

**IMPORTANT NOTICE: You must read the following before continuing.**

THE OFFERING DOCUMENT ATTACHED TO THIS DISCLAIMER IS AVAILABLE ONLY TO INVESTORS WHO ARE LOCATED OUTSIDE THE UNITED STATES AND EITHER (A) "QUALIFIED INVESTORS" (AS DEFINED IN THE PROSPECTUS DIRECTIVE, INCLUDING THE 2010 PD AMENDING DIRECTIVE) (**QUALIFIED INVESTORS**) IN THE EUROPEAN ECONOMIC AREA (THE **EEA**) OR (B) OUTSIDE THE EEA, IN EACH CASE IN RELIANCE ON REGULATIONS UNDER THE U.S. SECURITIES ACT OF 1933, AS AMENDED (THE **SECURITIES ACT**), AND AS OTHERWISE PERMITTED UNDER APPLICABLE SECURITIES LAWS.

**IMPORTANT:** You must read the following before continuing. The following disclaimer applies to the attached offering document (the **Offering Document**), which has been accessed via internet or otherwise received and you are therefore advised to read this disclaimer carefully before reading, accessing or making any other use of the Offering Document. In accessing the Offering Document, you agree to be bound by the following terms and conditions, including any modifications to them from time to time, any time you receive any information, as the case may be, as a result of such access. Capitalized terms used but not defined in this notice have the meanings ascribed to such terms in the Offering Document.

NOTHING IN THIS ELECTRONIC TRANSMISSION CONSTITUTES AN OFFER OF SECURITIES FOR SALE IN ANY JURISDICTION WHERE IT IS UNLAWFUL TO DO SO. NO ACTION HAS BEEN OR WILL BE TAKEN THAT WOULD, OR IS INTENDED TO, PERMIT A PUBLIC OFFERING OF THE SECURITIES DESCRIBED IN THE OFFERING DOCUMENT IN ANY JURISDICTION OTHER THAN SWITZERLAND. IN PARTICULAR, THE OFFERING HAS NOT BEEN AND WILL NOT BE REGISTERED WITH THE U.S. SECURITIES AND EXCHANGE COMMISSION OR ANY STATE SECURITIES COMMISSION OR OTHER REGULATORY AUTHORITY IN THE UNITED STATES AND, SUBJECT TO CERTAIN EXCEPTIONS, THE SECURITIES DESCRIBED IN THE OFFERING DOCUMENT MAY NOT BE OFFERED, SOLD, RESOLD, DELIVERED, ALLOTTED, TAKEN UP, TRANSFERRED OR RENOUNCED, DIRECTLY OR INDIRECTLY, IN OR INTO THE UNITED STATES, OR SOLD WITHIN THE UNITED STATES OR TO, OR FOR THE ACCOUNT OR BENEFIT OF, U.S. PERSONS (AS DEFINED IN REGULATIONS UNDER THE SECURITIES ACT).

The Offering Document is being provided to you on a confidential basis for informational use solely in connection with your consideration of the purchase of the securities referred to therein. Its use for any other purpose is not authorized, and you may not, nor are you authorized to, copy or reproduce the Offering Document in whole or in part in any manner whatsoever or deliver, distribute or forward the Offering Document or disclose any of its contents to any other person. Failure to comply with this directive may result in a violation of the Securities Act or the applicable laws of other jurisdictions. If you are not the intended recipient of the Offering Document, you are hereby notified that any dissemination, distribution or copying of the Offering Document is strictly prohibited.

**Confirmation of your representation:** In order to be eligible to view the Offering Document or make an investment decision with respect to the securities described therein, potential investors must be located outside the United States and either (a) Qualified Investors or (b) outside the EEA. You have been sent this disclaimer with the attached Offering Document on the basis that you have confirmed to the relevant parties that (i) you and any customers that you represent are not U.S. Persons, (ii) the electronic mail (or e-mail) address to which it has been delivered is not located in the United States, its territories and possessions, any State of the United States or the District of Columbia (where "possessions" include Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, Wake Island and the Northern Mariana Islands), and (iii) you consent to delivery by electronic transmission.

You are reminded that the Offering Document has been delivered to you on the basis that you are a person into whose possession the Offering Document may be lawfully delivered in accordance with the laws of the jurisdiction in which you are located and you may not, nor are you authorized to, deliver the Offering Document to any other person.

This disclaimer does not constitute or contain any offer to sell or invitation to subscribe or make commitments for or in respect of any security in any jurisdiction where such an offer or invitation would be unlawful. There are restrictions on the distribution of this disclaimer and the Offering Document and/or the offer or sale of the securities described in the Offering Document in certain jurisdictions. If a jurisdiction requires that the offering be made by a licensed broker or dealer and a bank involved in the offering or any affiliate of such bank is a licensed broker or dealer in that jurisdiction, the offering shall be deemed to be made by such bank or any affiliate of such bank on behalf of the Issuer in such jurisdiction.

The Offering Document has been sent to you in electronic form. You are reminded that documents transmitted via this medium may be altered or changed during the process of electronic transmission and, consequently, none of the involved parties in the offering, or their respective affiliates, directors, officers, employees or agents accepts any liability or responsibility whatsoever in respect of any difference between the Offering Document distributed to you in electronic format and any hard copy version that may have been delivered to you by third parties.

You are responsible for protecting against viruses and other destructive items. Your receipt of the Offering Document via electronic transmission is at your own risk and it is your responsibility to take precautions to ensure that it is free from viruses and other items of a destructive nature.



**Santhera Pharmaceuticals Holding AG**  
(incorporated in Liestal, Switzerland, with limited liability)

**CHF 60 million Senior Unsecured Convertible Bonds due 2022**

This prospectus (the **Prospectus**) relates to the offering (the **Offering**) of 5.0 per cent bonds in the aggregate principal amount of Swiss francs (**CHF**) 60 million due 2022 (each and collectively the **Bonds**) of Santhera Pharmaceuticals Holding AG (the **Issuer**), convertible into 694,440 registered shares with a nominal value of CHF 1.00 each of the Issuer (the **Shares**, and each a **Share**), and the listing of the Bonds on the SIX Swiss Exchange Ltd (**SIX Swiss Exchange**). The Issuer is not rated and the Bonds are not expected to be rated. Capitalized terms used and not otherwise defined herein have the meanings ascribed to them in the Terms of the Bonds (Section V).

