

# ANNUAL REPORT

# 2013



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## Dear Shareholders

We are glad to report clear progress, both financially and operationally, towards a successful turnaround of Santhera. After a difficult start into the year 2013, we implemented a series of restructuring measures and, as a result, have secured the going concern of the Company until the next development and regulatory milestones will be reached. In line with your mandate given to us at the last Annual Shareholders' Meeting, we preserved and advanced the Company's assets and, thereby, increased their value in the shareholders' best interests. Specifically, we implemented an operational restructuring with an emphasis on retaining our drug development skills as well as clinical and regulatory expertise. Combined with a financial restructuring, these efforts resulted in reduced expenses and financial obligations. The equity financing instrument and the recently closed private placement will fund the continuation of Santhera's business operations well into 2015.

Raxone<sup>®</sup> in Leber's Hereditary Optic Neuropathy is our product opportunity closest to the market. During the last year, we collected additional efficacy data from an Expanded Access Program in the treatment of patients as well as extensive natural history data for comparison. Based on this convincing set of data, Raxone<sup>®</sup> was recently granted a temporary authorization for use in France, allowing LHON patients to receive reimbursed treatment with our drug. This additional clinical evidence of efficacy supports our Marketing Authorization Application, which will be filed shortly with the European Medicines Agency. We expect their decision in the first half of 2015.

Over the last 15 months, we also advanced the development of our two follow-on programs. The DELOS study in Duchenne Muscular Dystrophy is on track to deliver pivotal data for steroid-non user patients in the upcoming weeks. In fall 2013, we regained European rights to the program, which is protected by patents and orphan drug designations, offering now the opportunity for a global partnership. Finally in primary progressive Multiple Sclerosis, we continue the phase II study with the US National Institutes of Health. In addition, we extended this collaboration and secured an exclusive license to a granted US patent for this indication.

In 2013, we diligently evaluated strategic alternatives and opted to continue independently as currently the best strategic alternative for Santhera and its shareholders. With the completion of restructuring measures, we have secured additional funding to allow business continuation. Diligent management of our funds and operations will enable us to reach the next regulatory and clinical milestones as an independent company. This promising outlook is a major achievement by everyone at Santhera. We thank our employees for their commitment and engagement and you, as our shareholders, for your continued support and trust.



Martin Gertsch  
Chairman



Thomas Meier  
Chief Executive Officer

## Santhera's Late-stage Pipeline Focuses on Raxone<sup>®</sup>/Catena<sup>®</sup> in Three Orphan Indications

Santhera focuses on rare diseases, areas of high unmet medical need which include many indications with no current therapies. Traditionally, these diseases have been neglected by research and public health interest. As a result, competition is scarce, if any, offering opportunities for dedicated develop-

**Orphan drugs meet a high medical need and offer interesting opportunities**

ment programs. Regulators worldwide grant incentives such as market exclusivity to spur drug development for orphan diseases. Santhera develops and commercializes innovative pharmaceutical products for the treatment of mitochondrial and neuromuscular diseases. All programs enjoy patent protection or orphan drug status in North America and in Europe. Currently, Santhera concen-

trates all efforts on Raxone<sup>®</sup>/Catena<sup>®</sup> (INN: *idebenone*) for which the full clinical and commercial potential are explored in multiple orphan indications. *Idebenone* has a dual mode of action: It enhances mitochondrial function and acts as a cell-protecting antioxidant. Raxone<sup>®</sup> and Catena<sup>®</sup> are trademarks for Santhera's proprietary *idebenone* 150 mg tablets for use in Europe and North America, respectively.

### **Raxone<sup>®</sup> as the first treatment option for LHON**

Leber's Hereditary Optic Neuropathy (**LHON**) is a genetic eye-disease causing rapid blindness. The disorder typically presents in young men as painless loss of central vision in one eye, followed by visual loss in the fellow eye within a few months of the onset of symptoms. Over 95% of patients harbor one of three pathogenic mutations of the mitochondrial DNA which cause a defect in the complex I subunit of the mitochondrial respiratory chain. This defect leads to decreased cellular energy production, increased oxidative stress and retinal ganglion cell dysfunction, which cause progressive loss of visual acuity and blindness.

Efficacy data from the placebo-controlled **RHODOS** trial as well as supportive efficacy data collected from Santhera's ongoing Expanded Access Program show that Raxone<sup>®</sup> can prevent further vision loss in patients with residual vision and can restore vision in blind patients. Santhera will submit a marketing authorization application for Raxone<sup>®</sup> in the European Union early in the second quarter of 2014. In France, a temporary authorization for use granted in January 2014 allows Santhera to provide Raxone<sup>®</sup> to LHON patients before such a European marketing authorization is granted.

**Raxone<sup>®</sup> can prevent from vision loss and restore vision in blind patients**

## Phase III data for Catena<sup>®</sup>/Raxone<sup>®</sup> in DMD due in first half 2014

Duchenne Muscular Dystrophy (DMD) is one of the most common and devastating types of muscle loss. The inherited disease is characterized by a complete loss of *dystrophin* leading to cell damage, im-

**Catena<sup>®</sup>/Raxone<sup>®</sup> may stabilize or improve respiratory functions in Duchenne patients**

paired calcium homeostasis, elevated oxidative stress and reduced energy production in muscle cells. The absence of the protein results in rapidly progressing muscle wasting and early morbidity due to respiratory failure.

Clinical data from a placebo-controlled phase II trial (DELPHI) showed that respiratory function in Duchenne patients treated with Catena<sup>®</sup>/Raxone<sup>®</sup> may stabilize or improve. To confirm these findings, Santhera is conducting a phase III trial (DELOS) in ambulatory and non-ambulatory patients with DMD of any mutational etiology. The results for non-steroid-using participants are expected in the second quarter of 2014.

## Santhera collaborates with the NIH to investigate Catena<sup>®</sup>/Raxone<sup>®</sup> 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. Mitochondrial dysfunction and aberrant formation of reactive oxygen species underlie the development of progressive tissue destruction in ppMS.

Given its pharmacological properties, *idebenone* is considered a treatment of choice for this disease. Supported by Santhera, the US National Institutes of Health are investigating the efficacy of Catena<sup>®</sup> in a phase II clinical trial in patients with ppMS (IPPoMS). Santhera has recently obtained the exclusive rights to a patent granted in the USA and pending in Europe.

**The pharmacological properties make *idebenone* a treatment of choice**

## *Omigapil*, Santhera's second compound, to be tested in CMD

Congenital Muscular Dystrophies (CMD) are a group of inherited neuromuscular diseases characterized by different forms of progressive loss of muscle tissue. Patients suffer from reduced body weight, skeletal deformations and respiratory distress resulting in immobility and early mortality. Severe forms can affect newborns or young children with life-threatening muscle weakness.

Nonclinical studies indicate that *omigapil* inhibits cell death and reduces body weight loss and skeletal deformation while increasing locomotor activity and protecting from early mortality. Santhera and the US National Institutes of Health supported by US and European patient organizations are preparing for a clinical trial to investigate the safety, tolerability and the pharmacokinetic profile of a new liquid formulation of *omigapil* in pediatric and adolescent patients.

## Management Discussion and Analysis

The financial results for 2013 highlight marked reductions in cash burn and liabilities. The cash position at year end amounted to CHF 5.0 million. The operating result improved to CHF –7.3 million and the net result to CHF –5.8 million. The Company's financial situation has been strengthened by a Standby Equity Distribution Agreement (SEDA) for up to CHF 10 million signed with YA Global Master SPV Ltd. (YA Global) and a recent private placement of CHF 1 million with new investor IGLU Group. At the end of the first quarter 2014, Santhera had cash reserves of CHF 5.3 million slightly above year-end 2013.

### Key achievements for the past 15 months:

- Successful operational and financial restructuring resulting in reduced cash burn and liabilities
- Supportive efficacy data for Raxone® in Leber's Hereditary Optic Neuropathy (LHON)
- Preparation of Marketing Authorization Application (MAA) for Raxone® in LHON to be filed shortly with the European Medicines Agency (EMA)
- Temporary authorization for use (*autorisation temporaire d'utilisation dite de cohorte*) for Raxone® in LHON granted by the French National Agency for the Safety of Medicines and Health Products (ANSM)
- Successful futility analysis of the phase III DELOS trial with Raxone®/Catena® in Duchenne Muscular Dystrophy (DMD)
- Agreement for exclusive patent license signed with US National Institutes of Health (NIH) for Catena®/Raxone® in the treatment of primary progressive Multiple Sclerosis (ppMS)
- US patent granted protecting the use of the oromucosal administration route for *fipamezole* in the field of neurodegenerative diseases
- Financing of operations and going concern secured by a SEDA for a maximum of CHF 10 million with YA Global and a private placement of CHF 1 million with new investor IGLU Group

### CHF 5.0 million cash at year-end 2013 and significant reduction in net cash burn

As of December 31, 2013, Santhera had cash and cash equivalents of CHF 5.0 million (2012: CHF 12.3 million). Net change in cash was CHF –7.2 million (2012: CHF –11.1 million) driven by a reduction in average monthly net cash burn from CHF 0.7 million in the first quarter to CHF 0.3 million in the fourth quarter of 2013 as a result of rigorous cost control and use of the SEDA. Operational and financial restructuring measures reduced current and non-current liabilities from CHF 6.9 million to CHF 2.6 million. Total equity at year-end 2013 was CHF 7.1 million (2012: CHF 11.4 million).

### **Revenues from product sales**

In 2013, Catena<sup>®</sup> generated net sales of CHF 1.3 million (2012: CHF 3.5 million) primarily in Canada in the indication Friedreich's Ataxia. Sales from the Named Patient Program increased to TCHF 467 (2012: TCHF 352). In line with the sharp reduction in operating expenses (CHF 8.7 million in 2013 vs. CHF 34.7 million in 2012), the operating result improved to CHF -7.3 million (2012: CHF -31.2 million including substantial impairments on intangibles and the write-down of inventories). Expenses in Development were CHF 4.7 million (2012: CHF 28.7 million). Marketing and sales expenses were halved to CHF 0.9 million (2012: CHF 1.8 million) while expenses for general and administrative were reduced to CHF 3.1 million (2012: CHF 4.1 million). As a result, Santhera reduced the net loss to CHF 5.8 million in 2013 (2012: CHF 31.4 million).

### **Outlook**

In the coming weeks, the MAA for Raxone<sup>®</sup> for the treatment LHON will be filed with the EMA whose decision is expected in the first half of 2015. Meanwhile Raxone<sup>®</sup> is made available to LHON patients in France under the cohort ATU granted by the ANSM in January 2014, allowing Santhera to generate product sales. In the second quarter of 2014, pivotal data of the DELOS phase III study with Catena<sup>®</sup>/Raxone<sup>®</sup> in DMD will become available from the cohort of patients not using steroids. The results will clarify the development and regulatory path forward for this program. In ppMS, Santhera continues its collaboration with the NIH in a randomized, placebo-controlled phase II trial (IPPoMS) with Catena<sup>®</sup>/Raxone<sup>®</sup> followed by a 12-months open-label extension study.

