----------------------------|---------------------|---------------------|---------------------|
|                         | Increase assumption        | Decrease assumption | Increase assumption | Decrease assumption |
| Discount rate +/- 0.25% | -180                       | 195                 | -21                 | 22                  |
| Salary increase +0.25%  | 55                         | -                   | -2                  | -                   |
| Live expectancy +1 year | 43                         | -                   | 4                   | -                   |

*Mortality rate:*

| Life expectancy at age 65 | 2014  | 2013  |
|---------------------------|-------|-------|
| Male                      | 21.49 | 21.39 |
| Female                    | 23.96 | 23.86 |

The expected employer contributions for fiscal year 2015 amount to approximately TCHF 256 (2014: TCHF 232). No benefit obligations for pensioners were calculated as per December 31, 2014 (2013: none). The duration of the plan liabilities calculated is 20.8 years as per December 31, 2014 (2013: 20.1 years).

## 21 Financial Income/Expenses

### Financial income

|  | In CHF thousands | 2014      | 2013         |
|--|------------------|-----------|--------------|
| Interests on cash and cash equivalents         |                  | 4         | 5            |
| Realized and unrealized foreign exchange gains |                  | 50        | 200          |
| Settlement finance lease liabilities           |                  | 0         | 1,526        |
| <b>Total</b>                                   |                  | <b>54</b> | <b>1,731</b> |

### Financial expenses

|   | In CHF thousands | 2014       | 2013        |
|---|------------------|------------|-------------|
| Interest expenses                               |                  | -7         | -9          |
| Interest expenses for finance lease             |                  | 0          | -12         |
| Realized and unrealized foreign exchange losses |                  | -62        | -161        |
| <b>Total</b>                                    |                  | <b>-69</b> | <b>-182</b> |

## 22 Currency Translation Differences

Currency translation differences derive from currency valuation differences from investments in subsidiaries and their assets and liabilities. The loss of CHF 0.1 million in 2014 is primarily related to the valuation of intangible assets denominated in EUR (2013: CHF 0.1 million).

## 23 Income Taxes

|                                     | In CHF thousands | <b>2014</b> | <b>2013</b> |
|-------------------------------------|------------------|-------------|-------------|
| Current income tax income/(expense) |                  | -2          | 5           |
| Deferred tax income/(expense)       |                  | 0           | 0           |
| <b>Total</b>                        |                  | <b>-2</b>   | <b>5</b>    |

The following is a theoretical reconciliation of the income taxes calculated at the Group's expected effective income tax rate:

|   | In CHF thousands | <b>2014</b> | <b>2013</b> |
|---|------------------|-------------|-------------|
| Result before taxes                                     |                  | -7,532      | -5,760      |
| Tax income of applicable tax rate of 20% <sup>1</sup>   |                  | 1,506       | 1,152       |
| Effect of tax rate change                               |                  | 0           | 0           |
| Value adjustments on investments and intercompany loans |                  | 0           | 1,201       |
| Unrecognized deferred taxes on tax loss carryforwards   |                  | -1,508      | -2,347      |
| Effective tax income/(expense)                          |                  | -2          | 5           |
| Effective tax rate                                      |                  | 0.03%       | 0.09%       |

<sup>1</sup> The tax rate of 20% represents the Group's expected long-term tax rate based on rates applicable in those jurisdictions where taxable income should be generated in the future.

According to currently applicable Swiss tax law, the period to offset tax loss carryforwards against taxable profit is limited to seven years. According to currently applicable German tax law, tax loss carryforwards can, besides other conditions, be offset against taxable profit for an unlimited period but only to an amount of EUR 1.0 million and in addition for 60% of further amounts beyond this threshold per annum.

## 24 Earnings/Loss per Share

Basic earnings/loss per share is calculated by dividing the net profit/net loss attributable to equity holders by the weighted average number of shares issued and outstanding during the reporting period, excluding shares held as treasury shares.

|  | <b>2014</b>  | <b>2013</b>  |
|--|--------------|--------------|
| Net result attributable to equity holders (in CHF)       | -7,533,925   | -5,754,752   |
| Weighted average number of shares issued and outstanding | 4,704,000    | 3,708,260    |
| <b>Basic and diluted net result per share (in CHF)</b>   | <b>-1.60</b> | <b>-1.55</b> |

For the years ended December 31, 2014 and 2013, basic and diluted result per share is based on the weighted average number of Shares issued and outstanding, and excludes Shares to be issued upon the future exercise of employee stock options or warrants, as they would be anti-dilutive. In case Santhera shows a profit in the future, the options may have a dilutive effect on the net profit per Share and will need to be considered for the purpose of this calculation.

## 25 Related Party Transactions

### Board and Executive Management compensation

#### *Total compensation of Board and Executive Management*

|  | In CHF thousands | <b>2014</b> | <b>2013</b> |
|--|------------------|-------------|-------------|
| Compensation, wages and salaries   |                  | 504         | 456         |
| Post-employment benefits (pension fund contributions)                      |                  | 35          | 43          |
| Share-based payment expenses (fair value according to IFRS 2) <sup>1</sup> |                  | 184         | 153         |

<sup>1</sup> Fair values consist of option grants and modifications of existing grants from 2014 and 2013, respectively, as well as option grants from earlier years whose vesting periods include the reporting periods. Employee stock options are expensed over their vesting periods in accordance with IFRS 2, and the fair values included in above table are derived from the disclosed fair values of issued stock options as accounted for in the consolidated statement of changes in equity.

#### *Executive Management compensation*

|   | In CHF thousands | <b>2014</b> | <b>2013</b> |
|---|------------------|-------------|-------------|
| Wages and salaries, inclusive variable compensation   |                  | 427         | 326         |
| Post-employment benefits (pension fund contributions) |                  | 35          | 43          |
| Stock option grants (number)                          |                  | 52,000      | 0           |

In 2014, the only remuneration for the Executive Management was paid to Thomas Meier, Chief Executive Officer (CEO). He received a gross compensation of TCHF 427 and 52,000 stock options. In 2013, the only remuneration for the Executive Management was paid to Thomas Meier, CEO. He received a gross compensation of TCHF 326 and no stock options.

*Board compensation*

|                        | In CHF thousands | 2014   | 2013   |
|------------------------|------------------|--------|--------|
| Compensation fix       |                  | 77     | 130    |
| Stock options (number) |                  | 29,500 | 10,500 |

In 2014, the highest compensation to a member of the Board was paid to Martin Gertsch, Chairman of the Board. He received a gross compensation of TCHF 45 and 16,500 stock options. In 2013, the highest compensation to a member of the Board was paid to Martin Gertsch, Chairman of the Board. He received a gross compensation of TCHF 45 and 7,000 stock options.

*Transactions with members of the Board and Executive Management*

There are no loans outstanding or guarantee commitments granted to members of the Board and Executive Management.

*Shareholdings of members of the Board and Executive Management*

The table below sets forth the number of stock options and Shares individually held or controlled by members of the Board and the Executive Management:

| Per December 31             | 2014 Total<br>number of<br>Shares | 2014 Total<br>number of<br>stock options | 2013 Total<br>number of<br>Shares | 2013 Total<br>number of<br>stock options |
|-----------------------------|-----------------------------------|--|-----------------------------------|--|
| <b>Board</b>                |                                   |  |                                   |  |
| Martin Gertsch, Chairman    | 21,609                            | 16,500                                   | 1,230                             | 17,000                                   |
| Jürg Ambühl                 | 17,000                            | 13,000                                   | 800                               | 7,000                                    |
| <b>Total</b>                | <b>38,609</b>                     | <b>29,500</b>                            | <b>2,030</b>                      | <b>24,000</b>                            |
| <b>Executive Management</b> |                                   |  |                                   |  |
| Thomas Meier, CEO           | 38,508                            | 108,144                                  | 14,613                            | 80,039                                   |

In 2014, 24,000 options were exercised by members of the Board (2013: 0 stock options exercised). 23,895 stock options were exercised by the Executive Management (2013: 0 stock options exercised).

The table below shows the total number of options granted to the members of the Board in the three preceding years and the respective exercise prices (including former members of the Board):

| Year of grant | Total number of options | Exercise prices in CHF |
|---------------|-------------------------|------------------------|
| 2011          | 1,000                   | 9.40                   |
| 2011          | 1,000                   | 8.55                   |
| 2011          | 1,000                   | 7.90                   |
| 2011          | 2,500                   | 7.36                   |
| 2012          | 8,000                   | 6.34                   |
| 2012          | 1,000                   | 4.53                   |
| 2012          | 1,000                   | 4.27                   |
| 2012          | 23,000                  | 4.27                   |
| 2013          | 2,500                   | 4.04                   |
| 2013          | 1,000                   | 3.56                   |
| 2013          | 7,000                   | 1.91                   |
| 2014          | 1,000                   | 3.78                   |
| 2014          | 27,000                  | 3.89                   |
| 2014          | 1,500                   | 22.25                  |

The table below shows the total number of stock options granted to the members of the Executive Management in the three preceding years and their respective exercise prices (including former members of the Executive Management):

| Year of grant | Total number of options | Exercise prices in CHF |
|---------------|-------------------------|------------------------|
| 2011          | 0                       | 0                      |
| 2012          | 15,000                  | 4.53                   |
| 2012          | 41,144                  | 4.27                   |
| 2013          | 0                       | 0                      |
| 2014          | 52,000                  | 3.89                   |

The detailed disclosures regarding executive remuneration that are required by Swiss law are included in the Compensation Report.

## 26 Risk Management Objectives and Policies

Santhera Pharmaceuticals Holding AG maintains a Group-wide corporate risk management system consisting of the areas corporate governance, financial internal controls and quality control / quality assurance.

On a regular basis, operational corporate risks are identified and their likelihood and impact assessed (gross risks). By defining and undertaking appropriate measures, these risks are managed accordingly to either reduce or avoid such risk (net risk). The results of this process are discussed at Board meetings.

Those risks as identified within the area of accounting and financial reporting as well as related control processes are further covered by the Company's Group-wide internal control system.

Santhera conducts development activities primarily in Switzerland, the EU and the US and is exposed to a variety of financial risks, such as, but not limited to, foreign exchange rate risk, credit risk, liquidity risk, cash flow and interest rate risk. Part of Santhera's overall risk management focuses on financial risks and the unpredictability of financial markets seeking to minimize potential adverse effects on the financial performance of the Group. Special guidelines and policies approved by the Board exist for overall risk management, financial internal controls and treasury management and are monitored by the Executive Management and the Board on a regular basis. The risk of foreign exchange rate fluctuations on the expenses can partly be managed by entering into foreign exchange derivative contracts. In accordance with the relevant treasury guidelines, Santhera only concludes contracts with selected high-quality financial institutions of good reputation and is not allowed to engage in speculative transactions. In addition, Santhera's treasury guidelines currently limit the Company to engage in money market deposits or similar instruments with a maturity beyond 12 months.