<b>Offering</b>	The Offering consists of (i) a public offering of Bonds to investors in Switzerland and (ii) private placements of Bonds in certain other jurisdictions outside Switzerland, the United States, Canada, Japan and Australia in reliance on Regulation S under the U.S. Securities Act of 1933, as amended, on exemptions provided by the directive 2003/71/EC, and in accordance with applicable securities laws.
<b>Offering Size</b>	CHF 60,000,000.
<b>Principal Amount/Denomination</b>	CHF 5,000 per Bond.
<b>Issue Price</b>	100% of the Principal Amount.
<b>Interest Rate</b>	5.00% per annum, payable semi-annually in equal instalments in arrears on February 17 and August 17, for the first time on August 17, 2017.
<b>Placement Price</b>	According to demand.
<b>Issue and Payment Date</b>	February 17, 2017.
<b>Maturity Date</b>	February 17, 2022.
<b>Redemption Price</b>	100% of the Principal Amount.
<b>Reference Share Price</b>	CHF 71.9969.
<b>Initial Conversion Price</b>	CHF 86.4006.
<b>Initial Conversion Premium</b>	20.0% (rounded down).
<b>Initial Conversion Ratio</b>	57.8700 Shares per Bond.
<b>Reset</b>	If the average of the daily VWAPs of the Shares during 20 consecutive Trading Days immediately preceding the 5th Trading Day prior to the date that is 12 months after the Payment Date (the <b>Reset Date</b> ) is lower than the Reference Share Price, the Initial Conversion Price shall be replaced, with effect as per the Reset Date, by the higher of (a) 120% of the average of the daily VWAPs of the Shares during the 20 consecutive Trading Days immediately preceding the 5th Trading Day prior to the Reset Date and (b) 75% of the Conversion Price prevailing at the Payment Date.
<b>Conversion Period</b>	May 17, 2017 – February 17, 2022.
<b>Status</b>	Senior, unsecured.
<b>Form of the Bonds</b>	The Bonds will be issued as uncertificated securities ( <i>Wertrechte</i> ) in accordance with article 973c of the Swiss Code of Obligations ( <b>CO</b> ) and registered as intermediated securities ( <i>Bucheffekten</i> ) in the main register ( <i>Hauptregister</i> ) with SIX SIS Ltd. Neither the Bondholders (as defined in the Terms of the Bonds) nor any other parties will have the right to request printing and physical delivery of individually certificated Bonds.
<b>Early Redemption at the option of the Issuer</b>	The Issuer may, by giving not less than 30 and not more than 60 calendar days' prior notice, redeem all but not only some of the outstanding Bonds at their Principal Amount, together with unpaid accrued interest, if any, at any time after the second anniversary of the Payment Date, if the volume weighted average price of a Share on each of at least 20 out of 30 consecutive Trading Days ending not earlier than 5 Trading Days prior to the giving of notice of redemption is at least 160% of the prevailing Conversion Price.
<b>Clean-up Call</b>	The Issuer may, by giving not less than 30 and not more than 60 calendar days' prior notice, redeem all but not only some of the outstanding Bonds at their Principal Amount, together with unpaid accrued interest, if any, at any time after the Payment Date and prior to the Maturity Date if less than 15% of the aggregate Principal Amount of the Bonds originally issued is outstanding.
<b>Assurances</b>	Negative pledge clause (with restrictions), <i>pari passu</i> clause, cross default clause (subject to CHF 5 million threshold), events of default clause, anti-dilution provision, all as provided in the Terms of the Bonds.
<b>Escrow</b>	Out of the net proceeds of the Bonds, an amount corresponding to the interest payable on the Bonds for the first three years of their term will be put into escrow to be used for such interest payments.
<b>Trading</b>	The Bonds are expected to be provisionally admitted to trading on the SIX Swiss Exchange as of February 16, 2017. The last trading day is expected to be February 15, 2022.
<b>Listing</b>	Listing of the Bonds will be applied for at the SIX Swiss Exchange. The Shares are listed on the SIX Swiss Exchange in accordance with the International Reporting Standard.
<b>Selling Restrictions</b>	<b>United States of America, U.S. persons, European Economic Area, United Kingdom</b> , in particular. See Selling Restrictions of this Prospectus.
<b>Governing Law and Jurisdiction</b>	Swiss law; place of jurisdiction is the city of Zurich, Switzerland.

**Lead Managers**

**Bank am Bellevue**

**Kepler Cheuvreux**

	<b>Bonds</b>	<b>Shares</b>
Swiss Security Number:	35395519	2714864
ISIN:	CH0353955195	CH0027148649
Ticker symbol:	SAN17	SANN

Prospectus dated February 10, 2017

## I. SELLING RESTRICTIONS

### A. United States of America / U.S. persons

- (a) The Bonds have not been and will not be registered under the U.S. Securities Act of 1933, as amended (the **Securities Act**), and may not be offered or sold within the United States of America (the **United States**) or to, or for the account or benefit of, United States persons each as defined in Regulation S under the Securities Act except pursuant to an exemption from, or in a transaction not subject to, the registration requirements of the Securities Act.

The Issuer and the Lead Managers have not offered or sold and will not offer or sell any Notes within the United States or to or for the account or benefit of United States persons, except in accordance with Rule 903 of Regulation S under the Securities Act.

Accordingly, none of the Issuer, the Lead Managers and their affiliates or any persons acting on their behalf have engaged or will engage in any selling activities directed to the United States with respect to the Notes.

Terms used in this paragraph have the meanings given to them by Regulation S.

- (b) The Lead Managers have not entered and will not enter into any contractual arrangement with respect to the distribution or delivery of the Bonds except with their affiliates or with the prior written consent of the Issuer.

### B. Public offer selling restrictions under the Prospectus Directive

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a **Relevant Member State**), the Lead Managers have represented and agreed that with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State (the **Relevant Implementation Date**) they have not made and will not make an offer of Bonds which are the subject of the offering contemplated by this Prospectus to the public in that Relevant Member State except that they may, with effect from and including the Relevant Implementation Date, make an offer of such Bonds to the public in that Relevant Member State:

- (a) in the period beginning on the date of publication of a prospectus in relation to those Bonds which has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the Prospectus Directive, and ending on the date which is 12 months after the date of such publication;
- (b) at any time to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- (c) at any time to fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Directive), subject to obtaining the prior consent of the Lead Managers; or
- (d) at any time in any other circumstances falling within article 3(2) of the Prospectus Directive,

provided that no such offer of Bonds referred to in (b) to (d) above shall require the Issuer or the Lead Managers to publish a prospectus pursuant to article 3 of the Prospectus Directive, or supplement a prospectus pursuant to article 16 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer of Bonds to the public" in relation to any Bonds in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the Bonds to be offered so as to enable an investor to decide to purchase or subscribe the Bonds, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

## **C. United Kingdom**

The Lead Managers listed on the front page of this Prospectus have represented and agreed that: (i) they have complied and will comply with all applicable provisions of the Financial Services and Markets Act 2000 (the **FSMA**) with respect to anything done by them in relation to the Bonds in, from or otherwise involving the United Kingdom; and (ii) they have only communicated or caused to be communicated and they will only communicate or cause to be communicated any invitation or inducement to engage in investment activity (within the meaning of section 21 of the FSMA) received by them in connection with the issue or sale of any Bonds in circumstances in which section 21(1) of the FSMA would not, if the Issuer were not an authorized person, apply to the Issuer.