Santhera closed the first quarter 2014 with cash of CHF 5.3 million, slightly above year-end 2013 reflecting inflows of funds from the SEDA and a private placement with IGLU Group in February 2014.

Despite the SEDA and the recent capital increase, Santhera's ability to continue business operations into 2015 and beyond remains contingent on the availability of additional financial resources. The Board of Directors and Management of Santhera therefore continue their efforts to secure adequate financing, including through further use of the SEDA, and to explore M&A opportunities and/or sale or licensing of assets.

# Consolidated Financial Statements

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## Consolidated Balance Sheet

	In CHF thousands	Notes	31.12.2013	31.12.2012 Restated <sup>1</sup>	1.1.2012 Restated <sup>1</sup>
<b>Assets</b>					
Tangible assets		5	39	81	171
Intangible assets		6	4,225	4,714	24,856
Financial assets long-term		10	85	362	361
Deferred tax assets		13	0	0	139
<b>Noncurrent assets</b>			<b>4,349</b>	<b>5,157</b>	<b>25,527</b>
Prepaid expenses and accrued income			301	179	117
Inventories		8	0	27	2,391
Trade and other receivables		9	42	639	593
Cash and cash equivalents		11	5,044	12,283	23,406
<b>Current assets</b>			<b>5,387</b>	<b>13,128</b>	<b>26,507</b>
<b>Total assets</b>			<b>9,736</b>	<b>18,285</b>	<b>52,034</b>
<b>Equity and liabilities</b>					
Share capital		12	3,934	3,677	3,673
Capital reserves and share premium			274,896	274,441	274,012
Retained earnings			-265,304	-259,550	-228,104
Employee benefit reserve		24	405	-368	-525
Treasury shares		12	-221	-177	-177
Other components of equity			-6,604	-6,658	-6,420
<b>Total equity</b>			<b>7,106</b>	<b>11,365</b>	<b>42,459</b>
Long-term finance lease liabilities		10	0	2,171	2,207
Pension liabilities		17, 24	997	1,821	1,710
<b>Total noncurrent liabilities</b>			<b>997</b>	<b>3,992</b>	<b>3,917</b>
Trade and other payables		14	597	674	876
Short-term finance lease liabilities		10	0	36	34
Accrued expenses		15	1,036	2,218	4,514
Short-term provisions		16	0	0	234
<b>Total current liabilities</b>			<b>1,633</b>	<b>2,928</b>	<b>5,568</b>
<b>Total liabilities</b>			<b>2,630</b>	<b>6,920</b>	<b>9,575</b>
<b>Total equity and liabilities</b>			<b>9,736</b>	<b>18,285</b>	<b>52,034</b>

1 Some positions have been restated, see note 17 "Adoption of IAS 19R Employee Benefits".

## Consolidated Income Statement

	For the year ended December 31, in CHF thousands	Notes	2013	2012 Restated <sup>1</sup>
Net sales		20, 21	1,319	3,538
<b>Revenue</b>			<b>1,319</b>	<b>3,538</b>
Cost of goods sold		21	-140	-349
<b>Gross profit</b>			<b>1,179</b>	<b>3,189</b>
Other operating income		22	256	357
Development		23	-4,709	-28,722
Marketing and sales		23	-926	-1,841
General and administrative		23	-3,109	-4,079
Other operating expenses		23	0	-56
<b>Operating expenses</b>		<b>23</b>	<b>-8,744</b>	<b>-34,698</b>
<b>Operating result</b>			<b>-7,309</b>	<b>-31,152</b>
Financial income		25	1,731	422
Financial expenses		25	-182	-558
<b>Result before taxes</b>			<b>-5,760</b>	<b>-31,288</b>
Income taxes		27	5	-157
<b>Net result</b>			<b>-5,755</b>	<b>-31,445</b>
<b>Basic and diluted loss per share (in CHF)</b>			<b>-1.55</b>	<b>-8.55</b>

<sup>1</sup> Some positions have been restated, see note 17 "Adoption of IAS 19R Employee Benefits".

## Consolidated Statement of Comprehensive Income

	For the year ended December 31, in CHF thousands	Notes	2013	2012 Restated <sup>1</sup>
<b>Net result</b>			<b>-5,755</b>	<b>-31,445</b>
<i>Items never to be reclassified subsequently to net income in subsequent periods:</i>				
Actuarial gains/(losses) on defined benefit plans		17, 24	773	157
<i>Items to be reclassified subsequently to net income in subsequent periods:</i>				
Currency translation differences		26	55	-239
<b>Other comprehensive result</b>			<b>828</b>	<b>-82</b>
<b>Total comprehensive result</b>			<b>-4,927</b>	<b>-31,527</b>

<sup>1</sup> Some positions have been restated, see note 17 "Adoption of IAS 19R Employee Benefits".

## Consolidated Cash Flow Statement

For the year ended December 31, in CHF thousands	Notes	2013	2012 Restated <sup>1</sup>
Result before taxes		<b>-5,760</b>	<b>-31,288</b>
Depreciation of tangible assets	5	47	107
Amortisation and impairment of intangible assets	6	551	19,965
Expenses for share options	19, 23	290	429
Change in pension liabilities	17, 24	-51	268
Change in short-term provisions	16	0	-234
Change in deferred tax assets	13	0	139
Taxes paid		-6	-18
Change in net working capital		-482	-468
Total financial result	10, 25	-1,549	136
Interest received	25	5	50
Interest paid	25	-21	-125
<b>Cash flow from operating activities</b>		<b>-6,976</b>	<b>-11,039</b>
Investments in tangible assets	5	-4	-18
Investments in intangible assets	6	0	-14
Proceeds from / investment in other financial assets	10	276	-1
<b>Cash flow from investing activities</b>		<b>272</b>	<b>-33</b>
Capital increases from options exercised	12	12	4
Proceeds from sale of treasury shares SEDA <sup>2</sup>	12	416	0
Cost of issuance of share capital		-50	0
Amortization of finance lease		-9	-36
Settlement of finance lease liabilities	10	-900	0
<b>Cash flow from financing activities</b>		<b>-531</b>	<b>-32</b>
Effects of exchange rate changes on cash and cash equivalents		-4	-19
<b>Net increase / (decrease) in cash and cash equivalents</b>		<b>-7,239</b>	<b>-11,123</b>
Cash and cash equivalents at January 1		12,283	23,406
<b>Cash and cash equivalents at December 31</b>		<b>5,044</b>	<b>12,283</b>

1 Some positions have been restated, see note 17 "Adoption of IAS 19R Employee Benefits".

2 Standby Equity Distribution Agreement, see note 12 "Share Capital".

## Consolidated Statement of Changes in Equity

In CHF thousands	Notes	Share capital	Capital reserves and share premium	Retained earnings	Employee benefit reserve	Treasury shares	Translation differences	Total
<b>Balance at January 1, 2012 (reported)</b>		<b>3,673</b>	<b>274,012</b>	<b>-228,104</b>	<b>0</b>	<b>-177</b>	<b>-6,420</b>	<b>42,984</b>
Restatement due to change in accounting policies (IAS 19R)	17	0	0	0	-525	0	0	-525
<b>Balance at January 1, 2012 (restated<sup>1</sup>)</b>		<b>3,673</b>	<b>274,012</b>	<b>-228,104</b>	<b>-525</b>	<b>-177</b>	<b>-6,420</b>	<b>42,459</b>
Net result		0	0	-31,445		0	0	-31,445
Other comprehensive result	24, 26	0	0	0	157	0	-239	-82
<b>Total comprehensive result for the period</b>		<b>0</b>	<b>0</b>	<b>-31,445</b>	<b>157</b>	<b>0</b>	<b>-239</b>	<b>-31,527</b>
Share-based payment transactions	19	0	429	0		0	0	429
Capital increase from options exercise	12	4	0	0		0	0	4
<b>Balance at December 31, 2012</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>
<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	-5,755
Other comprehensive result	24, 26	0	0	0	773	0	55	828
<b>Total comprehensive result for 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	19	0	290	0	0	0	0	290
Capital increase from options exercise	12	12	0	0	0	0	0	12
Capital increase SEDA <sup>2</sup>	12	160	300	0	0	-44	0	416
Commitment fee SEDA <sup>2</sup>	12	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>

1 Some positions have been restated, see note 17 "Adoption of IAS 19R Employee Benefits".

2 Standby Equity Distribution Agreement, see note 12 "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 7, 2014. They are subject to approval by the Annual Shareholders' Meeting (**ASM**) on May 20, 2014.

### 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.

## Material uncertainties and ability to continue operations

Material uncertainty remains as to whether Santhera's current funding is sufficient to support its going concern for another twelve months which creates significant doubts about its ability to continue as a going concern. Therefore the Company depends on further financing to ensure the continuation of its operations and to execute its strategy as outlined below.

In May 2013, the ASM supported the business continuation of Santhera as well as the evaluation of all strategic options. This vote was a mandate by the Shareholders to the Board and the Executive Management to continue to seek marketing approval from the European Medicines Agency's (EMA) for Raxone® in the treatment of Leber's Hereditary Optic Neuropathy (LHON), to continue ongoing development activities in Duchenne Muscular Dystrophy (DMD) and primary progressive Multiple Sclerosis (ppMS) and to preserve the Company's assets.

During 2013, Santhera collected additional supportive clinical data which will be used in the preparation of a new Marketing Authorization Application (MAA) in LHON. The application dossier will be submitted shortly to the EMA. Additionally, several operational and financial restructuring measures were implemented in order to reduce expenses and liabilities and to extend the cash reach. In October 2013, Santhera entered into a Standby Equity Distribution Agreement (SEDA) for up to CHF 10 million with Yorkville Advisors Global Master SPV Ltd., New York, United States of America (YA Global), which allows the Company to receive additional cash from the issue of Shares from its conditional capital. In January 2014, the French National Agency for the Safety of Medicines and Health Products (ANSM) granted an *Autorisation temporaire d'utilisation dite de cohorte (cohort ATU)*, for Raxone® in the treatment of LHON. This temporary authorization allows Santhera to sell Raxone® to hospitals in France and generate first sales with the product. Finally in February 2014, Santhera raised CHF 1 million in a private placement with IGLU Group, Zug, Switzerland.

The ability to continue business operations until the EMA reaches a decision on the MAA filing for Raxone® is contingent on the availability of sufficient financial resources. The Board and Management continues to seek for possibilities to secure additional financing including through the continued use of the SEDA as well as by exploring M&A opportunities and sale and/or licensing of assets. Shareholders should note that whilst the Board and Management continue to apply best efforts to evaluate available options, there can be no guarantee that any transaction can be realized or that such transaction would generate sufficient funds to finance further operations.

The availability of sufficient funds is decisive for Santhera and its ability to continue operations. Under the above described circumstances, the Board believes in the Company's chances to be able to meet all of its obligations for a further 12 months. Hence, the consolidated financial statements have been prepared on a going concern basis.