### Foreign exchange rate risk

Santhera holds cash amounts in four major currencies CHF, EUR, USD and CAD to cover the majority of future expected expenses. In addition, in order to reduce its foreign exchange rate exposure, Santhera occasionally enters into derivative currency contracts (forwards, options, structured derivatives) to hedge against additional major foreign currency exchange rate fluctuations. Evaluations based on market values were performed regularly. Any fair value changes of such currency positions are recorded accordingly in the income statement. Santhera's primary exposure to financial risk is due to fluctuation of exchange rates between CHF, EUR, USD and CAD.

Cash and cash equivalents held in EUR, USD and CAD are expected to cover estimated purchases in those currencies until end of 2014. No derivative currency contracts are outstanding as of December 31, 2014 and 2013.

The following table demonstrates the sensitivity to a reasonable possible change in EUR and USD exchange rate, with all other variables held constant, of the Group's result before taxes. There is no impact on the Group's equity.

|                      | Increase/decrease<br>foreign currency rate | Effect on result before taxes<br>in CHF thousands |
|----------------------|--|---|
| <b>EUR positions</b> |  |   |
| 2014                 | +5%  | -17   |
|                      | -20%                                       | 67  |
| 2013                 | +5%  | 8   |
|                      | -5%  | -8  |
| <b>USD positions</b> |  |   |
| 2014                 | +5%  | 4   |
|                      | -15%                                       | -11   |
| 2013                 | +10%                                       | 20  |
|                      | -5%  | -10   |

### Interest rate risk

Santhera earns interest income on cash and cash equivalents and its profit and loss may be influenced by changes in market interest rates. Santhera is either holding its cash on deposit/current accounts or investing cash through money market instruments in line with its treasury guidelines to follow its financial needs over time.

The following table demonstrates the sensitivity to a reasonable change in interest rates, with all other variables held constant, of the Group's result before taxes. There is no impact on the Group's equity.

As per end of 2014, variances of +/-50 basis points were calculated, resulting in fluctuations of +/-TCHF 87 before tax (end of 2013: +/-50 basis points resulting in fluctuations of +/-TCHF 25 before tax).

### Credit risk

Santhera has a certain concentration of credit risk. Short-term investments are invested as cash on deposit or in low risk money market funds, i.e. money market accounts with government-backed corporate banks, top-tier categorized banks or S&P A-1 rated money market investment instruments or similar ratings. No investment or contract with any single counterparty, except cash on deposit subject to the criteria above, comprises more than 20% of cash and cash equivalents at the date of investment.

Santhera has policies in place to ensure that sales of products or entered partnerships are made to customers or with partners with an appropriate credit history and a commitment to ethical business practices. The maximum credit risk exposure is limited to the carrying amount of its financial assets including derivatives.

**Liquidity risk**

Prudent liquidity risk management implies maintaining sufficient cash and cash equivalents. Currently, the Company is financed through equity and there is no interest-bearing funding through debt instruments. Santhera's treasury calculates on a rolling basis the needs for aligning the current expenses against the need for optimized financial investments.

*Contractual undiscounted cash flows*

| Year ended<br>December 31, 2014<br>in CHF thousands | On<br>demand | Less than<br>3 months | 3 to 12<br>months | 1 to 5<br>years | After<br>5 years | Total        | Book<br>value |
|---|--------------|-----------------------|-------------------|-----------------|------------------|--------------|---------------|
| Accrued expenses                                    | 0            | 861                   | 0                 | 0               | 0                | 861          | 861           |
| Trade payables                                      | 0            | 1,654                 | 0                 | 0               | 0                | 1,654        | 1,654         |
| <b>Total</b>  | <b>0</b>     | <b>2,515</b>          | <b>0</b>          | <b>0</b>        | <b>0</b>         | <b>2,515</b> | <b>2,515</b>  |

| Year ended<br>December 31, 2013<br>in CHF thousands | On<br>demand | Less than<br>3 months | 3 to 12<br>months | 1 to 5<br>years | After<br>5 years | Total        | Book<br>value |
|---|--------------|-----------------------|-------------------|-----------------|------------------|--------------|---------------|
| Accrued expenses                                    | 0            | 1,036                 | 0                 | 0               | 0                | 1,036        | 1,036         |
| Trade payables                                      | 0            | 597                   | 0                 | 0               | 0                | 597          | 597           |
| <b>Total</b>  | <b>0</b>     | <b>1,633</b>          | <b>0</b>          | <b>0</b>        | <b>0</b>         | <b>1,633</b> | <b>1,633</b>  |

**Categories of financial instruments**

| Year ended December 31, 2014<br>in CHF thousands | Book value    | Loans and receivables | Other liabilities at<br>amortized cost |
|--|---------------|-----------------------|--|
| <b>Assets</b>                                    |               |                       |  |
| Financial assets long-term                       | 85            | 85                    | 0                                      |
| Trade receivables                                | 610           | 610                   | 0                                      |
| Other receivables                                | 41            | 41                    | 0                                      |
| Cash and cash equivalents                        | 17,435        | 17,435                | 0                                      |
| <b>Total</b>                                     | <b>18,171</b> | <b>18,171</b>         | <b>0</b>                               |
| <b>Liabilities</b>                               |               |                       |  |
| Trade payables                                   | 1,654         | 0                     | 1,654                                  |
| <b>Total</b>                                     | <b>1,654</b>  | <b>0</b>              | <b>1,654</b>                           |

| Year ended December 31, 2013<br>in CHF thousands | Book value   | Loans and receivables | Other liabilities at<br>amortized cost |
|--|--------------|-----------------------|--|
| <b>Assets</b>                                    |              |                       |  |
| Financial assets long-term                       | 85           | 85                    | 0                                      |
| Trade receivables                                | 1            | 1                     | 0                                      |
| Other receivables                                | 2            | 2                     | 0                                      |
| Cash and cash equivalents                        | 5,044        | 5,044                 | 0                                      |
| <b>Total</b>                                     | <b>5,132</b> | <b>5,132</b>          | <b>0</b>                               |
| <b>Liabilities</b>                               |              |                       |  |
| Trade payables                                   | 597          | 0                     | 597                                    |
| <b>Total</b>                                     | <b>597</b>   | <b>0</b>              | <b>597</b>                             |

### Capital management

The first priority of Santhera's capital management is to provide adequate cash funds to ensure the financing of successful development and marketing activities so that future profits can be generated by gaining marketing authorization approvals for pharmaceutical products. As a company with currently one product on a smaller market, the capital management continues to be focused on the cash and cash equivalents position and is governed by specific Group treasury guidelines.

The funds raised in various private financing rounds, the private placement in 2008 and 2014, SEDA, the sale of Shares by an independent broker as well as funds generated through product sales and revenue from licensing enabled the group to be adequately financed. However, further financing could be needed for the Group to continue as a going concern, see note 2 "*Summary of Significant Accounting Policies*".

No changes in goals and policies of the treasury management have been made during the past two reporting years.

## 27 Events After the Reporting Date

In January 2015, Santhera announced that, with effect of February 1, 2015, it strengthened its leadership team by appointing Nicholas Coppard, PhD, SVP Head Development, Günther Metz, PhD, SVP Business Development, and Oliver Strub, General Counsel and Secretary to the Board, to the Executive Management Team headed by CEO Thomas Meier, PhD. Additionally, Giovanni Stropoli has been appointed as Chief Commercial Officer for Europe and Rest of World. He will also join the Executive Management.

## Report of the Statutory Auditor on the Consolidated Financial Statements

Basel, April 13, 2015

As statutory auditor, we have audited the consolidated financial statements of Santhera Pharmaceuticals Holding AG, which comprise the consolidated balance sheet, consolidated income statement, consolidated statement of comprehensive income, consolidated cash flow statement, consolidated statement of changes in equity and notes (pages 10 to 49), for the year ended 31 December 2014.

### **Board of Directors' responsibility**

The Board of Directors is responsible for the preparation of these consolidated financial statements in accordance with International Financial Reporting Standards (IFRS) and the requirements of Swiss law. This responsibility includes designing, implementing and maintaining an internal control system relevant to the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error. The Board of Directors is further responsible for selecting and applying appropriate accounting policies and making accounting estimates that are reasonable in the circumstances.

### **Auditor's responsibility**

Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We conducted our audit in accordance with Swiss law and Swiss Auditing Standards and International Standards on Auditing. Those standards require that we plan and perform the audit to obtain reasonable assurance whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers the internal control system relevant to the entity's preparation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control system. An audit also includes evaluating the appropriateness of the accounting policies used and the reasonableness of accounting estimates made, as well as evaluating the overall presentation of the consolidated financial statements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

## **Opinion**

In our opinion, the consolidated financial statements for the year ended 31 December 2014 give a true and fair view of the financial position, the results of operations and the cash flows in accordance with IFRS and comply with Swiss law.

## **Report on other legal requirements**

We confirm that we meet the legal requirements on licensing according to the Auditor Oversight Act (AOA) and independence (article 728 CO and article 11 AOA) and that there are no circumstances incompatible with our independence.

In accordance with article 728a paragraph 1 item 3 CO and Swiss Auditing Standard 890, we confirm that an internal control system exists, which has been designed for the preparation of consolidated financial statements according to the instructions of the Board of Directors.

We recommend that the consolidated financial statements submitted to you be approved.