## **D. General**

Neither the Issuer nor the Lead Managers represent that Bonds may at any time lawfully be sold in compliance with any applicable registration or other requirements in any jurisdiction, or pursuant to any exemption available thereunder, or assumes any responsibility for facilitating such sale. The distribution of this Prospectus and the offering of the Bonds in certain jurisdictions may be restricted by law. Persons into whose possession this Prospectus comes are required by the Issuer to inform themselves about and to observe any such restrictions. This Prospectus does not constitute, and may not be used for or in connection with, an offer or solicitation by anyone in any jurisdiction in which such offer or solicitation is not authorized or to any person to whom it is unlawful to make such offer or solicitation and no action is being taken in any jurisdiction that would permit a public offering of the Bonds or the distribution of this Prospectus in any jurisdiction where action for that purpose is required.

## **II. FORWARD-LOOKING STATEMENTS**

This Prospectus contains certain forward-looking statements. A forward-looking statement is a statement that does not relate to historical facts and events. Forward-looking statements are based on analyses or forecasts of future results and estimates of amounts not yet determinable or foreseeable. These forward-looking statements are identified by the use of terms and phrases such as "anticipate", "believe", "could", "estimate", "expect", "intend", "may", "plan", "predict", "project", "will" and similar terms and phrases, including references and assumptions. This applies, in particular, to statements in this Prospectus containing information on future earnings capacity, plans and expectations regarding the Issuer's business and management, its growth and profitability and general economic and regulatory conditions and other factors that affect the Issuer.

Forward-looking statements in this Prospectus are based on current estimates and assumptions that the Issuer makes to the best of its present knowledge. These forward-looking statements are subject to risks, uncertainties and other factors that could cause actual results, including the Issuer's financial condition and results of operations, to differ materially from and be worse than results that have expressly or implicitly been assumed or described in these forward-looking statements. The Issuer's business is also subject to a number of risks and uncertainties that could cause a forward-looking statement in this Prospectus to become inaccurate. Accordingly, investors are strongly advised to read the following sections of this Prospectus: "RISK FACTORS" and "SANTHERA AND ITS BUSINESS". These sections include more detailed descriptions of factors that might have an impact on the Issuer's business and the markets in which it operates.

In addition, neither the Issuer nor any of the Lead Managers assumes any obligation, except as required by law, to update any forward-looking statement or to conform any forward-looking statement to actual events or developments.

### **III. TABLE OF CONTENTS**

<b>I.</b>	<b>SELLING RESTRICTIONS.....</b>	<b>2</b>
<b>II.</b>	<b>FORWARD-LOOKING STATEMENTS.....</b>	<b>4</b>
<b>III.</b>	<b>TABLE OF CONTENTS .....</b>	<b>5</b>
<b>IV.</b>	<b>RISK FACTORS.....</b>	<b>6</b>
<b>V.</b>	<b>TERMS OF THE BONDS .....</b>	<b>26</b>
<b>VI.</b>	<b>SANTHERA AND ITS BUSINESS .....</b>	<b>45</b>
<b>VII.</b>	<b>INFORMATION ON THE ISSUER.....</b>	<b>55</b>
<b>VIII.</b>	<b>INFORMATION ON THE ISSUER'S SHARE CAPITAL AND THE SHARES .....</b>	<b>58</b>
<b>IX.</b>	<b>DESCRIPTION OF THE OFFERING AND GENERAL INFORMATION .....</b>	<b>63</b>
<b>X.</b>	<b>SWISS TAXATION .....</b>	<b>66</b>
<b>XI.</b>	<b>ANNEXES .....</b>	<b>69</b>

## IV. RISK FACTORS

*In addition to other information contained in this Prospectus, prospective Bondholders should consider carefully the risks related to any investment in the Bonds before purchasing or subscribing for the Bonds, including the risks described below. The risks described below are not the only ones applicable to the Issuer and/or its subsidiaries, i.e., the companies in which the Issuer directly or indirectly holds a majority share or other form of controlling interest (such companies together with the Issuer the **Group, Santhera, we or us**). Additional risks not presently known or currently deemed immaterial may also impair the Group's business, results of operations, financial condition or prospects. The realization of one or more of these risks individually or together with other circumstances may have a material adverse effect on the Group's business, results of operations, financial condition or prospects. In addition, each of the risks set out below could adversely affect the trading price of the Bonds or the Shares and Santhera's ability to perform its obligations under the Bonds, including its ability to repay the Bonds upon maturity.*

*The order in which the risks are presented below is not intended to indicate the probability of their occurrence or the materiality of the risk.*

*For a cautionary note on the forward-looking statements that this and other sections of this Prospectus contain please refer Section II ("FORWARD-LOOKING STATEMENTS") of this Prospectus.*

*Investment decisions should not be made solely on the basis of this Prospectus, as such information cannot serve as a substitute for individual advice and information which is tailored to the requirements, objectives, experience, knowledge and circumstances of each prospective investor individually. Only prospective investors who are fully aware of the risks associated with the investment in the Bonds and who are financially able to bear any losses that may arise should consider engaging in transactions of this type.*

*Capitalized terms used but not defined herein have the meanings ascribed to them elsewhere in this Prospectus.*

### A. Risks related to our business and financial situation

#### 1. Risks related to our financial position and capital needs

***We are an early stage company and have only one marketed product, Raxone® in Leber's hereditary optic neuropathy (LHON), which constitutes a relatively small business opportunity. We have incurred significant losses since our inception and expect to incur substantial losses and negative operating cash flows for the foreseeable future and may never achieve or maintain profitability.***

We are an early stage pharmaceutical company. With the exception of Raxone®, which has received marketing authorization in the European Union (the **EU**) in September 2015 for the treatment of Leber's hereditary optic neuropathy (**LHON**) and whose market is small, we have no products approved for commercial sale. We have incurred consistently negative cash flows and significant losses since our inception, including a net loss of CHF 7.95 million in 2014 (restated figure), of CHF 21.16 million in 2015 (excluding the effect of a reversal of an impairment), and an expected net loss of CHF 33 to 38 million in 2016 (see press release on preliminary key financial figures for 2016 in Annex C of this Prospectus).