## 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.

Various standards and interpretations of IFRS have been revised or were introduced with effective date January 1, 2013, or before:

IFRS 7	Amendment – Disclosures: –Offsetting Financial Assets and Financial Liabilities. Effective for annual periods beginning on or after January 1, 2013.
IFRS 10	Consolidated Financial Statements. Effective for annual periods beginning on or after January 1, 2013.
IFRS 11	Joint Arrangements. Effective for annual periods beginning on or after January 1, 2013.
IFRS 12	Disclosure of Interests in Other Entities. Effective for annual periods beginning on or after January 1, 2013.
IFRS 10, 11, 12	Consolidated Financial Statements, Joint Arrangements and Disclosure of Interests in Other Entities: Transition Guidance. Effective for annual periods beginning on or after January 1, 2013.
IFRS 13	Fair Value Measurement. Effective for annual periods beginning on or after January 1, 2013.
IFRIC 20	Stripping Costs in the Production Phase of a Surface Mine. Effective for annual periods beginning on or after January 1, 2013.



IAS 1	Amendment – Presentation of Items of Other Comprehensive Income. Effective for annual periods beginning on or after July 1, 2012.
IAS 19 (Revised)	Employee Benefits. Effective for annual periods beginning on or after January 1, 2013.  IAS 19 Revised ( <b>IAS 19R</b> ) led to the restatement of prior periods. The main impacts of the adoption of IAS 19R on Santhera's financial reporting are as follows: <ul style="list-style-type: none"> <li>– Elimination of the corridor approach: It is no longer possible to defer recognition of actuarial gains and losses using the corridor approach. They must be recognized immediately in other comprehensive income.</li> <li>– Calculation of pension costs: The previous practice of recognizing the expected return on plan assets and of calculating the interest expense on the defined benefit obligation is replaced by the recognition of net interest on the net defined benefit liability or the net defined benefit asset.</li> <li>– Past service costs are recognized immediately through the income statement when they occur.</li> <li>– Risk sharing: The new provision on sharing risk between the employees and employer has impacts on the defined benefit liability and the allocation of service costs.</li> </ul>
IAS 27 (Revised)	Separate Financial Statements. Effective for annual periods beginning on or after January 1, 2013.
IAS 28 (Revised)	Investments in Associates and Joint Ventures. Effective for annual periods beginning on or after January 1, 2013.

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. The most important changes relate to IFRS 9 Financial Instruments. Santhera will assess the impact of this standard once it has been published in its entirety and the IASB has set a mandatory effective date. None of the other amendments is currently expected to have a material impact on Santhera's accounting policies or financial performance but may lead to additional disclosures.

### 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, DMD and Friedreich's Ataxia (**FA**)). 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 Santhera company 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 shortterm. 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 and 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.

#### **i) 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.

#### **ii) 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). The EIP was only eligible to members of the Executive Management 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 expenses 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. If not agreed otherwise 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 settle 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 based on conclusion of new contracts or achievement of milestones, as defined in the 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.

## Research and development / intangible assets

Research and development (**R&D**) expenses are charged to the income statement as incurred. Development expenses 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:

- Going concern assumption, see note 2 *"Material uncertainties and ability to continue operations"*.
- 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"*.
- Assessment of contingent liabilities, see note 18 *"Commitments and Contingent Liabilities"*.
- 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 19 *"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 24 *"Employee Expenses and Benefits"*.

## 4 Exchange Rates of Principal Currencies

	Income statement in CHF average rates		Balance sheet in CHF year-end rates	
	2013	2012	2013	2012
1 euro ( <b>EUR</b> )	1.2307	1.2053	1.2257	1.2075
1 US dollar ( <b>USD</b> )	0.9270	0.9378	0.8904	0.9136
1 Canadian dollar ( <b>CAD</b> )	0.9004	0.9381	0.8325	0.9166

## 5 Tangible Assets

In CHF thousands	Laboratory and other equipment	IT hard- ware	Leasehold improvements – finance lease	Leasehold 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>
<b>2012</b>					
In CHF thousands	Laboratory and other equipment	IT hard- ware	Leasehold improvements – finance lease	Leasehold improvements	2012
<b>Cost</b>					
At January 1	1,277	631	2,314	540	4,762
Additions	0	18	0	0	18
Disposals	-944	-20	0	0	-964
<b>At December 31</b>	<b>333</b>	<b>629</b>	<b>2,314</b>	<b>540</b>	<b>3,816</b>
<b>Accumulated depreciation and impairment losses</b>					
At January 1	1,218	546	2,314	513	4,591
Additions	32	67	0	8	107
Disposals	-944	-20	0	0	-964
Exchange differences	0	1	0	0	1
<b>At December 31</b>	<b>306</b>	<b>594</b>	<b>2,314</b>	<b>521</b>	<b>3,735</b>
<b>Net book value</b>	<b>27</b>	<b>35</b>	<b>0</b>	<b>19</b>	<b>81</b>

The insurance value (including fire) of tangible assets amounted to CHF 3.0 million as of December 31, 2013 (December 31, 2012: CHF 3.0 million).



## 6 Intangible Assets

In CHF thousands	Raxone®/ Catena®	Capitalized development costs Raxone®/ Catena®	<i>Fipamezole</i>	IT software/ patents	2013
<b>Cost</b>					
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>

In CHF thousands	Raxone®/ Catena®	Capitalized development costs Raxone®/ Catena®	<i>Fipamezole</i>	IT software/ patents	2012
<b>Cost</b>					
At January 1	21,713	3,764	3,918	460	<b>29,855</b>
Additions	0	0	0	14	<b>14</b>
Disposals	-569	-102	0	-181	<b>-852</b>
Exchange differences	-163	0	0	0	<b>-163</b>
<b>At December 31</b>	<b>20,981</b>	<b>3,662</b>	<b>3,918</b>	<b>293</b>	<b>28,854</b>
<b>Accumulated amortization and impairment losses</b>					
At January 1	597	31	3,918	453	<b>4,999</b>
Additions	55	10	0	9	<b>74</b>
Impairment	16,878	3,013	0	0	<b>19,891</b>
Disposals	-569	-102	0	-181	<b>-852</b>
Exchange differences	19	0	0	0	<b>28</b>
<b>At December 31</b>	<b>16,989</b>	<b>2,952</b>	<b>3,918</b>	<b>281</b>	<b>24,140</b>
<b>Net book value</b>	<b>3,992</b>	<b>720</b>	<b>0</b>	<b>12</b>	<b>4,714</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, 2013 the market capitalization of Santhera was above the book value of its equity and therefore not indicating a potential impairment of the intangible assets (other than as of December 31, 2012).

### **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 2013 (2012: CHF 4.7 million) are the primary intangible assets of Santhera and form the basis of the Raxone®/Catena® development projects. Movements are mainly related to impairments in the amount of CHF 0.5 million (2012: CHF 19.9 million and FX valuation CHF 0.1 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.

Based on the strategic focus on LHON, the impairment test for 2013 continues to focus entirely on the cash flows to be derived from LHON in Europe.

The key assumptions for the tests were as follows:

	<b>2013</b>	2012
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 resulted in an impairment of the carrying value of "Raxone®/Catena®" of CHF 0.4 million and "Capitalized development costs Raxone®/Catena®" in the amount of CHF 0.1 million as of June 30, 2013.

### Sensitivity to changes in assumptions

A material uncertainty remains as to whether a final and successful market registration can be achieved for LHON. A risk of future adjustments to the carrying amount of the Raxone®/Catena® projects remains should the Company fail to obtain such registrations, see note 2 *“Material uncertainties and ability to continue operations”*.

## 8 Inventories

Inventories have a carrying amount of nil at the end of 2013 (December 31, 2012: TCHF 27 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 the negative opinion on Santhera's MAA in January 2013 (see note 2 *“Summary of Significant Accounting Policies”*), an allowance of CHF 2.3 million was booked on API through R&D expenses, half-finished goods and finished goods at the end of 2012.

## 9 Trade and Other Receivables

	In CHF thousands	<b>2013</b>	2012
Trade receivables		0	518
Other receivables (nonfinancial)		42	121
<b>Total at December 31</b>		<b>42</b>	639

Trade receivables in 2012 resulted from sales in the European Union (EU), see note 20 *“Segment and Geographic Information”*. Other receivables consist mainly of amounts due from the government for tax reimbursements (VAT) and other positions (reimbursement of expenses). 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, 2013, and 2012.

## 10 Financial Assets and Liabilities – Long-term

In April 2013, Santhera Pharmaceuticals (Schweiz) AG agreed with its landlord on a one-time payment of CHF 0.9 million to settle the finance lease liabilities (short- and long-term). The difference between the financial liability of CHF 2.2 million (as of December 31, 2012) and the settlement amount has been recorded as finance income. As a result, no finance lease liabilities are shown as of December 31, 2013 (December 31, 2012: short-term TCHF 36 and long-term CHF 2.17 million).

Financial assets long-term include cash deposits with the landlord and the government for customs clearance in the amount of TCHF 85 (2012: TCHF 362).

## 11 Cash and Cash Equivalents

	In CHF thousands	<b>2013</b>	2012
Cash at banks and on hand			
In CHF		4,347	4,836
In EUR		331	2,148
In USD		279	336
In CAD		87	1,463
Short-term money market deposits			
In CHF		0	3,500
<b>Total at December 31</b>		<b>5,044</b>	12,283

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 5.0 million (2012: CHF 12.3 million).

## 12 Share Capital

### Ordinary share capital

As of January 1, 2012, the share capital amounted to CHF 3,673,463, divided into 3,673,463 Shares at a nominal value of CHF 1 each. During 2012, 4,075 Shares were issued from conditional capital upon the exercise of stock options under the EIP. As a result, as of December 31, 2012, 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 for the 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.

### *Standby Equity Distribution Agreement (SEDA)*

In October 2013, Santhera entered into a SEDA with 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. In exchange for the funds, YA Global will receive Shares. Santhera paid an upfront fee of 3% of YA Global's total commitment in newly issued Shares from the existing conditional capital. This amount of TCHF 300 was settled with 85,070 Shares and represents cost of issuance share capital (non-cash relevant) as shown in the equity statement. During 2013, Santhera has drawn a total of TCHF 416 from YA Global for which 115,505 Shares were delivered.

### *Treasury shares*

In the context of the SEDA financing, Santhera issued 245,000 Shares, of which 85,070 were used as payment for the up-front fee, and 115,505 were delivered to YA Global draws in 2013. These transactions led to a net amount of 44,425 treasury shares to be used for further draws under the SEDA.

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 end 2014, beginning 2015.

In total, Santhera holds 52,453 treasury shares as of December 31, 2013 (2012: 8,028).

### **Authorized share capital**

At the ASM in April 2012, 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 April 22, 2014 through the issuance of up to 1,800,000 Shares with a nominal value of CHF 1 each. An increase in partial amounts is permitted. For each such increase, the Board shall 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 Shareholder's Meeting held on April 23, 2012, the shareholders approved a maximum increase of the share capital by an aggregate amount of CHF 700,000 (2012: CHF 700,000) through the issuance of a maximum of 700,000 (2012: 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, 2013, the Company had a conditional share capital, pursuant to the above provisions, whereby the share capital may be increased by

- (i) a maximum amount of CHF 684,414 (2012: 695,925) through the issuance of up to 684,414 (2012: 695,025) Shares, under the exclusion of shareholders' pre-emptive rights, for option rights being exercised under the Company's stock option plans, see note 19 "*Stock Option Plans*", and
- (ii) a maximum amount of CHF 355,000 (2012: CHF 600,000) by issuing up to 355,000 (2012: 600,000) 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.