Ernst & Young Ltd

Patrick Fawer  
Licensed audit expert (Auditor in charge)

Nicole Riggenbach  
Licensed audit expert

# Statutory Financial Statements

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## Balance Sheet

|   | As of December 31, in CHF thousands | 2014         | 2013         |
|---|-------------------------------------|--------------|--------------|
| <b>Assets</b>                               |                                     |              |              |
| Loans to Group companies                    |                                     | 0            | 0            |
| <b>Noncurrent assets</b>                    |                                     | <b>0</b>     | <b>0</b>     |
| Treasury shares                             |                                     | 177          | 0            |
| Prepaid expenses and accrued income         |                                     | 23           | 33           |
| Other receivables from Group companies      |                                     | 415          | 0            |
| Other receivables from third parties        |                                     | 8            | 18           |
| Cash and cash equivalents                   |                                     | 6,953        | 3,222        |
| <b>Current assets</b>                       |                                     | <b>7,576</b> | <b>3,273</b> |
| <b>Total assets</b>                         |                                     | <b>7,576</b> | <b>3,273</b> |
| <b>Equity and liabilities</b>               |                                     |              |              |
| Share capital                               |                                     | 4,974        | <b>3,934</b> |
| Legal reserves                              |                                     | 916          | 1,832        |
| Reserves from capital contributions         |                                     | 3,049        | 0            |
| Reserves for treasury shares                |                                     | 177          | 221          |
| Free reserves                               |                                     | 318          | 3,725        |
| Accumulated result                          |                                     | -2,593       | -6,582       |
| Results carried forward                     |                                     | -1,503       | 0            |
| Net result for the period                   |                                     | -1,090       | -6,582       |
| <b>Total equity</b>                         |                                     | <b>6,841</b> | <b>3,130</b> |
| Trade accounts payable from third parties   |                                     | 68           | 53           |
| Other accounts payable from Group companies |                                     | 49           | 0            |
| Other accounts payable from third parties   |                                     | 447          | 8            |
| Accrued expenses                            |                                     | 171          | 82           |
| <b>Total current liabilities</b>            |                                     | <b>735</b>   | <b>143</b>   |
| <b>Total liabilities</b>                    |                                     | <b>735</b>   | <b>143</b>   |
| <b>Total equity and liabilities</b>         |                                     | <b>7,576</b> | <b>3,273</b> |

## Income Statement

| For the year ended December 31, in CHF thousands       | <b>2014</b>   | <b>2013</b>   |
|--|---------------|---------------|
| Revenue from Group companies                           | 1,203         | 1,026         |
| <b>Total operating income</b>                          | <b>1,203</b>  | <b>1,026</b>  |
| Other operating income                                 | 1             | 4             |
| General and administrative expenses                    | -1,463        | -1,113        |
| Employee costs   | -845          | -545          |
| Allowances on investments and loans to Group companies | 0             | -6,005        |
| Other operating expenses                               | -2            | 0             |
| <b>Total operating expenses</b>                        | <b>-2,310</b> | <b>-7,663</b> |
| <b>Operating result</b>                                | <b>-1,106</b> | <b>-6,633</b> |
| Financial income                                       | 31            | 102           |
| Financial expenses                                     | -15           | -51           |
| <b>Financial result</b>                                | <b>16</b>     | <b>51</b>     |
| <b>Result before taxes</b>                             | <b>-1,090</b> | <b>-6,582</b> |
| Tax expenses   | 0             | 0             |
| <b>Net result</b>                                      | <b>-1,090</b> | <b>-6,582</b> |

## Notes to the Statutory Financial Statements

### Introduction

The financial statements of Santhera Pharmaceuticals Holding AG (**Company**) have been prepared in accordance with the requirements of the Swiss Code of Obligations.

### Uncertainties and ability to continue operations

Santhera is sufficiently funded to progress its two main development programs up to the regulatory decision point of the respective Marketing Authorisation Application (**MAA**).

Santhera filed an MAA with the European Medicines Agency (**EMA**) in Leber's Hereditary Optic Neuropathy (**LHON**) in June 2014. The Company expects a regulatory decision in the first half year 2015. Subject to a positive outcome, Raxone would be launched in the European markets and would provide positive cash flow. A negative decision, however, would have a major impact on the plans of the Company including but not limited to the time of achieving positive cash flow, questions regarding the regulatory pathway in other indications, and the necessity of additional clinical trials and funding thereof

The positive outcome of a phase III trial in Duchenne Muscular Dystrophy (**DMD**) reported in May 2014 forms the basis for regulatory filings in the European Union (**EU**) and the United States of America (**US**). Depending on the outcome of the MAA in LHON, the potential regulatory filing in DMD and the related commercialization strategy of Raxone in these indications, Santhera will require additional funding in order to finance its activities until revenues reach a level to sustain positive cash flows.

Under the above-described circumstances, the Board believes in the Company's chances to get sufficient funding to execute the current development and commercial strategy.

## Investments/Subsidiaries

|   | Share capital at December 31 | 2014    | 2013    |
|---|------------------------------|---------|---------|
| Santhera Pharmaceuticals (Schweiz) AG<br>Liestal, Switzerland   | CHF                          | 125,000 | 125,000 |
| Santhera Pharmaceuticals (Deutschland) GmbH<br>Lörrach, Germany | EUR                          | 25,000  | 25,000  |
| Santhera Pharmaceuticals (USA), Inc.<br>Charlestown, US         | USD                          | 1,000   | 1,000   |
| Santhera Pharmaceuticals (Canada), Inc.<br>Montréal, Canada     | CAD                          | 1,000   | 1,000   |
| Oy Santhera Pharmaceuticals (Finland) Ltd<br>Helsinki, Finland  | EUR                          | 2,500   | 2,500   |

In 2014 and 2013 all companies are 100% direct subsidiaries of Santhera Pharmaceuticals Holding AG. Santhera Pharmaceuticals (Schweiz) AG is the primary operational entity while Santhera Pharmaceuticals (Deutschland) GmbH, Santhera Pharmaceuticals (USA), Inc. and Oy Santhera Pharmaceuticals (Finland) Ltd are not employing any personnel.

## Share Capital

During 2014, the share capital was increased by a total amount of CHF 1,040,443 to CHF 4,974,492 as of December 31, 2014 (2013: CHF 3,934,049): The increase consisted of four parts: i) increase through the exercise of 197,126 employee stock options (from conditional capital); ii) increase through a private placement of 288,317 Shares (from authorized capital); iii) increase through the issuance of 355,000 Shares for the SEDA (from conditional capital) and iv) increase through the issuance of 200,000 Shares for the sale by an independent broker (from conditional capital).

## Authorized Share Capital

The Board of Directors (**Board**) is authorized, at any time until April 21, 2016, to increase the share capital by a maximum amount of CHF 1,500,000 through the issuance of up to 1,500,000 fully paid-in registered shares (**Shares**) with a nominal value of CHF 1 each. An increase in partial amounts shall be permitted. The Board shall determine the issue price, the type of payment, the date of issue of new Shares, the conditions for the exercise of pre-emptive rights and the beginning date for dividend entitlement.

## Conditional Share Capital

As of December 31, 2014, the Company had a conditional capital, pursuant to which the share capital of the Company may be increased by:

- a maximum amount of CHF 604,029 (2013: CHF 684,414) by issuing a maximum of up to 604,029 Shares (2013: 684,414), under the exclusion of shareholders' pre-emptive rights, for option rights being exercised under the Employee Stock Option Plan 2004 (**ESOP 2004**), the Executive Incentive Plan (**EIP**), the Employee Stock Option Plan 2008 (**ESOP 2008**), the Employee Stock Option Plan 2010 (**ESOP 2010**) and the Board Stock Option Plan (**BSOP 2011**); and
- a maximum amount of CHF 600,000 (2013: CHF 355,000) by issuing up to 600,000 Shares (2013: 355,000), through the exercise of warrants/options and/or notes granted in connection with bonds or similar debt instruments linked with option and/or conversion rights granted by the Company.

## Standby Equity Distribution Agreement

In October 2013, Santhera announced that it has entered into a Standby Equity Distribution Agreement (**SEDA**) with Yorkville Advisors Global Master SPV Ltd., New York, US (**YA Global**). Under the terms of the agreement, YA Global has committed to provide up to CHF 10 million in equity financing during a period of three years. The SEDA has been established in order to support the funding Santhera's operations. It remains at the sole discretion of Santhera to determine the timing of the funding. The remaining amount available for equity financing with YA Global sums up to CHF 8.1 million.

## Treasury Shares

In connection with the liquidation of Oy Juvantia Pharma, Turku, Finland (**Juvantia**), acquired in 2009, Santhera received 8,028 Shares from former Juvantia shareholders. These treasury shares serve as pledge from the former owners of Juvantia for compensation of a potential tax claim related to pre-acquisition activities of Juvantia and were received in February 2010 at CHF 22 each. At December 31, 2014, the number of shares remained the same at 8,028.

In the context of the SEDA, Santhera Pharmaceutical (Schweiz) AG keeps no treasury shares by end of the year 2014 (2013; 44,425 treasury shares).

## Loans to Group Companies

Loans to Group companies are fully impaired to CHF 0. They are subordinated loans to the Company's subsidiary Santhera Pharmaceuticals (Schweiz) AG and were primarily related to the Group's research and development activities (end of 2014: CHF 172.4 million; end of 2013: CHF 172.4 million). The recoverability of these loans is not ensured. The fair value of Santhera Pharmaceuticals (Schweiz) AG and the long-term recoverability of these loans depend on the future market success of the developed products, the positive opinion from the EMA on the Company's MAA for Raxone® in the treatment of LHON, and sufficient financing for future successful market launches of products in development.

## Risk Assessment

Santhera Pharmaceuticals Holding AG maintains a Group-wide corporate risk management system consisting of the areas corporate governance, financial internal controls and quality control / quality assurance.

On a regular basis, operational corporate risks are identified and their likelihood and impact assessed (gross risks). By defining and undertaking appropriate measures, these risks are managed accordingly to either reduce or avoid such risk (net risk). The results of this process are discussed at Board meetings.

Those risks as identified within the area of accounting and financial reporting as well as related control processes are further covered by the Company's Group-wide internal control system.

## Additional Information

### Property insurance value

As of December 31, 2014, the property insurance value for buildings and equipment amounts to TCHF 250 (2013: TCHF 250).

### Capital loans from Finnish Funding Agency for Technology and Innovation and capital loans from Finnish National Fund for Research and Development

In July 2009, Santhera exercised its option to acquire Juvantia. Upon closing of the acquisition, the titles of the capital loans granted to Juvantia by the Finnish Funding Agency for Technology and Innovation, Helsinki, Finland (**Tekes**), and the Finnish National Fund for Research and Development, Helsinki, Finland (**Sitra**), were transferred to Oy Santhera Pharmaceuticals (Finland) Ltd, Helsinki, Finland. As per December 31, 2014, the loans amounted to EUR 6.4 million including capitalized interest (2013: EUR 6.3 million).

#### *Capital loans from Tekes*

The loans from Tekes were granted in order to develop new medicines for movement disorders in Parkinson' disease (*fipamezole*). Once a first marketing approval for *fipamezole* in a major country as defined by the contract with Tekes would be granted, EUR 2.4 million plus accrued interests would become due and payable. Another EUR 2.4 million plus accrued interests would become due and payable one year following such first marketing authorization. As of December 31, 2014, Santhera had no ongoing development activities with *fipamezole* in movement disorders.

#### *Capital loans from Sitra*

The loans from Sitra were granted in order to develop new medicines for movement disorders in Parkinson' disease (*fipamezole*). Once a first marketing approval for *fipamezole* in a major country as defined by the contract with Sitra would be granted before December 31, 2014, EUR 0.2 million would become due and payable. Another EUR 0.2 million would become due and payable one year following such first marketing authorization. As of December 31, 2014, Santhera had no ongoing development activities with *fipamezole* in movement disorders.

In case of receiving marketing authorization for *fipamezole* and, as a consequence, these loans becoming due, the Company guarantees these amounts for repayment towards Tekes and Sitra as described above. Should no marketing authorization be granted, no payments would become due under these capital loans and the respective contingent liabilities would lapse. As of December 31, 2014, Santhera had no ongoing development work with *fipamezole* in movement disorders.