We expect to continue to incur significant operating losses for the foreseeable future, as we continue our research, development and commercialization efforts and make investments. We anticipate that our expenses will increase substantially over the coming years. To become and remain profitable, we must successfully complete the development of our product candidates, obtain marketing authorizations and pricing and reimbursement approvals for them, expand our product pipeline, maintain and manage our manufacturing arrangements with third parties, maintain and build up an effective internal sales and marketing organization, establish and maintain sales and marketing arrangements with third parties and raise sufficient funds to finance our activities. We may never succeed in these activities, and even if we do, we may never generate revenue that is significant enough to achieve profitability.

***We may need to obtain substantial additional funding for purposes of our continuing operations and capital expenditures and to meet our obligations under the Bonds. We may not be able to redeem the Bonds or to pay interest thereon when due. Future financing may not be available and may significantly dilute our shareholders (in the case of equity or equity-linked financing) and/or restrict our flexibility to operate or meet the obligations under the Bonds (in the case of debt financing).***

Our available cash position, together with our cash flow (if any) from our operations, may not be sufficient to fund our anticipated capital expenditures and working capital requirements up to profitability or to meet our obligations under the Bonds, including redemption and interest payments. Based on our current cash projections, we believe that (a) our currently available cash position (without the anticipated net proceeds from the Offering) will be sufficient to fund our operations and meet our obligations under the Bonds until the second quarter of 2018 and (b) our currently available cash position together with the anticipated net proceeds from the Offering may, but will not necessarily, be sufficient to fund our operations and meet our obligations under the Bonds until we are cash-flow positive. We have based these estimates on assumptions that may prove to be wrong, and we could use our capital resources sooner or for other purposes than we currently expect. Also, there is no assurance that our board of directors will continue to pursue our existing strategy and financial planning (see risk factor "*The composition of our board of directors is expected to significantly change in April 2017, and there is no assurance that our future board will pursue the same strategy as our existing board.*" in Section IV.A.6 for more information).

We may need to obtain substantial additional funds during the term of the Bonds in order to continue our operations and to become able to redeem the Bonds. Adequate additional financing may not be available to us on acceptable terms, or at all. If we fail to obtain additional funds on acceptable terms when needed, we may have to delay, reduce or terminate our development programs or the production and commercialization of our product, and we may not be able to redeem the Bonds or pay interest thereon when due. If we are unable to redeem the Bonds or otherwise suffer financial distress, the Shares into which Bondholders may convert the Bonds may not have a significant value, either.

If we raise additional equity or equity-linked instruments, which we may consider in the future, such issuance could significantly dilute our shareholders' participation. If we raise additional debt, we may become bound by restrictive covenants or security obligations that limit our flexibility in conducting future business activities, such as incurring additional debt or acquiring or licensing intellectual property rights. In addition, additional debt may limit our potential to redeem the Bonds upon maturity even more.

***If we are unable to maintain an asset value covering our liabilities, including the Bonds, we will be required to file for bankruptcy or insolvency, even long before maturity of the Bonds.***

If we are unable to use the proceeds of the Bonds in such a way as to result in assets (e.g., resulting from retained profits, if any) of same or higher value, the amount of assets covering our liabilities, including those in relation to the Bonds, will decrease. As a result, our equity may become negative, in which case we may be required to file for bankruptcy or insolvency if we are unable to restructure our balance sheet and/or raise further equity. This may occur even long before the maturity of the Bonds.

***Our only marketed product, Raxone® in LHON, will not allow us to become profitable and our future profitability, if any, will largely depend on us being able to obtain marketing authorization and pricing and reimbursement approvals for Raxone® in Duchenne muscular dystrophy (DMD) and potentially in other indications.***

In 2016, Raxone® in LHON, our only marketed product, has generated revenue of CHF 19 million. Even if Raxone® in LHON reaches its estimated peak sales potential, this product alone will not allow us to become profitable. If Raxone® in LHON remains our only marketed product in the future, we will not be able to recover our research, development and commercialization costs and may eventually have to shut down our operations.

Our future success and profitability (if any) will largely depend on our ability to obtain marketing authorization and pricing and reimbursement approvals for our late-stage product candidate, Raxone® in Duchenne



muscular dystrophy (**DMD**), in the EU and the United States (the **U.S.**). We have filed marketing authorization applications for Raxone® in patients with DMD who do not take concomitant steroids in the EU and Switzerland. We have not sought marketing authorization for Raxone® in patients who take concomitant steroids anywhere, and our phase III clinical trial (SIDEROS) for this subgroup of patients is still ongoing with uncertain outcome. We have not filed a New Drug Application (**NDA**) for Raxone® in DMD in the U.S., and it is currently not clear whether a NDA filing for DMD based on currently available data would be possible. Irrespective of the outcome of the SIDEROS trial, we may not be able to obtain marketing authorization for Raxone® in DMD in the U.S., the EU or elsewhere at all or on acceptable terms, and even if we do, our revenues will continue to depend on our ability to also grow sales of Raxone® in LHON.

If we are unsuccessful or significantly delayed in the development of Raxone® in DMD and its subsequent commercialization, or in the commercialization of Raxone® in LHON, we would be forced to rely on the further development of our early stage product candidates, Raxone® in primary progressive multiple sclerosis (**PPMS**) (currently in phase I/II) and omigapil in congenital muscular dystrophy (**CMD**) (currently in phase I). Given the uncertainties around the development and commercialization of pharmaceuticals, we may not be able to develop and commercialize any such products at all or timely enough to sustain our financing.

***News on our development and commercialization efforts that we expect to receive during the coming weeks or months and in the longer term may have a significant and potentially adverse effect on the value of the Group and, as a consequence, the market price of the Shares and the Bonds.***

The value of the Group strongly depends on the results of our clinical trials and on the decisions by regulatory authorities. We expect to receive material new information on such matters in the coming weeks or months and in the longer term. In particular, we expect an opinion from the European Medicines Agency's (**EMA**) Committee for Medicinal Products for Human Use (**CHMP**) on our marketing authorization application for Raxone® in certain DMD patients in the first or second quarter of 2017, and we expect the results of our phase III clinical trial of Raxone® in DMD patients who use concomitant steroids (SIDEROS) in the second half of 2019 and, potentially, interim results before that time. We also expect results of our early stage clinical trials in other indications in 2017 and 2018. Such news or its delay may have a significant adverse effect on the value of the Group and adversely affect its business and prospects. As a consequence, the market price of the Shares and the Bonds is expected to be volatile. Should any such news be unfavorable, the market price of the Shares and the Bonds may significantly decline and, potentially, not recover.

## **2. Risks related to the discovery and development of our product candidates**

***We focus our research and development efforts on compounds that target the function of the mitochondria, and our future success depends on the success of this therapeutic approach.***

We focus our therapeutic product research and development efforts on compounds that target the function of the mitochondria. This therapeutic area has only recently become the focus of research and clinical experts and there is limited experience with regulators on approvable trial designs and endpoints. Future exposure to competitive activities by companies (potentially significantly larger and with more resources than Santhera) is currently unclear and could constitute a significant business risk. Any failures or setbacks in the development of pharmaceuticals acting on mitochondrial function that we or other companies may experience could have a detrimental impact on our product pipeline or the prospects of our product candidates and could require us to redesign all of our current clinical research programs or to abandon our current research and development focus altogether. In addition, risks may arise due to limitations to identify other potential product candidates.