## 13 Deferred Taxes

### Net deferred taxes recorded

	In CHF thousands	<b>2013</b>	2012
Temporary differences on intangible assets		844	941
Tax loss carryforwards		-844	-941
<b>Deferred tax liabilities recognized</b>		<b>0</b>	<b>0</b>

Tax loss carryforwards		338,649	347,385
Of which recorded		-4,220	-4,703
<b>Of which unrecorded</b>		<b>334,429</b>	<b>342,682</b>

Expiring			
1 year		21,958	34,134
2 years		47,276	21,958
3 years		9,738	47,276
4 years		5,832	9,738
Five years		22,671	5,832
More than five years		198,433	196,805
Without expiration		28,521	26,939
<b>Total unrecorded tax loss carryforwards</b>		<b>334,429</b>	<b>342,682</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 997 per December 31, 2013 and TCHF 1,821 per December 31, 2012, respectively). Furthermore, there are no income tax consequences for Santhera of paying a dividend to its shareholders.

## 14 Trade and Other Payables

	In CHF thousands	<b>2013</b>	2012
Trade payables		597	654
Other payables (nonfinancial)		0	20
<b>Total at December 31</b>		<b>597</b>	<b>674</b>

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

## 15 Accrued Expenses

	In CHF thousands	2013	2012
Development programs		785	1,143
Liabilities to employees		53	188
Accrued marketing and sales expenses		27	304
Expenses for facility, consulting and other		171	583
<b>Total at December 31</b>		<b>1,036</b>	<b>2,218</b>

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## 16 Short-term Provisions

	In CHF thousands	2013	2012
At January 1		0	234
Reversal		0	-234
<b>Total at December 31</b>		<b>0</b>	<b>0</b>

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No short-term provisions were provided in 2013 (2012: CHF 0).

## 17 Adoption of IAS 19R Employee Benefits

### Consolidated balance sheet

	In CHF thousands	January 1, 2012 reported	Restatement	January 1, 2012 restated
Equity:				
Employee benefit reserve		0	-525	-525
Total equity		42,984	-525	42,459
Total noncurrent liabilities:				
Pension liabilities		1,185	525	1,710

### Consolidated balance sheet

	In CHF thousands	December 31, 2012 reported	Restatement	December 31, 2012 restated
Equity:				
Net actuarial gains from defined benefit plans		0	157	157
Net result		-31,448	3	-31,445
Total equity		11,730	-365	11,365
Total noncurrent liabilities:				
Pension liabilities		1,456	365	1,821

### Consolidated income statement and consolidated statement of comprehensive income

	2012 reported	Restatement	2012 restated
For the year ended December 31, in CHF thousands			
Development	-28,724	2	-28,722
General and administrative	-4,080	1	-4,079
Net result	-31,448	3	-31,445
Net actuarial gains/(losses) from defined benefit plans	0	157	157
Total comprehensive result	-31,687	160	-31,257

### Consolidated statement of cash flows

	2012 reported	Restatement	2012 Restated
For the year ended December 31, in CHF thousands			
Change in pension liabilities	271	-3	268

Basic and diluted loss per share was not affected.



## 18 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>2013</b>	2012
Within 1 year		125	320
1 year through 5 years		0	60
<b>Total at December 31</b>		<b>125</b>	<b>380</b>

#### *Commitment for finance lease*

	In CHF thousands	<b>2013</b> <b>Minimum</b> <b>payments</b>	<b>2013</b> <b>Present</b> <b>value of</b> <b>payments</b>	2012 Minimum payments	2012 Present value of payments
Within 1 year		0	0	162	153
1 year through 5 years		0	0	648	534
After 5 years		0	0	3,509	1,520
Total minimum lease payments		0	0	4,319	2,207
Less amounts representing financing charges		0	0	-2,112	0
<b>Total at December 31</b>		<b>0</b>	<b>0</b>	<b>2,207</b>	<b>2,207</b>

In April 2013, Santhera Pharmaceuticals (Schweiz) AG agreed with its landlord to settle the finance lease liabilities, see note 10 *"Financial Assets and Liabilities – Long-term"*. Therefore, no commitment for finance lease is shown as per December 31, 2013.

### 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 FA filed with the US Food and Drug Administration. In addition, Santhera has an obligation to pay to INSERM a running royalty equal to 3% of net sales, not to exceed TEUR 500 per year and Santhera has to pay 25% of any non-royalty sublicense income received in the US and Canada. As of December 2013, Santhera has discontinued all development activities for Catena® in FA.

#### *Collaboration and license agreement with Takeda*

In September 2013, Santhera licensed back all previously granted rights in FA and DMD in order to increase its strategic flexibility. In return, Takeda Pharmaceutical Company Ltd, Osaka, Japan (**Takeda**), is eligible to obtain a percentage from future licensing and/or sales income generated by Santhera in DMD. 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. Lastly, both companies agreed to terminate a similar agreement for FA signed in 2005 and Santhera's contingent liability of EUR 1 million payable to Takeda has been waived. As offset, Takeda is eligible to receive EUR 1 million as a percentage from future income generated by Santhera.

#### *Agreement with the University of Leuven*

In March 2005, Santhera entered into an agreement with Katholieke Universiteit Leuven, Leuven, Belgium (**K.U. Leuven**), under which K.U. Leuven assigned to Santhera its patents and patent applications relating to the use of Catena<sup>®</sup>/Raxone<sup>®</sup> 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 Catena<sup>®</sup>/Raxone<sup>®</sup> for the treatment of DMD.

K.U. Leuven is entitled to a success fee of up to TEUR 400 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, K.U. Leuven is entitled to receive 5% royalties on net sales. In the event Santhera grants commercialization rights to a third party, K.U. 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, 2013, Santhera had no ongoing development work 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, 2013, Santhera had no ongoing development work 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, 2013, Santhera had no ongoing development work 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 end of 2014 / beginning of 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 ppMS. 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.

*Contracts for clinical development*

Santhera has entered into contracts for clinical development with e.g. contract research organizations and clinics. Santhera compensates these parties for services provided on a regular basis. It has the right to terminate the agreements at any time at its sole discretion. In case of early termination, Santhera must pay for all cost incurred by the respective counterparty up to termination. The expected payments for these contracts are as follows:

	In CHF thousands	2013	2012
Within 1 year		635	751
1 year through 5 years		300	415
<b>Total at December 31</b>		<b>935</b>	<b>1,166</b>

**Contingent liabilities summary**

Santhera believes that the disclosures above and accruals (see note 15 *"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.

**19 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**

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 shall 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 29 *"Related Party Transactions"*.

Plan	Number of options			2013			2012		
	Exer- cised	Forfeit- ed	Expired	Out- standing	Exer- cised	Forfeit- ed	Expired	Out- standing	
EIP	10,737	0	0	44,598	4,075	0	0	55,335	

## Employee Stock Option Plans

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 shall 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 shall 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 will 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.

As of December 31, 2013, 369,993 stock options (2012: 270,577) are available for future grants.

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

Number of options	2013				2012			
	Exer- cised	Forfeit- ed	Expired	Out- standing	Exer- cised	Forfeit- ed	Expired	Out- standing
ESOP 2004	774	0	6,040	85,335	0	0	34,313	92,149
ESOP 2008	0	0	28,000	5,500	0	675	56,425	33,500
ESOP 2010	0	36,176	22,000	153,988	0	11,150	46,325	211,364
<b>Total</b>	<b>774</b>	<b>36,176</b>	<b>56,040</b>	<b>244,823</b>	<b>0</b>	<b>11,825</b>	<b>137,063</b>	<b>337,013</b>

## Board Stock Option Plan

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 allocated under this plan. The allocation of grants is made according to the Board compensation on a current basis. 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 shall 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 shall expire without value. Vested stock options of Board members leaving the Board in good faith will 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	2013				2012			
	Exer- cised	Forfeit- ed	Expired	Out- standing	Exer- cised	Forfeit- ed	Expired	Out- standing
<b>Total</b>	<b>0</b>	<b>18,500</b>	<b>0</b>	<b>25,000</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>33,000</b>

**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:

	2013	2012
Market price of stock	CHF 1.09 to 6.00	CHF 3.63 to 5.35
Exercise prices	CHF 1.97 to 3.66	CHF 3.90 to 4.77
Weighted average fair value of options granted	CHF 1.47	CHF 1.53
Expected volatility <sup>1</sup>	65% to 73%	65%
CHF risk-free interest rate	0.75% to 1.11% p.a.	0.60% to 0.85% p.a.
Option term <sup>2</sup>	10 years	10 years
Expected dividend yield	0%	0%

1 The expected volatility was determined on the basis of the historical volatility of relevant equity indices and implied volatilities of warrants on shares of selected biotech companies.

2 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	2013	2012
<b>Outstanding at January 1</b>		<b>425,348</b>	501,061
Granted <sup>1</sup>		11,300	79,750
Exercised <sup>2</sup>		-11,511	-4,075
Forfeited		-54,676	-11,825
Expired		-56,040	-139,563
<b>Outstanding at December 31</b>		<b>314,421</b>	425,348
<b>Exercisable at December 31</b>		<b>263,371</b>	203,609

1 In 2012, 148,014 options were modified.

2 The average closing share price of the trading days when options were exercised during the reporting period 2013 was CHF 2.56 (2012: CHF 4.59).

The value of stock options granted is recognized as personnel expenses over their vesting period. In 2013, stock option grants resulted in personnel expenses of TCHF 290 (TCHF 101 related to R&D, TCHF 26 related to Marketing & Sales (**M&S**) and TCHF 163 to General & Administration (**G&A**)) and in 2012, such grants resulted in personnel expenses of TCHF 429 (TCHF 185 related to R&D, TCHF 55 related to M&S and TCHF 189 to G&A).

Of the above mentioned TCHF 290, TCHF 41 were expensed in 2013 for the accelerated vesting in the course of the option plan modification from May/June 2012. During 2012, out of a total of TCHF 429, TCHF 3 were expensed for that option plan modification.

### Terms of options outstanding at December 31

Exercise price range for options (in CHF)	Number outstanding	Weighted average remaining contractual life (years)	2013 Number exercisable	Number outstanding	Weighted average remaining contractual life (years)	2012 Number exercisable
1.00	46,434	2.75	46,434	57,945	3.73	57,945
from 3.85 to 10.35	178,988	8.45	127,938	244,364	8.65	23,000
from 24.45 to 30.10	5,500	2.11	5,500	19,500	1.59	19,125
from 59.44 to 68.30	77,196	1.76	77,196	85,236	2.58	85,236
from 72.70 to 114.50	6,303	2.89	6,303	18,303	1.99	18,303
<b>Total</b>	<b>314,421</b>	<b>5.74</b>	<b>263,371</b>	<b>425,348</b>	<b>6.15</b>	<b>203,609</b>

## 20 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 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	2013	2012
North America		852	3,186
EU		467	352
<b>Total</b>		<b>1,319</b>	<b>3,538</b>

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

	In CHF thousands	2013	2012
EU (Germany)		3,590	3,992
Switzerland		674	803
<b>Total</b>		<b>4,264</b>	<b>4,795</b>

In 2013, net sales of Catena® amounted to CHF 0.85 million in Canada and to CHF 0.47 million in the EU through the Named Patient Program (NPP) (2012: CHF 3.2 million and CHF 0.35 million, respectively).