#### **Guarantee towards Swiss VAT authorities**

The Company is part of the value-added tax group of the Swiss affiliated companies of Santhera Pharmaceuticals and is therefore jointly and severally liable to the Swiss federal tax administration for their value-added tax liabilities.

#### **Guarantee towards Santhera Pharmaceuticals (Schweiz) AG**

The Company guarantees to pay for the liabilities of its subsidiary Santhera Pharmaceuticals (Schweiz) AG until the Annual Shareholders' Meeting in 2016.

#### **Guarantee towards Biovail (now Valeant)**

In August 2009, Santhera Pharmaceuticals (Schweiz) AG entered into a collaboration and license agreement with Biovail Laboratories International SRL, Montréal, Canada (**Biovail**), with respect to the development of *fipamezole*. In context with this transaction, Santhera Pharmaceuticals Holding AG guarantees an amount of up to USD 30 million towards Biovail for obligations of Santhera Pharmaceuticals (Schweiz) AG under said agreement which was terminated effective as of January 18, 2011.

### **Significant Shareholders (>3%)**

Pursuant to information from the Company's share register and disclosures of participations made to it with applicable stock exchange regulation, the following shareholders owned 3% or more of the Company's share capital as registered in the commercial register at December 31 (4,578,521 Shares at December 31, 2014; 3,677,538 at December 31, 2013):

|   | <b>2014</b>   | <b>2014</b> | <b>2013</b>   | <b>2013</b> |
|---|---------------|-------------|---------------|-------------|
|   | <b>Shares</b> | <b>%</b>    | <b>Shares</b> | <b>%</b>    |
| Iglu Group, Switzerland                       | 712,670       | 15.6        | 263,108       | 7.2         |
| Ares Life Sciences, Switzerland               | 545,777       | 11.9        | 545,777       | 14.8        |
| Consonance Capital Management, US             | 275,000       | 6.0         | n/a           | n/a         |
| RTW Investments, LTD, US                      | 140,354       | 3.1         | n/a           | n/a         |
| NGN Capital, Germany and US                   | 137,409       | 3.0         | 115,409       | 3.1         |
| YA Global Master SPV Ltd., US <sup>1</sup>    | n/a           | n/a         | 2,576,334     | 70.1        |
| Herculis Partners "Aries" Fund, Liechtenstein | n/a           | <3.0        | 133,822       | 3.6         |
| Varuma, Switzerland                           | n/a           | <3.0        | 131,932       | 3.6         |

<sup>1</sup> For 2014, the disclosure of YA Global "holdings" as required by SIX Swiss Exchange regulation has been omitted as it is not meaningful. To the Company's best knowledge, YA Global currently holds no Santhera shares.

Significant shareholders can also be directly searched on the SIX website under the following link:

[www.six-swiss-exchange.com/shares/companies/major\\_shareholders\\_en.html?fromDate=19980101&issuer=17778](http://www.six-swiss-exchange.com/shares/companies/major_shareholders_en.html?fromDate=19980101&issuer=17778)

**Disclosure of Shares and stock options held by members of the Board and Executive Management (and their respective related party) as of December 31, 2014**

|                             | Number of Shares | Number of vested stock options | Number of unvested stock options | Total number of stock options |
|-----------------------------|------------------|--------------------------------|----------------------------------|-------------------------------|
| <i>Board of Directors</i>   |                  |                                |                                  |                               |
| Martin Gertsch, Chairman    | 21,609           | 0                              | 16,500                           | 16,500                        |
| Jürg Ambühl                 | 17,000           | 0                              | 13,000                           | 13,000                        |
| <i>Executive Management</i> |                  |                                |                                  |                               |
| Thomas Meier, CEO           | 38,508           | 48,644                         | 59,500                           | 108,144                       |

**Disclosure of Shares and stock options held by members of the Board and Executive Management (and their respective related party) as of December 31, 2013**

|                             | Number of Shares | Number of vested stock options | Number of unvested stock options | Total number of stock options |
|-----------------------------|------------------|--------------------------------|----------------------------------|-------------------------------|
| <i>Board of Directors</i>   |                  |                                |                                  |                               |
| Martin Gertsch, Chairman    | 1,230            | 17,000                         | 7,000                            | 24,000                        |
| Jürg Ambühl                 | 800              | 7,000                          | 0                                | 7,000                         |
| <i>Executive Management</i> |                  |                                |                                  |                               |
| Thomas Meier, CEO           | 14,613           | 65,039                         | 15,000                           | 80,039                        |

**Events After the Reporting Date**

None.

## Proposals of the Board of Directors to the Annual Shareholders' Meeting

### Proposal of the Board for the result to be carried forward, subject to the approval of the Annual Shareholders' Meeting

|   | In CHF | 2014              | 2013              |
|---|--------|-------------------|-------------------|
| Result carried forward  |        | -1,502,786        | 0                 |
| Net result of the year  |        | -1,089,895        | -6,582,326        |
| <b>Accumulated result</b>                                     |        | <b>-2,592,681</b> | <b>-6,582,326</b> |
| Offsetting with legal reserves                                |        | 0                 | 916,368           |
| Offsetting with free reserves                                 |        | 0                 | 3,651,489         |
| Offsetting with share premium of private placement (Feb 2014) |        | 0                 | 511,683           |
| <b>Result to be carried forward</b>                           |        | <b>-2,592,681</b> | <b>-1,502,786</b> |

## Report of the Statutory Auditor on the Financial Statements

Basel, April 13, 2015

As statutory auditor, we have audited the financial statements of Santhera Pharmaceuticals Holding AG, which comprise the balance sheet, income statement and notes (pages 53 to 61), for the year ended 31 December 2014.

### **Board of Directors' responsibility**

The Board of Directors is responsible for the preparation of the financial statements in accordance with the requirements of Swiss law and the company's articles of incorporation. This responsibility includes designing, implementing and maintaining an internal control system relevant to the preparation of financial statements that are free from material misstatement, whether due to fraud or error. The Board of Directors is further responsible for selecting and applying appropriate accounting policies and making accounting estimates that are reasonable in the circumstances.

### **Auditor's responsibility**

Our responsibility is to express an opinion on these financial statements based on our audit. We conducted our audit in accordance with Swiss law and Swiss Auditing Standards. Those standards require that we plan and perform the audit to obtain reasonable assurance whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers the internal control system relevant to the entity's preparation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control system. An audit also includes evaluating the appropriateness of the accounting policies used and the reasonableness of accounting estimates made, as well as evaluating the overall presentation of the financial statements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

### **Opinion**

In our opinion, the financial statements for the year ended 31 December 2014 comply with Swiss law and the company's articles of incorporation.

**Report on other legal requirements**

We confirm that we meet the legal requirements on licensing according to the Auditor Oversight Act (AOA) and independence (article 728 CO and article 11 AOA) and that there are no circumstances incompatible with our independence.

In accordance with article 728a paragraph 1 item 3 CO and Swiss Auditing Standard 890, we confirm that an internal control system exists, which has been designed for the preparation of financial statements according to the instructions of the Board of Directors.

We recommend that the financial statements submitted to you be approved.

Ernst & Young Ltd

Patrick Fawer  
Licensed audit expert (Auditor in charge)

Nicole Riggenbach  
Licensed audit expert

# Compensation Report

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## Introduction

This Compensation Report describes Santhera's compensation system and the compensation of Santhera's Board of Directors (**Board**) and Executive Management (**EM**) members.

The Board will submit the Compensation Report to a consultative vote at the Annual Shareholders' Meeting (**ASM**) on May 11, 2015. In the same ASM, the Board will propose various changes to the compensation policy to comply with the new legal framework in the Ordinance against Excessive Compensation at Public Corporations (**OaEC**).

The proposed revisions to the Articles of Incorporation include rules on the principles applicable to performance-related pay and to the allocation of equity securities, convertible rights and options (Article 27), additional amounts for payments to Executive Committee members appointed after the vote on pay at the ASM (Article 26), the vote on pay at the General Meeting of Shareholders (Article 25), post-employment benefits for Executive Management and Board members (Article 28) and finally loans and credit facilities for Executive Management and Board members (Article 29). The invitation to the ASM contains the text of the proposed revisions and the explanations thereto in more detail.

## Principles of the Decision-making Process

As the Board currently consists of two members only, both are also members of the Compensation Committee. As in the past, the Compensation Committee does not meet separately, but takes its decisions at the occasion of the Board meetings. The Board members take all decisions in compensation- and nomination-related matters. They approve the Company's stock option plans and grants on an individual basis, approve salary increases and bonus payments.

The Board establishes principles for the selection of candidates for election to the Board and the EM, reviews and approves candidates for membership on the Company's Board and EM, and reviews the Company's regulations and charter to remain in compliance with requirements from the SIX Swiss Exchange and Swiss and international corporate best practice standards.

The Board deliberates over the corporate goals and the amount of incentives to be paid upon achievement of the targets as well as employment packages for senior managers and overall stock option grants to the employees. In January 2014, to retain its employees, the Board granted 351,000 stock options to directors, officers and employees as incentive to stay with the Company until after the opinion of the Committee for Medicinal Products for Human Use (**CHMP**) opinion on a new Marketing Authorization Application (**MAA**) for Raxone® in Leber's Hereditary Optic Neuropathy (**LHON**), which is expected to be obtained in the first half of 2015. The options were granted on January 23, 2014, and can be converted 1:1 into Santhera Shares. The exercise price is CHF 3.89 per option. All such options vest on (i) the earlier of (a) five stock exchange trading days following the public announcement of the CHMP opinion on the MAA for LHON and (b) April 30, 2015, (ii) but in no case before one year after the grant date.

## Principles of the Compensation System

For Board members, the compensation system consists of a fixed fee and a fixed number of options. For the other Company employees, including the members of EM, it comprises base salary, a target bonus and stock options. The latter two compensation elements are based on the achievement of Company and individual goals.

In 2014, the Company evaluated the total compensation of the Board. To this end, it used data published in annual reports of peer companies and Pricewaterhouse Cooper's (PwC) survey "Executive Compensation & Corporate Governance, Insights 2014". Santhera also benchmarked all positions within the Company with the help of a compensation survey of the Pharmaceutical and Health Sciences industries (Survey) prepared by Towers Watson and based on publicly available data of the compensation of CEOs of Actelion, Basilea Pharma, Sonova, Galenica, Cytos, Siegfried, Ypsomed, Bachem, Straumann, Addex, Cosmo, Evolva, Newron and Therametrics. This Survey consists of a data set of job descriptions, international gradings, incumbent seniority and the related compensation and contains information from 98 companies in Switzerland. The Board also retained PwC to discuss the elements and adequacy of the compensation system. With the exception of tax matters, PwC were not awarded any additional mandates within the Company.