***We rely on only two compounds in our development and commercialization efforts. Any factor that may adversely affect our lead compound, idebenone (the active ingredient of Raxone®), may affect our marketed product and our most important product candidates at once.***

Our product, Raxone® in LHON, our late-stage product candidate, Raxone® in DMD, and our phase I/II product candidate, Raxone® in PPMS, are all based on our sole lead compound, idebenone. We additionally explore omigapil, and our only clinical program that is based on this compound is at an early clinical stage (phase I). Future product candidates may be based on either of these two compounds. Any factor that may adversely affect idebenone's effects on the human body, its manufacture, supply, distribution or marketing, the intellectual property or market exclusivity associated with it, or any intervention of regulators in relation to it, could affect our marketed product and our most important product candidates at once.

***Our product candidates must prove their efficacy and safety in rigorous clinical testing. Drug development involves a lengthy and expensive process, with an uncertain outcome. Failure may occur at any stage of clinical development.***

Before we may seek marketing authorization for any product candidate, we must conduct extensive clinical trials to demonstrate the safety and efficacy in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to its outcome. A failure of one or more clinical trials can occur at any stage of testing. Promising results in preclinical studies of a product candidate may not be predictive of similar results in humans during clinical trials, and successful results from early clinical trials may not be replicated in later and larger clinical trials or in clinical trials for different indications. For example, the results of our phase III clinical trial (DELOS) of Raxone® in certain DMD patients are not predictive of the results of our ongoing phase III clinical trial (SIDEROS) of Raxone® in a different DMD patient population; the results of our phase I/II trial of Raxone® in patients with PPMS (called IPPoMS) are not predictable and not predictive of the outcome of any future clinical trials, and our preclinical studies of omigapil as a potential treatment for CMD are not predictive of positive clinical results.

***The conduct of clinical trials may be prevented, delayed, or even futile, and delays in the commencement, enrollment or completion of clinical trials could result in increased costs, or prevent us from commercializing our product candidates on a timely basis, or at all.***

Before a clinical trial may begin, we must obtain approval from the competent regulatory authority. We may not obtain authorization for further testing of our product candidates. Clinical trials of our product candidates may not be conducted as planned, and commencement, enrollment or completion may not occur on schedule, if at all, for many reasons, which could result in increased costs to us. We have experienced delays of clinical trials and cost overruns in the past and may do so in the future. If we are not able to successfully complete clinical trials, we will not be able to seek marketing approval and will not be able to commercialize our product candidates.

***If we or our partners experience delays or difficulties in the enrollment of patients in clinical trials, the conduct and completion of clinical trials may be delayed or prevented.***

Initiation and successful and timely completion of clinical trials requires us to enroll a sufficient number of eligible patients in these trials. Given our focus on orphan drugs, our clinical trials look to enroll patients with characteristics that are found in a small population and are likely to compete with other clinical trials with the same patient characteristics. As the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in these clinical trial sites. As some of the substances used in our trials are available over the internet and other unapproved sources, patients may be reluctant to enroll or the study results may be adversely affected by parallel use of such substances by patients in the placebo arm of the trial.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our clinical trials, which could prevent their completion. We are, for example, in the process of enrolling patients for a phase III clinical trial for Raxone® in certain DMD patients (called SIDEROS). Enrollment is still in early stage and based on our current estimates, we expect that the results of the SIDEROS trial will become

available in the second half of 2019. Should there be any further delays in patient recruitment or if we are unable to recruit enough patients, this trial (and, consequently, the availability of any data) could be significantly delayed or even prevented.

***We may not be successful in our efforts to build up our pipeline of product candidates or to spend our limited resources on the most promising product candidates.***

While our research and development efforts to date have resulted in one marketed product and three product candidates, we may not be able to identify and develop these or further product candidates that are safe and effective despite spending substantial technical, financial, and personnel resources thereon. We may spend our limited resources on the wrong or less successful product candidates and thereby fail to capitalize on more promising product candidates. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive and achieve marketing approval and achieve market acceptance.

***We rely and will in the future have to rely on third parties to conduct clinical trials for our product candidates, and if they do not properly and successfully perform their obligations, we may not be able to successfully complete the respective development of our product candidates.***

We rely on Clinical Research Organizations (**CROs**) and other third parties to assist in managing, monitoring and otherwise carrying out clinical trials for our product candidates. Together with the salaries paid to our employees in the development department, the fees and expenses of these CROs make up most of our development expenses. We compete with many other companies for the resources of these third parties. These third parties generally may terminate their engagements at any time.

If the quality or accuracy of the data that these third parties obtain is compromised due to their failure to adhere to clinical trial protocols or to regulatory requirements, or if they otherwise fail to comply with clinical trial protocols or meet expected deadlines, the clinical trials of our product candidates may not meet regulatory requirements. If clinical trials do not meet regulatory requirements or if these third parties need to be replaced for any reason, the development of our product candidates may be delayed, may be more expensive than planned or may ultimately fail. For instance, we terminated our relationship with a CRO for cause in 2016 and we had to switch to another CRO to complete the clinical trial conducted by the former CRO.

Although we extensively rely on third parties to conduct our development work, we remain responsible for ensuring that the respective clinical trials are conducted in accordance with their general investigational plan, protocol, legal and regulatory requirements and scientific standards. Any shortcoming in meeting responsibilities may expose us to financial and regulatory risks and could have a material adverse effect on our business, results of operations, financial conditions or prospects.

***We may not be successful in maintaining existing or establishing and maintaining additional collaborations.***

The clinical development of omigapil in the phase I trial (CALLISTO) is being conducted in collaboration with the National Institute of Neurological Disease and Strokes (**NINDS**), an institute within the National Institutes of Health (**NIH**) in the U.S., and was previously supported by a public-private partnership (see Section VI.F.2.b for further information). Likewise, the development of Raxone® in PPMS relies on the collaboration with the NINDS. We may not be able to maintain these or any future collaborations or partnerships for reasons beyond our control. In the event of termination of a collaboration, we may be unable to progress the relevant product candidates on our own or may be unable to successfully find a replacement of our previous collaboration partner. Also, any termination of a collaboration by our respective partner could make it difficult for us to attract new strategic partners or adversely affect how we are perceived in scientific and financial communities.

We face significant competition in seeking partners for future development collaborations. We have to convince potential partners of the attractiveness and economic value of our product candidates and of the proposed collaboration. The negotiation process is time-consuming and complex. Even if we successfully establish new collaborations, their terms may not be favorable to us.