## 21 Gross Profit Breakdown

	In CHF thousands	2013	2012
Net sales		1,319	3,538
<b>Revenue</b>		<b>1,319</b>	<b>3,538</b>
<hr/>			
Cost of goods sold		-140	-349
Of which amortization of intangibles		0	-63
<b>Gross profit</b>		<b>1,179</b>	<b>3,189</b>

## 22 Other Operating Income

This position consists primarily of reimbursements from scientific programs and income from disposal of assets.

## 23 Operating Expenses by Nature

	In CHF thousands	2013	2012 restated <sup>1</sup>
External R&D expenses		-1,826	-5,700
Patent and license expenses		-345	-388
Marketing expenses		-441	-929
Employee expenses		-3,925	-5,660
Of which non-cash-relevant expenses for share-based payments		-290	-429
G&A expenses		-1,314	-1,388
Depreciation, amortization and impairment		-598	-20,009
Lease expenses		-295	-568
Other operating expenses		0	-56
<b>Total operating expenses</b>		<b>-8,744</b>	<b>-34,698</b>

<sup>1</sup> Some positions have been restated, see note 17 "Adoption of IAS 19R Employee Benefits".

Amortization of intangible assets is recognized in costs of good sold, R&D and G&A expenses. Impairment of intangible assets is recognized in R&D expenses. Allowances on inventory are recognized in R&D expenses.



## 24 Employee Expenses and Benefits

### Employee expenses

	In CHF thousands	2013	2012 restated <sup>1</sup>
Wages and salaries		-3,169	-4,342
Social security and other personnel-related expenses <sup>2</sup>		-466	-889
Of which non-cash-relevant adjustments of pension fund		51	-268
Share-based payments		-290	-429
<b>Total employee costs</b>		<b>-3,925</b>	<b>-5,660</b>
<hr/>			
<b>Average number of full-time equivalents<sup>3</sup></b>		<b>16.8</b>	24.9
<b>Full-time equivalents at year-end</b>		<b>11.8</b>	23.1
<b>Total headcount at year-end</b>		<b>14</b>	26

1 Some positions have been restated, see note 17 "Adoption of IAS 19R Employee Benefits".

2 Thereof TCHF 16 was expensed for defined contribution plans in North America (2012: TCHF 17).

3 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 2013 and 2012, 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, Wintherthur (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	2013	2012 restated <sup>1</sup>
<b>Present value of obligation, January 1</b>		<b>7,048</b>	7,131
Current employer service cost		447	669
(Gain)/loss on settlement		-310	0
Interest cost		141	178
Employee contributions		166	176
Benefits paid / transfer payments		-1,180	-869
Insurance premiums		-90	-121
Plan settlement		-1,247	0
Remeasurements <sup>2</sup>		-799	-116
<b>Present value of obligation, December 31</b>		<b>4,176</b>	7,048

1 Some positions have been restated, see note 17 "Adoption of IAS 19R Employee Benefits".

2 Details of remeasurements:

	In CHF thousands	2013	2012 restated <sup>1</sup>
Actuarial (gain)/loss due to changes in demographic assumptions		0	221
Actuarial (gain)/loss due to changes in financial assumptions		-236	439
Actuarial (gain)/loss due to experience adjustments		-563	-776
<b>Subtotal (gain)/loss</b>		<b>-799</b>	-116
(Return)/loss on plan assets (excluding interest income)		26	-41
<b>Total remeasurements in other comprehensive income (gain)/loss</b>		<b>-773</b>	-157

1 Some positions have been restated, see note 17 "Adoption of IAS 19R Employee Benefits".

*Changes in plan assets*

	In CHF thousands	2013	2012 restated <sup>1</sup>
<b>Fair value of assets, January 1</b>		<b>5,227</b>	5,421
Interest income on assets		108	143
Employer contributions		221	436
Employee contributions		166	176
Benefits paid / transfer payments		-1,180	-869
Insurance premiums		-90	-121
Plan settlement		-1,247	0
Remeasurements (return/(loss) on plan assets (excluding interest income))		-26	41
<b>Fair value of assets, December 31</b>		<b>3,179</b>	5,227

1 Some positions have been restated, see note 17 "Adoption of IAS 19R Employee Benefits".

*Net defined benefit asset/(obligation)*

	In CHF thousands	2013	2012 restated <sup>1</sup>
Present value of obligation, December 31		4,176	7,048
Fair value of assets, December 31		3,179	5,227
<b>Net defined asset / (obligation)</b>		<b>-997</b>	<b>-1,821</b>

1 Some positions have been restated, see note 17 "Adoption of IAS 19R Employee Benefits".

*Asset breakdown*

Assets of the defined benefit plan are not quoted since AXA fully insures them. Therefore the entire amount of 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 %	2013	2012
Discount rate		2.3	2.0
Expected future salary increases		1.5	1.5

*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%	-195	180	-22	21
Salary increase +0.25%	-55	-	-2	-
Live expectancy + 1 year	-43	-	-4	-

*Mortality rate:*

Life expectancy at age 65	2013	2012
Male	21.39	21.29
Female	23.86	23.76

The expected employer contributions for fiscal year 2014 amount to approximately TCHF 232 (2013: TCHF 336).

No benefit obligations for pensioners were calculated as per December 31, 2013 (2012: none).

The duration of the plan liabilities calculated is 20.1 years as per December 31, 2013 (2012: 19.1 years).

## 25 Financial Income / Expenses

### Financial income

	In CHF thousands	2013	2012
Interests on cash and cash equivalents		5	50
Realized and unrealized foreign exchange gains		200	372
Settlement finance lease liabilities		1,526	0
<b>Total</b>		<b>1,731</b>	<b>422</b>

### Financial expenses

	In CHF thousands	2013	2012
Interest expenses		-9	0
Interest expenses for finance lease		-12	-125
Realized and unrealized foreign exchange losses		-161	-433
<b>Total</b>		<b>-182</b>	<b>-558</b>

## 26 Currency Translation Differences

Currency translation differences derive from currency valuation differences from investments in subsidiaries and their assets and liabilities. The gain of CHF 0.1 million in 2013 is primarily related to the valuation of intangible assets denominated in EUR (2012: CHF -0.2 million).

## 27 Income Taxes

	In CHF thousands	2013	2012
Current income tax income/(expense)		5	-18
Deferred tax income/(expense)		0	-139
<b>Total</b>		<b>5</b>	<b>-157</b>

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

	In CHF thousands	2013	2012
Result before taxes		-5,755	-31,288
Tax income of applicable tax rate of 20% <sup>1</sup>		1,151	6,258
Effect of tax rate change		0	0
Value adjustments on investments and intercompany loans		1,201	33,314
Unrecognized deferred taxes on tax loss carryforwards		-2,347	-39,729
Effective tax income/(expense)		5	-157
Effective tax rate		0.1%	0.5%

<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.

## 28 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.

	2013	2012 restated <sup>1</sup>
Net result attributable to equity holders (in CHF)	-5,754,752	-31,445,093
Weighted average number of shares issued and outstanding	3,708,260	3,676,874
<b>Basic and diluted net result per share (in CHF)</b>	<b>-1.55</b>	<b>-8.55</b>

<sup>1</sup> Some positions have been restated, see note 17 "Adoption of IAS 19R Employee Benefits".

For the years ended December 31, 2013 and 2012, 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.

## 29 Related Party Transactions

### Board and Executive Management compensation

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

	In CHF thousands	2013	2012
Short-term benefits: wages and salaries / Board compensation		456	445
Post-employment benefits (pension fund contributions)		43	58
Other long-term benefits		0	0
Termination benefits		0	0
Share-based payment expenses (fair value according to IFRS 2) <sup>1</sup>		153	350

<sup>1</sup> Fair values consist of option grants and modifications of existing grants from 2013 and 2012, 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	2013	2012
Wages and salaries, inclusive variable compensation		326	323
Post-employment benefits (pension fund contributions)		43	35
Termination benefits		0	0
Stock option grants (number) <sup>1</sup>		0	15,000

<sup>1</sup> In 2012, 41,144 options have been modified.

In 2013, the only remuneration for the Executive Management was paid to Thomas Meier, Chief Executive Officer (CEO). He received a gross compensation of TCHF 326 and no stock options. In 2012, the highest and only remuneration for the Executive Management was paid to Thomas Meier, CEO. He received a gross compensation of TCHF 323 and 15,000 stock options (with 41,144 stock options being modified).

#### *Board compensation*

	In CHF thousands	2013	2012
Compensation fix		130	122
Post-employment benefits (pension fund contributions)		0	23
Termination benefits		0	0
Stock options (number) <sup>1</sup>		10,500	10,000

<sup>1</sup> In 2012, an additional 23,000 options have been granted as modification of options – besides the 10,000.

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. In 2012, the highest compensation to a member of the Board was paid to Timothy Rink. He received a gross compensation of TCHF 45 and 1,000 stock options with 9,000 stock options being modified besides the 1,000).

*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 total number of stock options held by the members of the Board amounted to 24,000 as of December 31, 2013 (2012: 113,595 stock options). By the end of 2013 the members of the Board held 2,030 Shares (2012: 2,960 Shares).

The total number of stock options held by the Executive Management amounted to 80,039 as of December 31, 2013 (2012: 80,039 stock options). As per December 31, 2013, the members of the Executive Management held 14,613 Shares (2012: 14,613 Shares).

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	<b>2013 Total number of Shares</b>	<b>2013 Total number of stock options</b>	2012 Total number of Shares	2012 Total number of stock options
<b>Board</b>				
Martin Gertsch, Chairman	1,230	17,000	1,230	10,000
Jürg Ambühl	800	7,000	800	6,000
Timothy Rink <sup>1</sup>	–	–	0	10,000
Klaus Schollmeier <sup>2</sup>	–	–	930	87,595
<b>Executive Management</b>				
Thomas Meier, CEO	<b>14,613</b>	<b>80,039</b>	14,613	80,039

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

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

In 2013, 10,737 options were exercised by a former member of the Board (2012: 0 stock options). No stock options were exercised by the Executive Management (2012: 0 stock options).

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
2010	6,000	24.45
2010	2,000	25.00
2010	4,000	27.85
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 <sup>1</sup>	4.27
2013	2,500	4.04
2013	1,000	3.56
2013	7,000	1.91

<sup>1</sup> These options represent those which were modified in 2012 – not newly granted.