Based on the benchmarking, the Board came to the conclusion that only minor compensation adjustments were required in order for Santhera to remain competitive as an employer where base salaries are concerned. Target bonuses as evaluated using Towers Watson data currently range from 8% of the base salary to 42%. Target bonuses have in the past been paid based on the achievement of company targets. The target bonuses are currently under review, as they tend to be somewhat low when compared to Towers Watson data. There may therefore be an increase in bonuses to extent that the Company evolves from a development company to a fully integrated one with cash flow positive business. In the past, bonuses have been paid for the achievement of corporate goals while moving forward, the Board intends to pay bonuses based on the achievement of both corporate and individual objectives. Generally speaking, the higher the position of an employee, the more the achievement of corporate goals (as opposed to individual goals) might be relevant for the bonus determination. For the Chief Executive Officer (CEO), for example, the weighting of the achievement of corporate goals could be in the magnitude of between 90% and 100%. The same mechanism might apply to the grant of stock options. Among others, this system is currently under review.

Where the Board's own compensation was concerned, an increase for 2015 appeared to be indicated, reflecting the significantly higher amount of work required from both Board members. For details, see below.

## Board Compensation

Each Board member receives an annual cash fee and stock options. Both of these components are fixed and do thus not depend on the individual performance of a Board member or the achievement of corporate goals. Accordingly, Board members do not receive bonuses.

### Annual Fees

In 2011, the annual fees of the Chairman had been reduced from CHF 96,000 to CHF 45,000. For the period from January 1, 2015 up to the date of the ASM, the fees have been increased to CHF 75,000 p.a. Since Santhera's IPO in 2006, the fees for other Board members had amounted to CHF 32,000, while the chairman of the audit committee was entitled to receive an additional CHF 15,000. As there are currently only two Board members who more or less share the entire Board workload equally, there was considerable rationale to bring the compensation of the other Board member in line with that of the Chairman. For the period from January 1, 2015 up to the date of the ASM, the fees of the other Board member have been increased to CHF 65,000 p.a.

It is intended to submit to the 2015 ASM that the Board compensation be determined for the period starting immediately after the ASM and lasting until the day before the ASM in the following year.

### Options

Until the end of 2014, the chairman of the Board received 1,500 annual stock options, while the other member of the Board received 1,000. These options had a vesting period of a year. From the ASM 2015 onward, the Board proposes to increase the number of options to be granted to 3,000 for each member of the Board. As of January 1, 2015, it has introduced a staggered vesting thereof. After a period of 2 years from the grant, 50% of the options vest, an additional 25% after 3 years while the balance 25% vest after 4 years. The exercise is the share price at the day of the grant. As indicated above, this option allocation is subject to shareholders' approval of the total Board compensation at the 2015 ASM.

### Summary of compensation of members of the Board for the year 2014 (Audited)

| In CHF         | Compensation  | Social security on compensation | Social security on option exercise | Stock options <sup>1</sup> | Compensation total | Number of stock options granted |
|----------------|---------------|---------------------------------|------------------------------------|----------------------------|--------------------|---------------------------------|
| Martin Gertsch | 45,000        | 3,690                           | 34,890                             | 90,450                     | 174,030            | 16,500                          |
| Jürg Ambühl    | 32,000        | 1,851                           | 3,626                              | 25,330                     | 62,807             | 13,000                          |
| <b>Total</b>   | <b>77,000</b> | <b>5,541</b>                    | <b>38,516</b>                      | <b>115,780</b>             | <b>236,837</b>     | <b>29,500</b>                   |

<sup>1</sup> Reflects value of share-based payments in accordance with IFRS 2 at grant, i.e. the value of unvested stock options attributable at grant. The tax value of such stock options is 0 until stock options would be exercised. Such stock option values are theoretical values and do not reflect income tax values and do also take into consideration certain vesting provisions. During such vesting periods, stock options may lapse subject to certain conditions as defined by the respective stock option plans. For information about the underlying stock option plans, see note 16 "Stock Option Plans" in the consolidated financial statements. For information about the Company's compensation procedures, consult the Corporate Governance Report.

Option grants were made to Board members in 2014. No other payments, allowances or loans were made to the members of the Board or their related parties in 2014. Stock option grants to members of the Board are subject to the Compensation Policy as well as the Board Stock Option Plan (BSOP).

### Disclosure of compensation of members of the Board for the year 2013 (Audited)

| In CHF                         | Cash compensation | Social security on compensation | Social security on option exercise | Stock options <sup>3</sup> | Compensation total | Number of stock options granted |
|--------------------------------|-------------------|---------------------------------|------------------------------------|----------------------------|--------------------|---------------------------------|
| Martin Gertsch                 | 45,000            | 3,690                           | 0                                  | 7,840                      | 56,530             | 7,000                           |
| Jürg Ambühl                    | 32,000            | 2,624                           | 0                                  | 2,070                      | 36,694             | 1,000                           |
| Timothy Rink <sup>1</sup>      | 16,913            | 704                             | 0                                  | 2,150                      | 19,767             | 1,000                           |
| Klaus Schollmeier <sup>2</sup> | 36,000            | 2,952                           | 1,332                              | 3,105                      | 43,389             | 1,500                           |
| <b>Total</b>                   | <b>129,913</b>    | <b>9,970</b>                    | <b>1,332</b>                       | <b>15,165</b>              | <b>156,380</b>     | <b>10,500</b>                   |

<sup>1</sup> Board member until May 13, 2013

<sup>2</sup> Chairman of the Board until May 13, 2013

<sup>3</sup> Reflects value of share-based payments in accordance with IFRS 2 at grant, i.e. the value of unvested stock options attributable at grant. The tax value of such stock options is 0 until stock options would be exercised. Such stock option values are theoretical values and do not reflect income tax values and do also take into consideration certain vesting provisions. During such vesting periods, stock options may lapse subject to certain conditions as defined by the respective stock option plans. For information about the underlying stock option plans, see note 16 "Stock Option Plans" in the consolidated financial statements. For information about the Company's compensation procedures, consult the Corporate Governance Report.

Option grants were made to Board members in 2013. No other payments, allowances or loans were made to the members of the Board or to their related parties in 2013. Stock option grants to members of the Board are subject to the Compensation Policy as well as the BSOP.

### Executive Compensation

The Board reviews and determines the total remuneration paid to the members of the Executive Management (fix and variable elements). For the period under review, this was only required for the CEO as until February 1, 2015, he had been the only member of Executive Management.

By combining short- and long-term incentive elements, the Board believes that the compensation system is designed in a way that the interests of the CEO are aligned with the interests of the Company and its shareholders. The Company's compensation system does not set any unintended enticements or contain any components that could be counterproductive to the objectives of the compensation system.

In 2014, the Bonus payment was CHF 94,000 (28.2% of the base salary), while the value of the stock options granted was CHF 92,560 (27.8% of the base salary). For 2014, the CEO's salary was increased by 2% compared to his 2013 salary, in line with the general salary increase for all employees. The variable cash compensation for 2014 equaled a 100% bonus, while in 2013, the CEO did not receive any bonus. For the period from January 1, 2015 up to the date of the ASM, the base salary of the CEO was increased to CHF 365,000 and his target bonus to CHF 120,000 (32.9% of the base salary).

It is intended to submit to the 2015 Annual Shareholders' Meeting on May 11, 2015 that the compensation of the Executive Management members be determined for the period from July 1 of a certain year to June 30 of the following year.

The employment contract with the CEO provides for a one year's termination period. In the very specific case of a change of control and related thereto (i) a substantial change of the terms of their employment, or (ii) a dismissal without cause, the said agreements provide for a severance payment of a full year's salary, while no termination period has to be observed. Other than that, and with the exception of those set out in the Corporate Governance Report about section on DCG 7.2, there are no change of control provisions or other severance arrangements. The Board believes that this severance arrangement is in compliance with the OaEC.

#### Disclosure of compensation of members of the Executive Management for the year 2014 (Audited)

| In CHF            | Compen-<br>sation fix | Compen-<br>sation<br>variable | Social<br>security on<br>compensation | Social<br>security on<br>option exercise | Stock<br>options <sup>1</sup> | Total          | Number<br>of stock<br>options<br>granted |
|-------------------|-----------------------|-------------------------------|---------------------------------------|--|-------------------------------|----------------|--|
| Thomas Meier, CEO | 332,947               | 94,000                        | 76,563                                | 6,160                                    | 92,560                        | 602,230        | 52,000                                   |
| <b>Total</b>      | <b>332,947</b>        | <b>94,000</b>                 | <b>76,563</b>                         | <b>6,160</b>                             | <b>92,560</b>                 | <b>602,230</b> | <b>52,000</b>                            |

<sup>1</sup> Reflects value of share-based payments in accordance with IFRS 2 at grant, i.e. the value of unvested stock options attributable at grant; tax value of such stock options is 0 until stock options would be exercised. Such stock option values are theoretical values and do not reflect income tax values and do also take into consideration certain vesting provisions. During such vesting periods, stock options may lapse subject to certain conditions as defined by the respective stock option plans. For information about the underlying stock option plans, see note 16 "Stock Option Plans" in the consolidated financial statements. For information about the Company's compensation procedures, consult the Corporate Governance Report.

#### Disclosure of compensation of members of the Executive Management for the year 2013 (Audited)

| In CHF            | Cash<br>compen-<br>sation fix | Cash<br>compen-<br>sation<br>variable | Social<br>security on<br>compensation | Social<br>security on<br>option exercise | Stock<br>options <sup>1</sup> | Total          | Number<br>of stock<br>options<br>granted |
|-------------------|-------------------------------|---------------------------------------|---------------------------------------|--|-------------------------------|----------------|--|
| Thomas Meier, CEO | 326,419                       | 0                                     | 73,348                                | 0  | 0                             | 399,767        | 0  |
| <b>Total</b>      | <b>326,419</b>                | <b>0</b>                              | <b>73,348</b>                         | <b>0</b>                                 | <b>0</b>                      | <b>399,767</b> | <b>0</b>                                 |

<sup>1</sup> Reflects value of share-based payments in accordance with IFRS 2 at grant, i.e. the value of unvested stock options attributable at grant; tax value of such stock options is 0 until stock options would be exercised. Such stock option values are theoretical values and do not reflect income tax values and do also take into consideration certain vesting provisions. During such vesting periods, stock options may lapse subject to certain conditions as defined by the respective stock option plans. For information about the underlying stock option plans, see note 16 "Stock Option Plans" in the consolidated financial statements. For information about the Company's compensation procedures, consult the Corporate Governance Report.

## Compensation of Former Members of the Board and Executive Management

In the reporting period and in 2013, several former members of the Board and EM have exercised options. The proceeds from the options constitute an element of the salary which is subject to social security payments. As (former) employer, Santhera has to contribute to such payments in accordance with applicable laws.