If we fail to establish or maintain a collaboration related to a particular product candidate, we will bear all of the related development cost and risk and we may be unable to develop that product candidate on our own.

***If serious adverse events or undesirable or unacceptable side effects are identified during the development of our product candidates or after commercialization of our product or any future products, we may need to abandon the development of some of our product candidates or withdraw the respective product from the market.***

If our product candidates are associated with undesirable or unacceptable side effects in clinical trials or have characteristics that are unexpected, we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which such side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Serious procedure- or treatment-related side effects may occur at any stage of development and even after the commercialization of a product and may require us to abandon or limit the development of some of our product candidates or to withdraw the respective product from the market.

### **3. Risks related to marketing approval of our product candidates and legal compliance matters**

***Following clinical development, our product candidates will require marketing authorization. If we are not able to obtain marketing authorization at all, in a timely manner or on acceptable terms for our product candidates at all or as planned, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.***

Our product candidates require marketing authorizations by the U.S. Food & Drug Administration (the **FDA**), by the EMA in the EU and by comparable regulatory authorities in other relevant jurisdictions (such as Swissmedic in Switzerland), prior to commercialization. The process of obtaining marketing authorizations is expensive and takes many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Failure to obtain marketing authorization for a product candidate will prevent us from commercializing the product candidate. So far, we have received only one marketing authorization, namely from the EMA for Raxone® in LHON, and filed two further marketing authorization applications, namely with the EMA and Swissmedic for Raxone® in certain DMD patients. Thus, our experience in filing and supporting the applications necessary to gain marketing authorizations is limited. For example, we have never filed a NDA with, or obtained marketing authorization from, the FDA in the U.S., which is a significant pharmaceutical market. We have started (but may fail) to build up in-house capacities in the view of obtaining marketing authorization for Raxone® in DMD in the U.S., and we will in any case have to rely on external advisors for the marketing authorization process in the U.S.

Regulatory authorities have substantial discretion in the timing and substance of the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. They may also limit the circle of potential patients or require extensive warnings, thereby limiting the potential market for the product. For example, it is possible that the FDA may not consider the SIDEROS trial of Raxone® in DMD or any additional studies that it may request, if performed and completed, sufficient to approve any NDA that we submit. If any of these outcomes occur, we may be forced to abandon our planned NDA for Raxone® in certain DMD patients.

If we or our advisors and partners experience delays in obtaining or fail to obtain marketing authorizations for our product candidates, their commercial prospects may be harmed or eliminated. As a result, our ability to generate revenues will be materially impaired.

***Fast track, breakthrough therapy and similar designations for some of our product candidates may not lead to a faster development or regulatory review or approval process, do not increase the likelihood of receiving marketing authorization and may be revoked.***

We have received fast track designation and rare pediatric disease designation from the FDA for Raxone® in DMD and for omigapil in CMD (see Sections VI.E.3 and VI.F.2.c, respectively, for further information). We may seek fast track or similar designations for Raxone® in PPMS and/or any future product candidates. Further, we have received a designation as Promising Innovative Medicine (PIM) from the UK's Medicines and Healthcare Products Regulatory Agency (the MHRA) for Raxone® in certain DMD patients (see Section VI.E.3 for further information). We may seek designations comparable to breakthrough therapy designations or PIM in other jurisdictions and for other products.

Regulatory authorities typically have broad discretion in granting fast track, break through medicine, PIM and similar designations and may typically rescind or revoke such designations. Even if such designation is granted, such designation is not predictive of future trial results, does not necessarily result in a faster development process, review or marketing approval compared to conventional approval procedures and does not increase the likelihood that a product candidate will receive marketing authorization. Many drugs that have received such designations have failed to obtain marketing authorization. If we fail to obtain such designation or the existing designations are revoked, further development of our product candidates or commercialization of products and thereby our business, results of operations, financial conditions or prospects could be materially adversely affected.

***Our product Raxone® in LHON is, and any product candidate for which we may obtain marketing authorization will be, subject to extensive post-marketing regulatory requirements and could be subject to post-marketing restrictions or withdrawal from the market, and we may be subject to penalties if we or the third parties with which we collaborate fail to comply with regulatory requirements or experience unanticipated problems with our products.***

Raxone® in LHON (our marketed product) is, and any product candidates for which we may receive marketing authorization will be, subject to comprehensive regulation by regulatory authorities. There are requirements regarding the testing, manufacture, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution of pharmaceutical products. For example, we need to submit safety and other post-marketing information and reports, ensure that our contract manufacturers observe current Good Manufacturing Practice (cGMP) requirements and comply with requirements regarding safety monitoring and pharmacovigilance. Regulatory authorities may also impose requirements for expensive post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. For example, under the EMA's marketing authorization "under exceptional circumstances" of Raxone® in LHON, we are required to conduct and are currently conducting additional phase IV clinical trials on the long-term effects and safety of Raxone® in LHON and have to maintain a registry of LHON patients treated with Raxone® (see Section VI.D.5 for further information). Any such requirements may have material adverse effects on our profit and cash flow generated from the respective products, and such additional clinical trials involve the risks associated with any clinical trials, as described elsewhere in this section. Also, later discovery of previously unknown adverse effects or other problems with our products, manufacturers or manufacturing processes and non-compliance with regulatory requirements may have serious consequences for the Group, including withdrawal of a product from the market and sanctions.

***Our relationships with customers and third-party payers and our general business operations are and will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm or diminished earnings, among other things.***

Healthcare providers and third-party payers play a primary role in the recommendation and prescription of Raxone® and any product candidates for which we may obtain marketing authorizations. Our and our current and future distributors' future arrangements with healthcare providers, third-party payers and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we or our distributors market, sell and distribute our products (if approved). Efforts to ensure that business arrangements

with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. If authorities conclude that our or our distributors' business practices do not comply with applicable laws and regulations, we or our employees or distributors may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government-funded healthcare programs such as Medicare and Medicaid, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, or the curtailment or restructuring of our operations.

***If we or our third-party contractors or employees fail to comply with environmental, health and safety laws, we could become subject to civil or criminal penalties, other remedial measures or incur costs that could harm our business.***

We are subject to a variety of environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of biological materials and hazardous materials and wastes. The operations of our third-party manufacturers and suppliers involve the use of hazardous and flammable materials, including chemicals and biological materials, and also produce hazardous waste products. We cannot eliminate the risk of contamination or injury from these materials or wastes. In the event of such contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources. Non-compliance by us or our third-party contractors or employees with environmental, health and safety laws and regulations, or efforts to comply with such laws and regulations, could adversely affect our business, financial condition, results of operations or prospects.