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
2009	16,000	44.45
2009	40,000	28.20
2010	61,000	9.45
2011	0	0
2012	15,000	4.53
2012	41,144 <sup>1</sup>	4.27
2013	0	0

<sup>1</sup> These options represent those which were modified in 2012 – not newly granted.

The detailed disclosures regarding executive remuneration that are required by Swiss law are included in the notes to the financial statements of Santhera Pharmaceuticals Holding AG.

### 30 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.

In a semiannual bottom-up process, operational corporate risks are identified and their likelihood and impact assessed (gross risks). Out of a pool of these identified risks, the Company defines corporate key risks. By defining and undertaking appropriate measures these corporate key risks are managed accordingly to either reduce or avoid such risk (net risk). The result of this process is a risk report which is assessed and approved by the Board generally on an annual basis. The corporate key risks are assessed on an ongoing basis by the Executive Management at its regular meetings, additional key risks are being discussed and measures identified if required.

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, USD, EUR 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, USD, EUR and CAD.

Cash and cash equivalents held in USD, EUR and CAD are expected to cover estimated purchases in those currencies until end of 2013. No derivative currency contracts are outstanding as of December 31, 2013 and 2012.

The following table demonstrates the sensitivity to a reasonable possible change in USD, EUR and CAD 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 foreign currency rate	Effect on result before taxes in CHF thousands
<b>USD positions</b>		
2013	+5%	8
	-5%	8
2012	+10%	29
	-5%	-14
<b>EUR positions</b>		
2013	+15%	20
	-5%	-10
2012	+5%	99
	-5%	-99

## 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 2013, variances of +/- 50 basis points were calculated, resulting in fluctuations of +/- TCHF 25 before tax (end of 2012: +/- 50 basis points resulting in fluctuations of +/- TCHF 61 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 December 31, 2013 in CHF thousands	On demand	Less than 3 months	3 to 12 months	1 to 5 years	After 5 years	Total	Book 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>
Year ended December 31, 2012 in CHF thousands	On demand	Less than 3 months	3 to 12 months	1 to 5 years	After 5 years	Total	Book value
Accrued expenses	0	2,218	0	0	0	2,218	2,218
Financial liabilities	0	41	121	648	3,509	4,319	2,207
Trade payables	0	654	0	0	0	654	654
<b>Total</b>	<b>0</b>	<b>2,913</b>	<b>121</b>	<b>648</b>	<b>3,509</b>	<b>7,191</b>	<b>5,079</b>

**Categories of financial instruments**

Year ended December 31, 2013 in CHF thousands	Book value	Loans and receivables	Other liabilities at amortized cost
<b>Assets</b>			
Financial assets long-term	85	85	0
Financial assets short-term	0	0	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>			
Long- and short-term debt	0	0	0
Financial liabilities long-term	0	0	0
Trade payables	597	0	597
Financial liabilities short-term	0	0	0
<b>Total</b>	<b>597</b>	<b>0</b>	<b>597</b>
<b>Year ended December 31, 2012 in CHF thousands</b>			
<b>Assets</b>			
Financial assets long-term	362	362	0
Financial assets short-term	0	0	0
Trade receivables	518	518	0
Other receivables	8	8	0
Cash and cash equivalents	12,283	12,283	0
<b>Total</b>	<b>13,171</b>	<b>13,171</b>	<b>0</b>
<b>Liabilities</b>			
Long- and short-term debt	0	0	0
Financial liabilities long-term	2,171	0	2,171
Trade payables	654	0	654
Financial liabilities short-term	36	0	36
<b>Total</b>	<b>2,861</b>	<b>0</b>	<b>2,861</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 initial public offering in 2006, the private placement in 2008, SEDA 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.

## 31 Events After the Reporting Date

In January 2014, the ANSM granted a cohort ATU for Raxone® in the treatment of LHON. This temporary authorization allows Santhera to sell the Raxone® to hospitals in France and generate first sales with the product.

In January 2014, Santhera granted a total of 351,000 options at an exercise price of CHF 3.89 to members of the Board and its employees as retention measure to retain the talent needed for the execution of the strategy.

In January 2014, Santhera Pharmaceuticals (Schweiz) AG issued additional 355'000 Shares from the conditional capital to be used for further draws under the SEDA.

On February 26, 2014 Santhera raised CHF 1 million in a private placement with IGLU Group. Santhera sold 288,317 Shares at a price of CHF 3.47 per share, representing a 8% discount to the lowest volume-weighted average share price of the last five trading days. The newly issued shares have a lock-up period of 100 days. The transaction strengthens Santhera's financial flexibility.

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

Basel, April 7, 2014

As statutory auditor, we have audited the consolidated financial statements of Santhera Pharmaceuticals Holding AG, which comprise the balance sheet, income statement, statement of comprehensive income, cash flow statement, statement of changes in equity and notes (pages 7 to 51), for the year ended December 31, 2013.

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

The Board of Directors is responsible for the preparation and fair presentation of the consolidated financial statements in accordance with IFRS and the requirements of Swiss law. This responsibility includes designing, implementing and maintaining an internal control system relevant to the preparation and fair presentation 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, 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 and fair presentation 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 December 31, 2013, 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.

## **Emphasis of matter**

We draw attention to note 2 of the consolidated financial statements, which indicates the existence of a material uncertainty which may cast significant doubt about the Group's ability to continue as a going concern as well as note 7 to the financial statements, which describes a material uncertainty regarding the valuation of the intangible assets. Our opinion is not qualified in respect of these matters.

## **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 AG

André Schaub  
Licensed audit expert  
(Auditor in charge)

Jörg Schmidt  
Licensed audit expert

# Statutory Financial Statements

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## Balance Sheet

	As of December 31, in CHF thousands	<b>2013</b>	2012
<b>Assets</b>			
Investments in Group companies		0	0
Loans to Group companies		0	642
<b>Noncurrent assets</b>		<b>0</b>	642
Treasury shares		0	0
Prepaid expenses and accrued income		33	0
Other receivables from Group companies		0	8
Other receivables from third parties		18	31
Cash and cash equivalents		3,222	8,995
<b>Current assets</b>		<b>3,273</b>	9,034
<b>Total assets</b>		<b>3,273</b>	9,676
<b>Equity and liabilities</b>			
Share capital		<b>3,934</b>	3,677
Capital reserves and share premium		1,832	1,832
Reserves for treasury shares		221	177
Free reserves		3,725	15,492
Reserves from capital contributions		0	151,046
Accumulated result		-6,582	-162,769
Results carried forward		0	1,531
Net result for the period		-6,582	-164,300
<b>Total equity</b>		<b>3,130</b>	9,455
Trade accounts payable from third parties		53	22
Other accounts payable from third parties		8	49
Accrued expenses		82	150
<b>Total current liabilities</b>		<b>143</b>	221
<b>Total liabilities</b>		<b>143</b>	221
<b>Total equity and liabilities</b>		<b>3,273</b>	9,676



## Income Statement

For the year ended December 31, in CHF thousands	<b>2013</b>	2012
Revenue from Group companies	1,026	1,053
<b>Total operating income</b>	<b>1,026</b>	1,053
<hr/>		
Other operating income	4	1
General and administrative expenses	-1,113	-1,138
Employee costs	-545	-374
Depreciation and amortization	0	0
Allowances on investments and loans to Group companies	-6,005	-166,568
<b>Total operating expenses</b>	<b>-7,663</b>	-166,080
<b>Operating result</b>	<b>-6,633</b>	-167,026
<hr/>		
Financial income	102	5,445
Financial expenses	-51	-2,719
<b>Financial result</b>	<b>51</b>	2,726
<hr/>		
<b>Result before taxes</b>	<b>-6,582</b>	-164,300
<hr/>		
Taxes expenses		0
<b>Net result</b>	<b>-6,582</b>	-164,300
<hr/>		

## 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.

### Material uncertainties and ability to continue operations

Material uncertainty remains as to whether Santhera's current funding is sufficient to support its going concern for another twelve months which creates significant doubts about its ability to continue as a going concern. Therefore the Company depends on further financing to ensure the continuation of its operations and to execute its strategy as outlined below.

In May 2013, the ASM supported the business continuation of Santhera as well as the evaluation of all strategic options. This vote was a mandate by the Shareholders to the Board and the Executive Management to continue to seek marketing approval from the European Medicines Agency (**EMA**) for Raxone<sup>®</sup> in the treatment of Leber's Hereditary Optic Neuropathy (**LHON**), to continue ongoing development activities in Duchenne Muscular Dystrophy (**DMD**) and primary progressive Multiple Sclerosis (**ppMS**) and to preserve the Company's assets.

During 2013, Santhera collected additional supportive clinical data which will be used in the preparation of a new Marketing Authorization Application (**MAA**) in LHON. The application dossier will be submitted shortly to the EMA. Additionally, several operational and financial restructuring measures were implemented in order to reduce expenses and liabilities and to extend the cash reach. In October 2013, Santhera entered into a Standby Equity Distribution Agreement (**SEDA**) for up to CHF 10 million with Yorkville Advisors Global Master SPV Ltd., New York, United States of America (**YA Global**), which allows the Company to receive additional cash from the issue of Shares from its conditional capital. In January 2014, the French National Agency for the Safety of Medicines and Health Products (**ANSM**) granted an *Autorisation temporaire d'utilisation dite de cohorte* (**cohort ATU**), for Raxone<sup>®</sup> in the treatment of LHON. This temporary authorization allows Santhera to sell Raxone<sup>®</sup> to hospitals in France and generate first sales with the product. Finally in February 2014, Santhera raised CHF 1 million in a private placement with IGLU Group, Zug, Switzerland.

The ability to continue business operations until the EMA reaches a decision on the MAA filing for Raxone<sup>®</sup> is contingent on the availability of sufficient financial resources. The Board and Management continues to seek for possibilities to secure additional financing including through the continued use of the SEDA as well as by exploring M&A opportunities and sale and/or licensing of assets. Shareholders should note that whilst the Board and Management continue to apply best efforts to evaluate available options, there can be no guarantee that any transaction can be realized or that such transaction would generate sufficient funds to finance further operations.

The availability of sufficient funds is decisive for Santhera and its ability to continue operations. Under the above described circumstances, the Board believes in the Company's chances to be able to meet all of its obligations for a further 12 months. Hence, the statutory financial statements have been prepared on a going concern basis.

## Investments/Subsidiaries

	Share capital at December 31	2013	2012
<b>Santhera Pharmaceuticals (Schweiz) AG</b> Liestal, Switzerland	CHF	125,000	125,000
<b>Santhera Pharmaceuticals (Deutschland) GmbH</b> Lörrach, Germany	EUR	25,000	25,000
<b>Santhera Pharmaceuticals (USA), Inc.</b> Charlestown, US	USD	1,000	1,000
<b>Santhera Pharmaceuticals (Canada), Inc.</b> Montréal, Canada	CAD	1,000	1,000
<b>Oy Santhera Pharmaceuticals (Finland) Ltd</b> Helsinki, Finland	EUR	2,500	2,500

In 2013 and 2012 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 2013, the share capital was increased by a total amount of CHF 256,511 to CHF 3,934,049 as of December 31, 2013 (2012: CHF 3,677,538), through the exercise of 11,511 employee stock options and the issuance of 245,000 Shares for the SEDA using conditional share capital.