### Disclosure of compensation of former Board and EM members for the year 2014 (Audited)

In connection with option exercises in 2014 by former Board members, Santhera made the following payments (social security contributions):

|                   | In CHF | Total payment  |
|-------------------|--------|----------------|
| Klaus Schollmeier |        | 121,151        |
| Timothy Rink      |        | 41,777         |
| Peter Wolf        |        | 4,827          |
| <b>Total</b>      |        | <b>167,755</b> |

In connection with option exercises in 2014 by two former members of Executive Management, Santhera made total payments of CHF 44,760.

### Disclosure of compensation of former Board and EM members for the year 2013 (Audited)

In connection with option exercises in 2013 by former Board members, Santhera made the following payments (social security contributions):

|                   | In CHF | Total payment |
|-------------------|--------|---------------|
| Hans-Beat Gürtler |        | 143           |
| <b>Total</b>      |        | <b>143</b>    |

In 2013, no former members of EM exercised any options. In 2013, no other compensation has been granted to any current or former member of the EM and the Board of Directors.

## Report of the Statutory Auditor on the Compensation Report

Basel, April 13, 2015

We have audited the compensation report dated 13 April 2015 of Santhera Pharmaceuticals Holding AG for the year ended 31 December 2014 (section included in pages 67 to 70, marked as "Audited").

### Responsibility of the Board of Directors

The Board of Directors is responsible for the preparation and overall fair presentation of the compensation report in accordance with Swiss law and the Ordinance against Excessive Compensation in Stock Exchange Listed Companies (Ordinance). The Board of Directors is also responsible for designing the compensation system and defining individual compensation packages.

### Auditor's responsibility

Our responsibility is to express an opinion on the compensation report. We conducted our audit in accordance with Swiss Auditing Standards. Those standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the compensation report complies with Swiss law and articles 14 – 16 of the Ordinance.

An audit involves performing procedures to obtain audit evidence on the disclosures made in the compensation report with regard to compensation, loans and credits in accordance with articles 14 – 16 of the Ordinance. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatements in the compensation report, whether due to fraud or error. This audit also includes evaluating the reasonableness of the methods applied to value components of compensation, as well as assessing the overall presentation of the compensation report.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

### Opinion

In our opinion, the compensation report for the year ended 31 December 2014 of Santhera Pharmaceuticals Holding AG complies with Swiss law and articles 14 – 16 of the Ordinance.

Ernst & Young Ltd

Patrick Fawer  
Licensed audit expert (Auditor in charge)

Nicole Riggerbach  
Licensed audit expert

# Corporate Governance Report

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## General Information

The Company's corporate governance principles are laid out in its articles of incorporation (**Articles**), the organizational rules (Organizational Rules; Organisationsreglement), by-laws of the Company's executive management (**Executive Management**) adopted by the Board of Directors (**Board**) and a comprehensive set of group directives, including a Code of Conduct and insider trading rules that require a trading preclearance for the Board and the Company's officers and employees, as well as an internal control system, and a risk management process.

The information published below conforms to the Directive Corporate Governance (**DCG**) of the SIX Swiss Exchange (**SIX**). In order to avoid redundancies, references are inserted to other parts of the financial report and links to Santhera's website [www.santhera.com](http://www.santhera.com) that provide more detailed information.

## Group Structure and Shareholders (DCG 1)

### Group structure (DCG 1.1)

#### *Listed company*

|                       |   |
|-----------------------|---|
| Name                  | Santhera Pharmaceuticals Holding AG<br>( <b>Company</b> , together with its affiliates, <b>Santhera</b> )                       |
| Domicile              | Hammerstrasse 49, 4410 Liestal, Switzerland   |
| Register number       | CHE-105.388.338   |
| Listing               | SIX   |
| Symbol                | SANN  |
| Security ID           | 2714864   |
| ISIN                  | CH0027148649  |
| Market capitalization | CHF 423.1 million (December 30, 2014)   |
| Website               | <a href="http://www.santhera.com">www.santhera.com</a>  |
| Commercial register   | <a href="http://www.hrabl.ch">www.hrabl.ch</a>  |
| Duration of company   | Not limited   |
| Subsidiaries          | See following section as well as note " <i>Investments/Subsidiaries</i> " to the statutory financial statements of the Company. |

Santhera operates through its wholly owned subsidiaries, Santhera Pharmaceuticals (Schweiz) AG, Liestal, Switzerland (development of pharmaceutical drugs, administrative functions); Santhera Pharmaceuticals (Canada), Inc., Montréal, Canada (development of pharmaceutical drugs); Santhera Pharmaceuticals (USA), Inc., Charlestown, Massachusetts, United States of America (**US**) (administrative); Santhera Pharmaceuticals (Deutschland) GmbH, Lörrach, Germany (regulatory and development in the EU), and Oy Santhera Pharmaceuticals (Finland) Ltd, Helsinki, Finland (administrative; DCG 1.1.3). None of these subsidiaries is listed on a stock exchange (DCG 1.1.2). Their development and M&S activities are managed by Santhera Pharmaceuticals (Schweiz) AG and are performed in Switzerland, the EU and the US (DCG 1.1.1).

**Significant shareholders (DCG 1.2)**

See note "Significant Shareholders" to the statutory financial statements of the Company.

**Cross-shareholdings (DCG 1.3)**

There are no cross-shareholdings.

**Capital Structure (DCG 2)****Ordinary, conditional and authorized capital (DCG 2.1/2.2)**

The Company has one class of registered shares with a nominal value of CHF 1 each (Shares). Pursuant to its Articles, as of December 31, 2014, it had the following ordinary, authorized and conditional share capital:

| Type of capital   | Capital as per commercial register |                          | Effectively outstanding capital |                          | Expiry  | Section in Articles |
|---|------------------------------------|--------------------------|---------------------------------|--------------------------|---|---------------------|
|   | Amount in CHF                      | As % of ordinary capital | Amount in CHF                   | As % of ordinary capital |   |                     |
| <b>Ordinary capital</b>   | 4,578,521                          | 100.0                    | 4,974,492                       | 100.0                    |   | 3                   |
| <b>Authorized capital<sup>1</sup></b>   | 1,500,000                          | 32.8                     | 1,500,000                       | 30.2                     | May 21, 2016  | 3a                  |
| <b>Conditional capital for warrants/option rights granted in connection with debt instruments<sup>2</sup></b> | 800,000                            | 17.5                     | 600,000                         | 12.1                     | For conversion rights: 10 years from issue date.<br>For options: 7 years from issue date. | 3c                  |
| <b>Conditional capital for ESOP/BSOP/EIP<sup>3</sup></b>  | 800,000                            | 17.5                     | 604,029                         | 12.1                     |   | 3b                  |

1 On February 27, 2014, the Company raised CHF 1 million in a private placement through the issue of 288,317 Shares from authorized capital, reducing the latter to CHF 1,511,683. On May 20, 2014, at its Annual Shareholders' Meeting (ASM) the authorized capital was reduced to CHF 1,500,000.

2 In October 2013, YA Global Master (Yorkville) and Santhera entered into a Standby Equity Distribution Agreement (SEDA). By May 15, 2014, Santhera had sold 600,000 Shares to Yorkville, thus reducing the Company's conditional capital for warrants/option rights to zero. At its 2014 ASM, new conditional capital amounting to CHF 800,000 was created. After the ASM, 200,000 new Shares were issued and sold by an independent broker, reducing the conditional capital for warrants/option rights to CHF 600,000.

3 Employee Stock Option Plans (ESOP) 2004, 2008 and 2010; Board Stock Option Plan (BSOP); Executive Incentive Plan (EIP). For details pertaining to the ESOP and option and/or conversion rights with regard to debt instruments, see section on DCG 2.7. In 2014, certain holders of options exercised their rights to receive Shares which were issued from the Company's "Conditional Capital for ESOP": 1,155 Shares before the 2014 ASM and another 195,971 Shares thereafter until December 31, 2014. On February 28, 2015, the creation of the new Shares was entered into the Commercial Register, resulting in ordinary share capital of CHF 4,974,492 conditional capital for Financing and M&A of CHF 600,000 and conditional capital for ESOP of CHF 604,029.

For details with regard to terms and conditions of potential share issues under the Company's authorized and conditional share capital, see sections 3b and 3c of the Company's Articles, which can be downloaded from [www.santhera.com/corporate-governance](http://www.santhera.com/corporate-governance), and the section on DCG 2.7 below.

For details with regard to the Company's ESOP, BSOPs and EIP, see note 16 "*Stock Option Plans*" to the consolidated financial statements.

### **Changes in share capital (DCG 2.3)**

For changes in capital that occurred in 2012 and 2013, see the Company's Annual Report 2013, which can be downloaded from [www.santhera.com/reports](http://www.santhera.com/reports). For changes that took place in 2014, see notes "*Share Capital*," "*Authorized Share Capital*" and "*Conditional Share Capital*" to the statutory financial statements of the Company.

### **Shares, participation and dividend right certificates (DCG 2.4/2.5)**

As of December 31, 2014, the Company had one single class of registered Shares with a nominal value of CHF 1 each. All Shares were fully paid in and are nonassessable. The Company has not issued any participation certificates or any profit-sharing certificates.

As a consequence of the Swiss Federal Intermediated Securities Act (**FISA**) that entered into force on January 1, 2010, the Company may issue its Shares in the form of uncertificated securities, single certificates or global certificates. The shareholder has no right to demand the printing and delivery of share certificates. However, a registered shareholder may, at any time, request the Company to confirm in writing its shareholding as entered into the share register. The transfer of the Shares is effected via electronic book entry only by the intermediary holding the securities account, usually a bank. The transferability of the Shares is not affected by the changes required by FISA.

Subject to section 5 in the Company's Articles on share register, transfer restrictions and nominees, each Share carries one vote (see section on DCG 2.6) and is entitled to dividends if the ASM resolves in favor of a dividend payment.

### **Limitations on transferability and nominee registrations (DCG 2.6)**

The Company's Shares are freely transferable, provided that the acquirers declare that they acquired the Shares in their own name and for their own account. There is no percentage limitation (DCG 2.6.1), and accordingly, the Company did not grant any exception (DCG 2.6.2).

The Board may register individual nominees (Nominees) with the right to vote in the share register up to 2% of the share capital as set forth in the commercial register. Shares in excess of 2% of the total share capital are entered without voting rights, unless the Nominee discloses the names, addresses and number of Shares of persons for whose account it holds such excess Shares. Nominees are persons who do not explicitly declare to hold Shares for their own account. Groups of persons who are interrelated or otherwise act in concert to circumvent the Nominee provisions are treated as a Nominee (DCG 2.6.3). In the year under review, the Company granted no exception.