#### **4. Risks related to the commercialization of our product candidates and marketing and sale of our products**

***Our product, Raxone® in LHON, and any of our product candidates (if approved) may fail to achieve the degree of market acceptance by physicians, patients, third-party payers and others in the medical community necessary for commercial success despite having received marketing authorization.***

Raxone® in LHON (our marketed product), and any product candidates for which we may receive marketing authorization, may fail to gain sufficient market acceptance by physicians, patients, third-party payers and others in the medical community despite having received marketing authorization. For example, other novel products may be preferred to ours. If our products do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable.

***Off-label and unlicensed uses of currently available idebenone may adversely affect our revenue from Raxone®.***

Physicians may prescribe available products containing idebenone (the active ingredient of Raxone®) for uses for which they are not approved but which they view as a less expensive treatment or a better alternative. A considerable number of physicians in Europe, and to a lesser degree in the U.S. and other countries, have been prescribing or recommending idebenone to their LHON patients on an off-label basis. The substance is either acquired from internet sources or countries where it is already approved and marketed for other indications. For example, Takeda's Mnesis®, 45mg tablets containing idebenone, is registered in Italy for the treatment of "cognitive-behavioral deficits resulting from cerebral pathologies whether from vascular or degenerative origin" and is used off-label and prescribed as an unlicensed medicine in indications other than the approved one in Italy and in certain other countries. Sweden's Medical Products Agency (MPA) has, in our view, wrongly, granted several licenses for the prescription and reimbursement of Mnesis® for the treatment of LHON. We have initiated a number of court proceedings to challenge these MPA decisions. Any off-label or illegal use of idebenone from inexpensive sources may reduce our potential revenue from Raxone®.

***We have only started to develop our marketing and sales organization, have limited experience in marketing products and do not expect to have significant marketing synergies between our prod-***

***uct and our product candidates (if approved). If we are unable to establish and expand our marketing and sales capabilities or enter into distribution agreements with third parties, we may not be able to generate product revenue.***

We have only started to develop our own marketing, sales and distribution capabilities and have yet to commercialize Raxone® in LHON outside the EU. We have limited experience in marketing products in Europe and have no experience in marketing products in the U.S. and elsewhere. We are marketing Raxone® in LHON in European countries through a small internal sales and marketing force that we have been building up since January 2015 and through the third-party distributor Ewopharma in eleven countries in Eastern Europe and the Baltics. In the U.S., certain pre-launch activities have started, while a full commercialization would only be possible upon receipt of a marketing authorization of Raxone® in DMD.

To the extent that any of our product candidates will be approved, we will need to develop further in-house marketing, sales and distribution capabilities to commercialize such products. This would require significant capital expenditures, management resources and time. At the same time, we may engage additional third-party distributors to perform these services. Any revenue that we receive or may receive from our current or future third-party distributors will depend upon the efforts of such distributors, over which we may have little or no control. We may not be able to develop and expand in-house marketing, sales and distribution capabilities or establish or maintain relationships with third-party collaborators to successfully commercialize Raxone® or any other approved product in key markets. As a consequence, we may not be able to generate product revenue.

As Raxone® and each of our product candidates (if approved) will have different prescriber bases (primarily ophthalmologists in the case of Raxone® in LHON; primarily neurologists in the case of Raxone® in DMD and our early stage product candidates), we expect to have somewhat limited commercial synergies between our products and may have to build separate sales channels for each of our products, which is expensive and may result in low profit margins or a lack of profitability of our products.

***We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do, as well as reducing the price at which we are able to sell our products.***

The development and commercialization of new products is highly competitive. While Raxone® in LHON is to our knowledge the first and only approved treatment for LHON, there are a number of pharmaceutical and biotechnology companies pursuing the development of products for the treatment of the same and other disease indications that we focus on. For overviews of the competitive landscape of our product and product candidates see Sections VI.D.6, VI.E.4, VI.F.1.c and VI.F.2.d. The fact that our lead compound, idebenone (the active ingredient in Raxone®), does not enjoy composition of matter patent protection lowers entry barriers for competitors.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive or are better marketed than Raxone® or any other products that we may develop. Our competitors may obtain marketing authorizations for their products more rapidly than we may, which could result in them establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected by third-party payers seeking to encourage the use of products that are less expensive than ours.

***Should we or our distributors be found to have improperly promoted off-label uses, we may become subject to significant liability.***

Given that our marketed product, Raxone® in LHON, is also a product candidate for several other indications, physicians may prescribe Raxone® to their patients in a manner that is inconsistent with our EU marketing authorization or any future marketing authorizations. If we cannot successfully manage the marketing of our products by restricting off-label promotion or if we or our current or future distributors promote our products beyond their approved indications, we could become subject to enforcement action for off-label promotion and significant liability.

***The insurance coverage and reimbursement status of newly-approved products is uncertain. Failure to obtain or maintain coverage and adequate reimbursement for our product or product candidates (if approved) and price controls could limit our ability to market those products and decrease our ability to generate revenue.***

The availability and extent of coverage and reimbursement by governmental and private third-party payers is essential for most patients to be able to afford expensive treatments. Sales of Raxone® in LHON (our marketed product) and our product candidates (if approved) will depend substantially on the extent to which the costs will be paid by third-party payers. Also, we rely on the efforts of third-party distributor Ewopharma to obtain pricing and reimbursement approvals in eleven countries in Eastern Europe and the Baltics and may enter into similar arrangements with other third parties for other territories, and may have little or no control over the efforts of such third parties.

Seeking third party reimbursement is a time-consuming and expensive process, which typically requires us to provide scientific and clinical support and pharmaco-economic arguments for the use of the respective product to each third-party payer separately. We may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, and third-party payers may nonetheless refuse reimbursement. Also, one third-party payer's decision to provide coverage for a product does not assure that other payers will also provide coverage, and pricing negotiations may continue after reimbursement has been obtained. The sales uptake of Raxone® in LHON in 2016 was somewhat slower than originally expected due to the complex pricing and reimbursement processes in several EU markets and may continue to be slow. Third-party payers in several major EU countries have rejected our requests for pricing and reimbursement and we have been involved in legal proceedings in relation to such decisions. Irrespective of the level of initial pricing, we expect the prices of our current and any future products to erode substantially during any market exclusivity period and even more so thereafter.

If reimbursement is not available or only to limited levels, we may not succeed in commercializing a product even if marketing authorization has been obtained. Even if coverage is provided, the approved reimbursement amount may not allow us to realize a sufficient return on our investment.