## Authorized Share Capital

The Board of Directors (**Board**) is authorized, at any time until April 22, 2014, to increase the share capital by a maximum amount of CHF 1,800,000 through the issuance of up to 1,800,000 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, 2013, the Company had a conditional capital, pursuant to which the share capital of the Company may be increased by:

- (i) a maximum amount of CHF 684,414 (2012: CHF 695,925) by issuing a maximum of up to 684,414 (2012: 695,925) Shares, 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
- (ii) a maximum amount of CHF 355,000 (2012: CHF 600,000) by issuing up to 355,000 (2012: 600,000) 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.

## Standby Equity Distribution Agreement

In October 2013, Santhera announced that it has entered into a SEDA with 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.

## 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, 2013, the number of shares remained the same at 8,028, whereas the value was adjusted to CHF 0 in order to reflect the uncertainties of the future share price development.

In the context of the SEDA, Santhera issued 245,000 Shares of which 85,070 Shares were used for payment of the up-front fee to YA Global. 115,505 Shares were delivered to YA Global for funding the draws in 2013, leading to a net amount of 44,425 treasury shares. These are kept by Santhera Pharmaceutical (Schweiz) AG to be used for further draws under the SEDA.

## 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 2013: CHF 172.4 million; end of 2012: 166.4 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.

In an annual bottom-up process, operational corporate risks are identified and their likelihood and impact assessed (gross risks). Out of a pool of these identified risks, the Company defines corporate key risks. By defining and undertaking appropriate measures, these corporate key risks are managed accordingly to either reduce or avoid such risk (net risk). The result of this process is a risk report which is assessed and approved by the Board on an annual basis. The corporate key risks are in addition assessed on an ongoing basis by the Executive Management at its regular meetings, additional key risks are being discussed and measures identified if required.

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, 2013, the property insurance value for buildings and equipment amounts to TCHF 250 (2012: 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, 2013, the loans amounted to EUR 6.3 million including capitalized interest (2012: EUR 6.1 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, 2013, Santhera had no ongoing development work 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.

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, 2013, 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 2015.

### 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**). In context with this transaction, Santhera Pharmaceuticals Holding AG guarantees an amount of up to USD 30.0 million towards Biovail for obligations of Santhera Pharmaceuticals (Schweiz) AG under the collaboration and license agreement. The agreement with Biovail 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 at December 31:

Shareholder's name	2013 Shares	2013 %	2012 Shares	2012 %
YA Global Master SPV Ltd., US <sup>1</sup>	2,576,334	70.1	n/a	n/a
Ares Life Sciences, Switzerland	545,777	14.8	545,777	14.9
Ralf Arnold, Switzerland	263,108	7.2	n/a	n/a
Herculis Partners "Aries" Fund, Liechtenstein	133,822	3.6	n/a	n/a
Varuma, Switzerland	131,932	3.6	146,932	4.0
NGN Capital, Germany and US	115,409	3.1	317,319	8.6
Heidelberg Innovation Fonds, Germany	n/a	< 3.0	125,985	3.4
Baker Brothers Life Sciences, US	n/a	< 3.0	249,390	6.8

<sup>1</sup> This disclosure, required by applicable SIX Swiss Exchange (**SIX**) regulations, is materially misleading as YA Global have entered into a SEDA with Santhera, under which the Company has the right from time to time to sell newly issued Shares to YA Global, see note 12 "*Share Capital*" of the consolidated financial statement. As per the SEDA, YA Global is prohibited to hold more than 9.9% of the Company's shares at any time.

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)

## Compensations to the Board and the Executive Management

### Disclosure of compensation of members of the Board for the year 2013

	In CHF	Cash compensation fix	Social security	Stock options <sup>3</sup>	Compensation total
Martin Gertsch		45,000	3,690	7,840	56,530
Jürg Ambühl		32,000	2,624	2,070	36,694
Timothy Rink <sup>1</sup>		16,913	2,952	2,150	19,767
Klaus Schollmeier <sup>2</sup>		36,000	704	3,105	42,057
<b>Total</b>		<b>129,913</b>	<b>9,970</b>	<b>15,165</b>	<b>155,048</b>

1 Board member until May 13, 2013

2 Chairman of the Board until May 13, 2013

3 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 19 "Stock Option Plans" in the consolidated financial statements. For information about the Company's compensation procedures, consult the Corporate Governance Report on pages 77 and 78.

Option grants were made to Board members in 2013. No other payments, allowances or loans were made to the members of the Board in 2013. 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 2012

	In CHF	Cash compensation fix	Car leasing	Termination compensation	Social security	Stock options <sup>2</sup>	Compensation total
Klaus Schollmeier, Chairman <sup>1</sup>		0	6,125	450,750	101,292	18,270	576,437
Jürg Ambühl		32,000	0	0	2,624	7,640	42,264
Martin Gertsch		45,000	0	0	3,690	11,590	60,280
Timothy Rink		45,103	0	0	2,010	11,820	58,933
<b>Total</b>		<b>122,103</b>	<b>6,125</b>	<b>450,750</b>	<b>109,616</b>	<b>49,320</b>	<b>737,914</b>

1 Klaus Schollmeier received no compensation for him being Chairman of the Board in 2012. All his compensations were paid for his function as former Chief Executive Officer and as a consequence represent termination compensation.

2 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 19 "Stock Option Plans" in the consolidated financial statements. For information about the Company's compensation procedures, consult the Corporate Governance Report on pages 77 and 78.

Option grants were made to all Board members in 2012, three of them participated also in the modification of options in June 2012. No other payments, allowances or loans were made to the members of the Board in 2012. Stock option grants to members of the Board are subject to the Compensation Policy as well as the BSOP.

**Disclosure of compensation of members of the Executive Management for the year 2013**

	In CHF	Cash com- pensation fix	Cash com- pensation variable	Social security	Stock options <sup>1</sup>	Total	Number of stock options granted
Thomas Meier, Chief Executive Officer		326,419	0	73,348	0	399,767	0
<b>Total</b>		<b>326,419</b>	<b>0</b>	<b>73,348</b>	<b>0</b>	<b>399,767</b>	<b>0</b>

1 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 19 "Stock Option Plans" in the consolidated financial statements. For information about the Company's compensation procedures, consult the Corporate Governance Report on pages 77 and 78.

**Disclosure of compensation of members of the Executive Management for the year 2012**

	In CHF	Cash com- pensation fix	Cash compen- sation variable	Termi- nation compen- sation	Social security	Stock options <sup>2</sup>	Total	Number of stock options granted
Thomas Meier, Chief Executive Officer		323,187	65,800	0	70,923	79,763	539,673	15,000 <sup>3</sup>
Former member of the Executive Man- agement <sup>1</sup>		0	0	240,394	46,170	0	286,564	0
<b>Total</b>		<b>323,187</b>	<b>65,800</b>	<b>240,394</b>	<b>117,093</b>	<b>79,763</b>	<b>826,237</b>	<b>15,000</b>

1 Contains all termination compensation expenses from the restructuring 2011 of which parts were paid in 2011 and 2012.

2 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 19 "Stock Option Plans" in the consolidated financial statements. For information about the Company's compensation procedures, consult the Corporate Governance Report on pages 77 and 78.

3 In addition to these 15,000 options, 41,144 existing options were modified in 2012, see note 19 "Stock Option Plans" in the consolidated financial statements.

Compensation to Mr Schollmeier, being Chairman of the Board since October 1, 2011, is disclosed on the table "Disclosure of compensation of members of the Board for the year 2012" above.



**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

*Executive Management*

Thomas Meier, CEO	14,613	65,039	15,000	80,039
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No other payments, allowances or loans were made to either the members of the Board, members of the Executive Management or their related parties in 2013.

**Disclosure of Shares and stock options held by members of the Board and Executive Management (and their respective related party) as of December 31, 2012**

	Number of Shares	Number of vested stock options	Number of unvested stock options	Total number of stock options
<i>Board of Directors</i>				
Klaus Schollmeier, Chairman	930	80,595	7,000	87,595
Jürg Ambühl	800	1,000	5,000	6,000
Martin Gertsch	1,230	0	10,000	10,000
Timothy Rink	0	0	10,000	10,000

*Executive Management*

Thomas Meier, CEO	14,613	23,895	56,144	80,039
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No other payments, allowances or loans were made to either the members of the Board, members of the Executive Management or their related parties in 2012.

**Events After the Reporting Date**

In January 2014, Santhera Pharmaceuticals (Schweiz) AG issued additional 355'000 Shares from the conditional capital to be used for further draws under the SEDA.

On February 26, 2014, Santhera raised CHF 1 million in a private placement with IGLU Group. Santhera sold 288,317 Shares at a price of CHF 3.47 per share, representing a 8% discount to the lowest volume-weighted average share price of the last five trading days. The newly issued shares have a lock-up period of 100 days. The transaction strengthens Santhera's financial flexibility.

## 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	2013	2012
Result carried forward		0	1,531,228
Net result of the year		-6,582,326	-164,299,838
<b>Accumulated result</b>		<b>-6,582,326</b>	<b>-162,768,610</b>
Offsetting with free reserves from capital contribution		0	151,045,795
Offsetting with free reserves		0	11,722,815
<b>Result to be carried forward</b>		<b>-6,582,326</b>	<b>0</b>

### The Board of Directors requests the approval of the Annual Shareholders' Meeting for the following release and transfer from capital reserves and share premium:

	In CHF
Capital reserves and share premium at December 31, 2013	1'832'073
Share premium of capital increase February 27, 2014	711,683
<b>Capital reserves and share premium</b>	<b>2,543,756</b>
Transfer from capital reserves and share premium to free reserves	-711,683
<b>Net capital reserves and share premium to free reserves</b>	<b>1,832,073</b>

No further appropriations to legal reserves are necessary as they already amount to more than the required 20% of the share capital.

### Subject to approval by the Annual Shareholders' Meeting, the free reserves develop as follows:

	In CHF
Free reserves at December 31, 2013	3,725,162
Transfer from capital reserves and share premium to free reserves	711,683
<b>Free reserves</b>	<b>4,436,845</b>

## Report of the Statutory Auditor on the Financial Statements

Basel, April 7, 2014

As statutory auditor, we have audited the financial statements of Santhera Pharmaceuticals Holding AG, which comprise the balance sheet, income statement and notes (pages 54 to 65), for the year ended December 31, 2013.

### **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 December 31, 2013, comply with Swiss law and the company's articles of incorporation.

### **Emphasis of matter**

We draw attention to note *“Material uncertainties and ability to continue operations”* of the financial statements which indicates the existence of a material uncertainty which may cast significant doubt about the Company's ability to continue as a going concern. If the Company were unable to continue as a going concern, its financial statements would need to be prepared on a liquidation basis.

### **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 AG

André Schaub  
Licensed audit expert  
(Auditor in charge)

Jörg Schmidt  
Licensed audit expert

# Corporate Governance

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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 (**ICS**), and a risk management process (**RM**).