The Board delegated the administration of the share register to the Chief Executive Officer (**CEO**) who may cancel registration of shareholders if such registration was based on false information and if the CEO has previously heard such shareholder or Nominee. No statutory privileges of limitations on transferability exist (DCG 2.6.4).

**Convertible bonds and warrants/options (DCG 2.7)***Convertible loans*

Santhera does not have any convertible or exchangeable bonds or loans outstanding.

*Options, warrants*

See the statutory financial statements of the Company and note 16 "*Stock Option Plans*" to the consolidated financial statements.

**Board of Directors (DCG 3)****Board and committee memberships (DCG 3.1/3.2/3.3.2 and 3.4)**

|                | Year of birth | Nationality | First elected | Elected until | Board    |
|----------------|---------------|-------------|---------------|---------------|----------|
| Jürg Ambühl    | 1949          | CH          | 2009          | 2015          | Member   |
| Martin Gertsch | 1965          | CH          | 2006          | 2015          | Chairman |

*Jürg Ambühl*

Jürg Ambühl is a seasoned marketing specialist with a long track record in the pharmaceutical industry. From 2003 to 2007, he worked in several senior management positions for the Serono group, lastly as senior executive vice president global marketing. In this capacity, he was responsible for worldwide marketing strategies for all of Serono's products. Prior to that, he served as chief executive officer of Metagen Pharmaceuticals, a Berlin-based oncology spin-off of Schering. From 2000 to 2001, Dr Ambühl was president of the regional business Europe/International at Knoll/BASF Pharmaceuticals when the company was sold to Abbott Laboratories. From 1987 to 1999, he held several senior management positions within MSD Sharp & Dohme in Germany, including general manager with business responsibility for the German market. From 1982 to 1987, Mr Ambühl worked for McKinsey and prior to that, from 1978 to 1982, he held several management positions within Eli Lilly's German subsidiary in sales and marketing. Mr Ambühl holds a PhD in chemistry from the Swiss Federal Institute of Technology (ETH), Zurich, Switzerland, and an MBA from the INSEAD, Fontainebleau, France.

*Martin Gertsch*

Martin Gertsch is an experienced executive and board member in the life science industry. He was chief financial officer (**CFO**) of Acino Holding AG until January 15, 2014. He currently serves as chairman of the audit committee on the board of Evolva Holding (SIX: EVE). He is former vice-president and head of finance EMEA at DePuy Synthes and former CFO and chief operating officer of Delenex Therapeutics and ESBATech, two privately held biotech companies. From 2002 to the beginning of 2006, he was chief financial officer of Straumann, which he had joined in 1997 as head of group controlling and reporting. Between 1986 and 1997, Mr Gertsch was an audit engagement manager at PricewaterhouseCoopers, Basel, Switzerland. He is a Swiss certified fiduciary and Swiss certified public accountant. Mr Gertsch has completed several executive-level development programs at IMD (International Institute for Management Development) in Lausanne, Switzerland.

### **Independence of Board members (DCG 3.1.b and c)**

All Board members are nonexecutive and none has ever been a member of the Executive Management of the Company or any of its subsidiaries.

### **Business connections between Board members and the Company (DCG 3.1.c)**

See note 25 "*Related Party Transactions*" to the consolidated financial statements.

### **Other activities and vested interests (DCG 3.2)**

Other than described above, none of the members of the Board has any position in governing or supervisory bodies of any major organization, institution or foundation under private or public law, permanent management or consultancy function for major interest groups, official function or political mandate.

### **Permitted mandates in other companies (DCG 3.3)**

In accordance with the Ordinance against Excessive Compensation with respect to Listed Stock Corporations (**OaEC**), Santhera currently intends to propose to its shareholders at the occasion of the 2015 ASM to limit the number of additional board mandates in listed companies to four and in privately held companies to eight.

### **Elections and terms of office (DCG 3.4)**

According to the Company's Articles, the Board consists of no more than eight members. The term of office of a Board member must not exceed one year, whereby a year means the period between two ASM. Directors are appointed or removed exclusively by a resolution of the shareholders. For the time of the first election and the remaining term of office for the members of the Board see the table in the section on DCG 3.1/3.2 and 3.4 above. The terms of the Board members both end at the 2015 ASM. The Board members are elected on an individual basis. The Chairman is elected by the shareholders.

### **Organizational structure/areas of responsibility and information flow (DCG 3.5)**

See also the table in the section on DCG 3.1.

#### *Allocation of tasks within the Board (DCG 3.5.1)*

In accordance with the Organizational Rules of the Company, the Chairman convenes and presides over the Board meetings. After consultation with the CEO, the Vice-President Finance & Accounting and the General Counsel, who also acts as the secretary to the Board, he decides on agenda items and motions. The other Board member may request that items be placed on the agenda. In case of urgency, the Chairman may approve transactions and measures on behalf of the full Board. The Board also approves the Company's news releases.

#### *The Board committees (DCG 3.5.2)*

Santhera has a Compensation Committee that consists of its two Board members. All tasks of the former Audit Committee have been allocated to the entire Board which formally abolished the Audit Committee in 2013.

## **Board – elections and areas of responsibility (DCG 3.5/3.6)**

### *Core tasks of the Board*

The Board is entrusted with the ultimate direction of the Company and supervision of the Executive Management. The Board's nontransferable and inalienable duties include the duty to (i) ultimately manage the Company and issue the necessary directives, (ii) determine the organizational structure of the Company, (iii) organize the accounting system, financial control (including the Company's internal control system, risk management as well as financial planning), and (iv) appoint, recall and ultimately supervise the persons entrusted with the management and representation of the Company. The nontransferable and inalienable duties also comprise responsibility for preparation of the Annual Report and the ASM, carrying out shareholders' resolutions, and notification to the judge in case of overindebtedness of the Company. The full Board approves the Company's budget and major contracts if they are not within budget. It also reviews filing strategies before regulatory authorities such as the European Medicines Agency (EMA) and the US Food and Drug Administration. It reviews and approves merger and acquisitions projects including licensing transactions of a material size and the Company's marketing strategy.

The Board has delegated the execution of the strategies defined by it and the day-to-day management of the Company to the CEO who relied on a management team where the main functional areas of the Company are represented. As of February 1, 2015, the Board nominated several senior members of staff to the newly created Executive Management which is headed by the CEO.

### **Work methods of the Board (DCG 3.5.3)**

The adoption of resolutions and elections by the Board require a majority of the votes cast. To validly pass a resolution, more than half of the members of the Board must be present at the meeting. In case of an impasse, the Chairman has a casting vote. In the period under review, all resolutions by the Board were taken unanimously. Meetings may be held by teleconference.

### *Audit-related tasks of the Board*

In addition to its other responsibilities, the Board also monitors the integrity of the financial statements of the Company, assesses the independent audit firm's and its representatives' qualifications, the performance of the Company's internal audit function and independent public accountants, and the compliance of the Company with legal and regulatory requirements. The Board reviews the Company's financial statements and budgets on a quarterly basis, while it reviews financial plans and liquidity reports on a monthly basis. It also assesses the Company's internal control system and is responsible for the Company's risk management, accounting principles and policies as well as tax structures. The Board communicates with the Company's external auditors concerning the results of their interim audits, audits of the annual and reviews of the interim financial statements and assesses important or critical accounting topics with the Executive Management and the external auditors.

### *Compensation-related tasks of the Board*

The compensation-related tasks of the Board are described in the Compensation Report.

### *Meetings in 2014*

In 2014, the Board held five meetings in person which on average lasted about five hours. In addition, the Board held eight teleconferences which on average lasted almost two hours. In two instances, the Board resolved by e-mail.

### **Information and control instruments vis-à-vis the Executive Management (DCG 3.7)**

As a rule, the CEO and the Board's Secretary, who is also the Company's General Counsel, participate in all Board meetings and report to the Board on the current course of business and all significant issues and transactions. The Vice-President Finance & Accounting is present when financial, accounting, reporting, controlling and budgeting topics are discussed. In addition, other members of senior management are invited for certain agenda items covering their area of expertise, for example, to discuss results and progress of clinical studies, submissions to regulatory authorities, potential new indications and additional fields of activities, and in- and out-licensing projects. From time to time, the Board also invites the Company's auditors and tax advisors to its meetings.

For the year under review, the Board decided that no formal risk management report would have to be prepared as the Company's risks had been clearly identified by the EM and that the Board was regularly briefed on these risks and involved in their management. Among the key risks identified had been the financial situation of the Company, the regulatory risk in the EU in connection with the MAA for Raxone in Leber's Hereditary Optic Neuropathy, the decision on the regulatory path forward with respect to Duchenne Muscular Dystrophy, the marketing strategy to launch Raxone in the European Union and the retention of key personnel.

Extraordinary transactions and issues must be reported by the CEO to the Board immediately. The CEO is in regular contact with the Board. Each member of the Board is entitled to request and receive information on all matters of the Company and has access to the Company's and the Company's subsidiaries' property, records and personnel.

Due to its size, Santhera does not have an internal audit function, but parts of this function have been allocated to its finance department and the manager of quality assurance.

### **Executive Management (DCG 4 and 3.6)**

In the reporting period, the EM consisted of the CEO only. As of February 1, 2015, the Board appointed Nicholas Coppard, Senior Vice-President (**SVP**), Development, Günther Metz, SVP, Development, Giovanni Stropoli, Chief Commercial Officer (**CCO**) Europe & Rest of World, and Oliver Strub, SVP, General Counsel as additional members of the Executive Management.

During the Board and Board committee meetings the CEO reports to the Board as well as whenever required on an ad hoc basis. Members of the Executive Management are appointed by the Board upon proposal by the CEO with the exception of the CEO himself who is appointed upon proposal by the Chairman of the Board.

The CEO, together with Executive Management, is responsible for implementation of the decisions taken by the Board and its Committees. With the support of the management team, he prepares the business strategy and business plan for decision by the Board. In accordance with the Group Directive "Competencies & Responsibilities," the CEO approves material contracts, decides on the

Company's Intellectual Property rights and the handling of lawsuits. He also allocates financial, personnel and other resources within Santhera and supervises the members of the management team. The management team has regular meetings that usually cover the following topics: product revenues, development programs and clinical studies, regulatory strategies, resource allocation, business development, competitive situation, risk management and internal control system, corporate affairs including important contracts, supply chain and information on subsidiaries, financing situation and strategies, internal and external financial reporting, financial controlling, public and investor relations, human resources, taxes, legal and compliance.