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 ( <b>Company</b> , together with its affiliates, <b>Santhera</b> )
Domicile	Hammerstrasse 49, 4410 Liestal, Switzerland
Register number	CH-270.3.012.442-0
Listing	SIX
Symbol	SANN
Security ID	2714864
ISIN	CH0027148649
Market capitalization	CHF 14.6 million (December 30, 2013)
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 on page 58.

Santhera operates through its wholly owned subsidiaries, Santhera Pharmaceuticals (Schweiz) AG, Liestal, Switzerland (research and development (**R&D**) of pharmaceutical drugs, administrative functions); Santhera Pharmaceuticals (Canada), Inc., Montréal, Canada (marketing and sales [**M&S**] of pharmaceutical drugs); Santhera Pharmaceuticals (USA), Inc., Charlestown, United States of America (**US**) (administrative); Santhera Pharmaceuticals (Deutschland) GmbH, Lörrach, Germany (regulatory and R&D 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 R&D 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 on page 61.

**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, 2013, 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 <sup>2</sup>	As % of ordinary capital	Amount in CHF	As % of ordinary capital		
Ordinary capital	3,677,538	100.0	3,934,049	100.0		3
Authorized capital <sup>1</sup>	1,800,000	48.9	1,800,000	45.8	April 22, 2014	3a
Conditional capital for warrants/option rights granted in connection with debt instruments <sup>2</sup>	600,000	16.3	355,000	9.0	For conversion rights: 10 years from issue date. For options: 7 years from issue date.	3b I
Conditional capital for ESOP/BSOP/EIP <sup>3</sup>	695,925	18.9	684,414	17.4		3b II

1 After the reporting period, 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.

2 In October 2013, YA Global Master (**Yorkville**) and Santhera have entered into a Standby Equity Distribution Agreement (**SEDA**) as further described on page 27 of the consolidated financial statements, under which the Company is entitled to sell Shares to Yorkville from time to time within a period of 36 months. In order to be able to deliver Shares to Yorkville, the Company has granted its wholly owned and direct subsidiary Santhera Pharmaceuticals (Schweiz) AG options to acquire Shares (one share for one option). At December 31, 2013, Santhera Pharmaceuticals (Schweiz) AG had exercised 245,000 options and transferred title to 200,575 Shares to Yorkville. By January 28, 2014, all remaining 355,000 options had been exercised, reducing the Company's conditional capital for warrants/option rights to zero.

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 the reporting period, certain holders of options exercised their rights to receive Shares which were issued from the Company's *"Conditional Capital for ESOP."* Until December 31, 2013, 11,511 Shares were newly issued under such programs and another 1,155 in 2014 until February 26, 2014. While conveying shareholders' rights upon conversion, these Shares have only been registered in the commercial register on February 27, 2014. With regard to the disclosure of participations in accordance with article 20 of the Swiss Stock Exchange Act, the entry in the commercial register is relevant.

For details with regard to terms and conditions of potential share issues under the Company's authorized and conditional share capital, see sections 3a and 3b 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 19 "*Stock Option Plans*" to the consolidated financial statements on pages 35 to 38.

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

For changes in capital that occurred in 2011 and 2012, see the Company's Annual Report 2012, which can be downloaded from [www.santhera.com/reports](http://www.santhera.com/reports). For changes that took place in 2013, see notes "*Share Capital*," "*Authorized Share Capital*" and "*Conditional Share Capital*" to the statutory financial statements of the Company on pages 58 and 59.

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

As of December 31, 2013, 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 shareholders' meeting (**Shareholders' Meeting**) 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 on page 59 and note 19 "*Stock Option Plans*" to the consolidated financial statements on pages 35 to 38.

## **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	2014	Member
Martin Gertsch	1965	CH	2006	2014	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. He is member of the board of directors of Euromedic International BV. 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 fiduci-

ary and Swiss certified public accountant. Mr Getsch 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 29 "*Related Party Transactions*" to the consolidated financial statements on pages 45 to 47.

#### **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.

#### **Elections and terms of office (DCG 3.3)**

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 three years, whereby a year means the period between two ordinary Shareholders' Meetings. In order to comply with the Minder Initiative implementing ordinance, the Ordinance against Excessive Compensation (**Minder Ordinance; VegüV**), the Company will propose to its shareholders to amend the Articles to reduce the term of office for Board members to one year. 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 Shareholders' Meeting 2014. The Board members are elected on an individual basis. So far, the Chairman has been elected by the Board. For the Shareholders' Meeting 2014, the Board will propose to the shareholders that the Chairman be elected by the shareholders.

#### **Organizational structure/areas of responsibility and information flow (DCG 3.4)**

See also the table in the section on DCG 3.1.

##### *Allocation of tasks within the Board (DCG 3.4.1)*

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 of 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 3.4.2)*

Currently, Santhera has no separate Board committee. Consisting of two members only, the Board allocated all tasks of the Audit Committee (**AC**) to the entire Board and formally abolished the AC in 2013. In view of the Company's operations, the Board considers the reduction of its size from four members to two to be adequate.

So as to comply with the Minder Ordinance, the Board will propose at the Shareholders' Meeting 2014 to formally set in place a Compensation Committee consisting of the two Board members, of which one will be the committee's chairman.

### **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 ICS, RM 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 Shareholders' Meeting, 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.

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 relies on a management team where the main functional areas of the Company are represented.

### **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 ICS and is responsible for the Company's RM, 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 Board takes all decisions in compensation- and nomination-related matters. It approves the Company's stock option plans and grants on a total Company basis and to the CEO on an individual basis. It approves salary increases, bonus payments and option pools granted to senior managers and employees on an aggregate basis. It also approves promotions of employees who are or will become direct reports of a member of the Executive Management. Further, it establishes

principles for the selection of candidates for election to the Board and the Executive Management, reviews and proposes candidates for membership on the Company's Board and Executive Management, and reviews the Company's regulations and charter to remain in compliance with SIX requirements 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 2013, the Board approved the corporate scorecard that contained the objectives for 2013. These were i) successful cash preservations; ii) securing the going concern; iii) a successful appeal against the negative opinion taken by the EMA's Committee for Medicinal Products for Human Use (**CHMP**) on the Company's Marketing Authorization Application (**MAA**) for Raxone<sup>®</sup> to treat Leber's Hereditary Optic Neuropathy (**LHON**); and iv) the achievement of certain milestones in its ongoing clinical programs. With the exception of the LHON appeal procedures, all other objectives had essentially been met. In view of the financial situation of the Company and in accordance with management's proposal, the Board resolved not to pay any cash bonus. To show its appreciation, the Board approved a general salary increase of 2%. 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 CHMP's opinion on a new MAA for Raxone<sup>®</sup> in LHON, which is expected in the first quarter 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.

#### *Meetings in 2013*

In 2013, the Board held five meetings in person which on average lasted more than two and a half hours. In addition, the Board held twelve teleconferences which on average lasted about three quarters of an hour. In three instances, the Board resolved by e-mail. In addition to other less formal contacts, the CEO briefed the Board on two occasions.

#### **Information and control instruments vis-à-vis the Executive Management (DCG 3.6)**

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 RM report would have to be prepared as the Company's risks had been clearly identified by the Executive Management and that the Board were regularly briefed on these risks and involved in their management. Among the key risks identified were the financial situation of the Company, the regulatory risk in the EU in connection with the MAA for Raxone<sup>®</sup> in LHON 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)

The Executive Management consists of the CEO only.

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 would be 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 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, RM and ICS, 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)

Name	Year of birth	Nationality	Position
Thomas Meier	1962	DE	Chief Executive Officer

#### *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-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, 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.

### **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.

### **Management contracts (DCG 4.3)**

There are no management contracts between the Company and companies not belonging to Santhera.

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

### **Content and method of determining compensation and share ownership programs (DCG 5.1)**

#### *Board compensation*

All members of the Board are compensated by means of a fixed fee payable in cash, consisting of CHF 45,000 and CHF 32,000 for the Chairman and the other member, respectively. In addition, they are granted stock options: initial onetime stock options at the next possible grant date after the time of their first election to the Board (grant dates are at the first day of a calendar quarter), under the condition, however, that at such time, they are independent and do not represent the interests of an investor. Otherwise, they obtain their initial grant as soon as they no longer represent such investor interests. The initial onetime stock options vest as follows: 50% on the second anniversary of the grant date, the next 25% on the third anniversary and the remaining options on the fourth anniversary. The Chairman and the other member received 7,000 and 1,000 options, respectively. In addition to the initial onetime stock options, nonexecutive members of the Board are entitled to an annual grant of stock options with a vesting period of one year (see below), i.e., the Chairman to 1,500 options and the other member to 1,000. For more detailed terms of all stock options, see note 19 "*Stock Option Plans*" to the consolidated financial statements on pages 35 to 38. Board members are not entitled to any variable compensation.

The total remuneration of the members of the Board for 2013 was considerably lower than for 2012 as a result of the departure of two Board members, the significant decrease of the fixed annual compensation of the Chairman (from CHF 96,000 to CHF 45,000) and the discontinuation of the payment of separate fees for the Chairman of the AC due to the dissolution of the latter.

#### *CEO compensation*

The Board reviews and determines the total remuneration paid to the members of Executive Management (fix and variable elements), i.e. currently, the CEO as he is the only member of Executive Management. The retention model introduced in 2010 was deemed no longer applicable as its retention power became ineffective due to the low share price. For 2013, the CEO's salary was increased by 1% compared to his 2012 salary.

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.

The employment contracts with the CEO provide 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 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 Minder Ordinance.

For additional information, see note "*Compensations to the Board and the Executive Management*" to the statutory financial statements on pages 62 to 64 and note 29 on pages 45 to 47 "*Related Party Transactions*" to the consolidated financial statements.

#### **Transparency of compensation for, shareholdings of and loans to issuers domiciled abroad (DCG 5.2)**

Not applicable, as the Company is domiciled in Switzerland.

### **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 corporate proxy, the independent proxy, by a depositary or by another shareholder.

#### **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 Shareholders' Meeting. 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 Shareholders' Meeting 2013, shareholders approved an "opting out" clause in the Company's 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 and 2010 and the BSOP 2011, 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 senior management contain a change of control provision. Please see section on DCG 5 (Compensation, Shareholdings and Loans).

Other than that, as of December 31, 2013, 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 André Schaub. He assumed his responsibility in 2013.

### 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	2013	2012
Audit services		158	309
Audit-related services		0	20

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 ICS and RM. 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 amounts for services in relation to general accounting matters. For reasons of good corporate governance, Santhera contracted the provision of tax and ICS/RM 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 through the AC. In particular, the AC 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. The primary objective of the AC is to support the Board in monitoring Santhera's financial planning, reporting and auditing, ICS, RM, accounting policies and principles, tax structures and cash flow management.

### **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 R&D.

The most important information tools are the Shareholders' Meetings, the Annual and 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 2013 Annual Report.

### **Corporate events 2014 (see also [www.santhera.com/events](http://www.santhera.com/events))**

Annual Shareholders' Meeting: Tuesday, May 20, 2014, in Liestal, Switzerland

## Forward-Looking Statements

This Interim 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 Interim 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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