#### **Members of the Executive Management (DCG 4.1)**

|                    | <b>Year of birth</b> | <b>Nationality</b> | <b>Position</b>                               |
|--------------------|----------------------|--------------------|---|
| Thomas Meier       | 1962                 | DE                 | CEO   |
| Nicholas Coppard*  | 1959                 | GB                 | SVP, Head of Development                      |
| Günther Metz*      | 1958                 | DE                 | SVP, Business Development                     |
| Giovanni Stropoli* | 1960                 | IT                 | CCO   |
| Oliver Strub*      | 1963                 | CH                 | SVP, General Counsel & Secretary to the Board |

\* as of February 1, 2015

##### *Thomas Meier*

Thomas Meier was appointed CEO of Santhera, effective October 1, 2011, after having served seven years as Chief Scientific Officer (CSO) for the Company. Mr Meier was the founder CEO of MyoContract, a Basel, Switzerland-based research company focused on orphan neuromuscular diseases, which he merged in 2004 with Graffinity of Heidelberg, Germany, to form today's Santhera. In 1999, Mr Meier became an independent research group leader and lecturer in the Department of Pharmacology and Neurobiology at the University of Basel, Switzerland, where he established MyoContract as first start-up of the Biozentrum. Mr Meier received his PhD in biology from the University of Basel, Switzerland, in 1992 and subsequently joined the University of Colorado Health Sciences Center, Denver, Colorado, US. He has a distinguished scientific track record in the field of neuromuscular research. Before joining the industry, Mr Meier was awarded the International Research Fellowship Award from the US National Institutes of Health and a long-term fellowship from the Human Frontier Science Foundation. In 2007, he received the BioValley Basel Award for his outstanding contributions to the life sciences in the area.

##### *Nicholas Coppard*

Nicholas Coppard has over 30 years of experience in the research and development of innovative medicines. Prior to joining Santhera as Head of Development in May 2008, he worked in small pharmaceutical and biotech companies providing oversight of critical phases in the preclinical and clinical development of a number of drug candidates. From 1995 to 2001, Mr Coppard was a lifecycle leader at Hoffmann La Roche, Basel, Switzerland, where he was responsible for the development, registration and lifecycle management of new medicines including Valcyt (valganciclovir) and Mabthera (rituximab). Between its establishment in 1983 and 1995, he oversaw research and development at Senetek, London, United Kingdom (UK). Mr Coppard earned a BSc in biochemistry at the University of Manchester, UK, and a PhD in chemistry from the University of Aarhus, Denmark.

### *Günther Metz*

Günther Metz spent more than 20 years in the life science industry and has been working for Santhera since its inception in 2004. Mr Metz began his career in drug discovery at the French company Fournier Pharma, and thereafter joined the German start-up Graffinity, which in 2004 merged with MyoContract to form Santhera. Mr Metz held various research management positions in cross-functional teams and while working at Santhera gained broad experience across the preclinical and clinical pharmaceutical value chain in diverse indications. In 2008, he transitioned to a new area of responsibilities in business development and licensing, taking up the role of Vice-President (**VP**) Business Development at Santhera. In 2011, he was appointed VP Operations and Alliance Management. Mr Metz received his PhD in biophysics from the University Freiburg, Germany, in 1992 and subsequently held a postdoctoral research position at Yale University, New Haven, Connecticut, US, supported by a fellowship from the Alexander von Humboldt Foundation.

### *Giovanni Stropoli*

Giovanni Stropoli is an experienced commercial manager in the pharmaceutical industry. Until January 2015, he served as SVP for the region called mid-sized countries at InterMune, Switzerland, an orphan drug company acquired by Roche in 2014. For InterMune, Mr Stropoli successfully launched Esbriet in 11 countries. Before this assignment he was holding several roles at Eisai, Tokyo, Japan, including country manager in Italy, regional manager for Mid-Sized Countries and finally SVP, New Markets, in London, UK, from 2005 until 2011. Before joining Eisai, Mr Stropoli was country manager Italy for ALK-Abelló, Copenhagen, Denmark, a market leader in vaccine therapy for allergy. Earlier he held several positions in marketing and sales at Eli Lilly, Indianapolis, Indiana, USA, with assignments in Italy, the US and Spain. Mr Stropoli started his professional career in 1998 as sales representative in Alfa-Wassermann, Bologna, Italy. Mr Stropoli holds a degree in veterinary medicine from Sassari University.

### *Oliver Strub*

Oliver Strub is an experienced commercial lawyer, also responsible for the company's general legal affairs, insurances, trademarks, human resources and IT. Mr Strub joined Santhera in 2006 as General Counsel, shortly before the Company listed its shares on the SIX. From 1995 to 2006, he was with Ciba-Geigy, then Ciba Specialty Chemicals (now part of BASF), both Basel, Switzerland, where he was Head Corporate Law and Chief Compliance Officer. Mr Strub holds a degree in law from Basel University, Basel, Switzerland.

### *Other activities and vested interests (DCG 4.2)*

The CEO does not have any position in governing or supervisory bodies of any major organization, institution or foundation under private or public law, permanent management or consultancy function for major interest groups, official function or political post.

### **Permitted mandates in other companies (DCG 4.3)**

In accordance with the OaEC, Santhera currently intends to propose to its shareholders at the occasion of the 2015 ASM to limit the number of additional board mandates in listed companies to four and in privately held companies to eight for the members of the Board. No member of Executive Management is proposed to have more than two additional board mandates in listed companies and four in privately held companies.

#### **Management contracts (DCG 4.4)**

There are no management contracts between the Company and third parties.

#### **Compensation, Shareholdings and Loans (DCG 5)**

An extensive description of the compensation system and the amounts paid in the year under review is available in the separate Compensation Report.

#### **Shareholders' Participation (DCG 6)**

##### **Voting rights and representation restrictions (DCG 6.1)**

There are no voting rights restrictions, no statutory group clauses and hence no rules on making exceptions. As a consequence, there is neither a procedure nor a condition for their cancellation. A shareholder may be represented by his legal representative, the independent proxy or by another shareholder. Shareholders can instruct the independent proxy by completing an instruction form.

##### **Statutory quora (DCG 6.2)**

There are no statutory quora which differ from the applicable legal provisions.

##### **Convocation of the Shareholders' Meeting (DCG 6.3)**

There are no statutory rules on the convocation of the shareholders' meeting that differ from the applicable legal provisions.

##### **Agenda rules (DCG 6.4)**

The Board decides on the agenda of the ASM. Shareholders with voting rights whose combined holdings represent Shares with a nominal value of at least CHF 1 million or 10% of the Company's share capital may, up to 60 days before the date of the meeting, demand that items be included in the agenda. Such a request must be in writing and must specify the items and the motions to be submitted.

##### **Registrations in the share register (DCG 6.5)**

Shareholders entered into the share register as shareholders on a specific qualifying day designated by the Board (record date), which is usually less than five business days before the shareholders' meeting, are entitled to attend such meeting and to exercise their votes.

## Changes of Control and Defense Measures (DCG 7)

### Duty to make an offer (DCG 7.1)

At the 2013 ASM, shareholders approved an “opting out” clause in the Articles by which it completely excluded the obligation of a shareholder to submit a public takeover offer for all outstanding Shares if he had acquired 33⅓% of all the Company's voting rights (Art. 53 SESTA in conjunction with Art. 22 para. 3 SESTA).

### Clauses on changes of control (DCG 7.2)

The ESOP 2004, 2008, 2010, 2015 and the BSOP 2011 and 2015 under which most options to receive Shares have been granted, contain clauses according to which all options granted under these plans vest immediately upon a sale of more than 50% of the Shares.

The employment contracts with the CEO and another member of Executive Management contain a change of control provision. Please see the Compensation Report for additional details.

Other than that, as of December 31, 2014, agreements and plans from which members of the Board and/or the Executive Management or other members of senior management benefit or may benefit contain no clauses on changes of control.

## Auditors (DCG 8)

### Duration of the mandate and term of office of the lead auditor (DCG 8.1)

Ernst & Young, Basel, assumed the existing auditing engagement for Santhera's predecessor company MyoContract in 2002. The Shareholders' Meeting elects the Company's auditors for a term of office of one year. The auditor in charge is Patrick Fawer. He assumed his responsibility in 2014.

### Auditing fees and additional fees (DCG 8.2/8.3)

The following fees were charged for professional services rendered by Ernst & Young, for the 12-month period ended December 31:

|                        | In CHF thousands | 2014 | 2013 |
|------------------------|------------------|------|------|
| Audit services         |                  | 135  | 158  |
| Audit-related services |                  | 0    | 0    |

Audit services are defined as the standard audit work that needs to be performed each year in order to issue an opinion on the consolidated financial statements of Santhera and to issue reports on the local statutory financial statements. It also includes services that can only be provided by the Group auditor and includes the verification of the implementation of new or revised accounting policies and from reporting periods 2007 onwards the audit of the Company's internal control system and risk management. Audit-related services include those other services provided by auditors but not restricted to those that can only be provided by the auditor signing the audit report. They comprise services in relation to general accounting matters. For reasons of good corporate governance, Santhera contracted the provision of tax and internal control system/risk management services to a company other than Ernst & Young.

### **Supervisory and control instruments pertaining to the audit (DCG 8.4)**

The Board performs its supervisory and control functions towards the external auditors. In particular, the Board meets with the auditors at the end of an audit or review to discuss in depth the audit procedures, any findings made and recommendations proposed. The auditor's reports to the Board are also extensively discussed.

### **Information Policy (DCG 9)**

Santhera reports to its shareholders, employees, business partners and other public stakeholders in an open, transparent and timely manner. Equal treatment of all stakeholders is the guiding principle behind its partnership-based approach. In doing so, Santhera is able to promote an understanding of its objectives, strategy and business activities, and to ensure an increasing degree of awareness about Santhera. The Company has adopted a comprehensive disclosure policy to protect Santhera's interests and assets, to release material information in a timely and controlled manner, to observe the legal requirements and rules and in particular to also distinguish competencies and responsibilities of corporate and strategic disclosure and those applicable in M&S or development.

The most important information tools are the ASM, the Annual Report, the Interim Reports, news releases and the website [www.santhera.com](http://www.santhera.com).

Investors and other parties interested in subscribing to the Company's news service may do so by registering themselves on [www.santhera.com/subscription](http://www.santhera.com/subscription). For contact details, see reverse side of the 2014 Annual Report.

### **Corporate events 2015**

2015 ASM

Monday, May 11, 2015, in Basel, Switzerland

See also [www.santhera.com/events](http://www.santhera.com/events).

## Forward-Looking Statements

This Annual Report expressly or implicitly contains certain forward-looking statements concerning Santhera Pharmaceuticals Holding AG and its business. Such statements involve certain known and unknown risks, uncertainties and other factors, which could cause the actual results, financial condition, performance or achievements of Santhera Pharmaceuticals Holding AG to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. There can be no guarantee that any of the development projects described will succeed or that any new products or indications will be brought to market. Similarly, there can be no guarantee that Santhera Pharmaceuticals Holding AG or any future product or indication will achieve any particular level of revenue. In particular, management's expectations could be affected by, among other things, uncertainties involved in the development of new pharmaceutical products, including unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the 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 Annual Report 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.

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