***Recently enacted and future healthcare reform legislation involves a high degree of uncertainty and may adversely affect our business.***

We operate in a highly regulated industry. New laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could materially adversely affect our business, results of operations, financial condition or prospects. In the United States and other jurisdictions, there have been a number of legislative and regulatory changes, proposed changes and statements by the new President of the United States regarding the pharmaceutical industry and the healthcare system that could prevent or delay marketing authorization and pricing and reimbursement approvals of our product candidates or make them more expensive, or their terms less attractive, or restrict or regulate post-approval activities. All of these enacted or future measures may prevent us from generating revenue, attain profitability, commercialize or market our products.

***Pharmacies have been compounding idebenone. Future compounding may adversely affect our revenue.***

Compounding (also called pharmacy or magistral preparation) is a practice in which a licensed pharmacist prepares medicines in a pharmacy by combining, mixing, or altering pharmaceutical ingredients. Under certain conditions, the sale of compounded idebenone is legal. In the EU, such compounding exemption is based on Article 3 of the EU Directive 2001/83. We are aware that some pharmacies in Germany and the Netherlands have advertised compounded idebenone (the active ingredient of Raxone®) on the internet at considerably lower prices for the treatment of LHON, DMD and other indications, sometimes making reference to our clinical studies. In addition, we are aware of the case of a LHON patient in Austria whose third-party payer decided to reimburse the costs of compounded idebenone, but not of Raxone®. The respective patient has challenged this decision in court. Usually, such compounding in the respective country



and for the respective indication is illegal where there is an authorized product on the market. However, such compounding may continue and may reduce our revenue from Raxone®.

***Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of our product or any product candidates (if approved).***

We face an inherent risk of product liability exposure related to the sale of Raxone® in LHON (our marketed product) or any product candidate (if approved) or to the use of product candidates in clinical trials. Even after approval, a drug may fail or produce side effects. If we cannot successfully defend ourselves against claims that our products or product candidates caused injuries, we may incur substantial liabilities.

We currently have product liability insurance for Raxone® and our product candidates. However, our current product liability coverage may not be adequate in scope to protect us in the event of a successful product liability claim. Further, we may not be able to maintain our current insurance or obtain general product liability insurance on reasonable terms and at acceptable cost, and our insurance may in any event provide insufficient coverage against potential liabilities. As a result, we may have to bear substantial uninsured losses.

## **5. Risks related to market exclusivity rights and intellectual property**

***Our business model relies on orphan drug exclusivity for our product, Raxone® in LHON, and our current or future clinical product candidates. Orphan drug designation can be difficult to obtain and maintain, and in any event, orphan drug exclusivity provides only limited protection from competition, all of which could limit the potential profitability of our product and product candidates.***

It is our strategy to develop and commercialize product candidates in indications qualifying for orphan drug designation in order to obtain marketing exclusivity. Orphan drug designations are available in some jurisdictions, including the U.S. and the EU, for drugs with relatively small patient populations. Generally, if a product candidate with an orphan drug designation in a particular indication subsequently receives the first marketing authorization, then the product is entitled to a period of marketing exclusivity, *i.e.*, no other marketing authorizations will be granted for the same drug for the same indication during the exclusivity period. The applicable period is 7 years in the U.S. and 10 years in the EU (to be reduced to 6 years if a drug no longer meets the criteria or is sufficiently profitable). Orphan drug exclusivity may be lost if the respective regulatory authority determines that the request for designation was materially defective, if the manufacturer is unable to assure sufficient quantity of the drug to meet patient needs, or for other reasons.

To date, we have obtained orphan drug designations (a) for our product, Raxone® in LHON, in the EU (maximum duration until fall 2025) and the U.S.; (b) for our product candidate Raxone® in DMD, in the EU, the U.S. and Australia; and (c) for our product candidate omigapil in CMD, in the EU and the U.S.

Obtaining an orphan drug designation can be difficult, and we may not be successful in obtaining or maintaining orphan drug designations for our product or any of our product candidates. Further, orphan drug designation may be obtained for the same product in the same indication by several parties, and only the first such party to obtain marketing approval will receive marketing exclusivity for the relevant product in the relevant indication. Consequently, if a third party were to obtain orphan drug status and marketing exclusivity for any of the products in an indication targeted by us, we would be excluded from marketing such product in such indication during the applicable exclusivity period.

If we lose orphan drug designation or fail to maintain that designation for the duration of the applicable exclusivity period in relation to our product or any of our product candidates, we may be unable to make sufficient sales of such product or product candidate (if approved) to recover our development costs.

***Our product, Raxone® in LHON, is not patent protected and we can, if at all, only seek limited patent protection for our product candidates. Even granted patents may not be enforceable, and we may be subject to ownership disputes over patents or other intellectual property.***

As the composition of matter patent for our lead compound, idebenone (the active agent of Raxone®) has expired, we can only seek methods of use patent protection, as in the case of our use patent applications for DMD. Typically, method of use patents are considered to be less strong than composition of matter patents. They do not prevent a third party from using, applying or manufacturing the same compound for other applications and may not prevent a third party from finding a way to circumvent that patent. For these reasons, a third party may under certain conditions be able to use idebenone in different or comparable formulas, applications or indications.

Raxone® in LHON (our marketed product) enjoys no patent protection. For the use of Raxone® in DMD, Santhera has been granted use patent protection until March 2027 in the EU and Japan and until December 2027 in the U.S. Further, the use of Raxone® in PPMS is protected by a U.S. patent held by the NIH and exclusively licensed to us, and the use of omigapil in CMD is protected by U.S., EU and Canadian patents until 2027 (in the U.S.) and 2026 (EU and Canada), respectively. We may not be able to rely on patent protection for any of our future product candidates. Even granted patents may not be enforceable, as they may reflect prior art, a patent application by a third party may have a priority right, or for other reasons. Without extensive patent protection, we only rely upon orphan drug designation for a limited time period, which may be revoked or not granted and has other limitations (see risk factor "*Our business model relies on orphan drug exclusivity for our product, Raxone® in LHON, and our current or future clinical product candidates. Orphan drug designation can be difficult to obtain and maintain, and in any event, orphan drug exclusivity provides only limited protection from competition, all of which could limit the potential profitability of our product and product candidates.*" above). As a result of our inability to obtain or any loss of patent protection, we may be unable to prevent competitors from entering the market with a product that is similar to or the same as our product candidates or product. Further, we may be subject to ownership disputes over patents or other intellectual property with former employees, collaborators or other third parties.

***We have in-licensed our early stage product candidates and other intellectual property from third parties. We could lose our rights to use the licensed intellectual property in the event of termination of or dispute relating to the respective license or if such intellectual property is unenforceable for any reason.***

We have in-licensed omigapil for CMD from Novartis and idebenone in PPMS from the NIH (see Section VI.G.1 for further information). We are generally subject to the same risks with respect to protection of intellectual property that we license as we are for intellectual property that we own. If we or our licensors fail to prosecute, maintain and enforce such intellectual property or if such intellectual property is unenforceable or if a licensor would enter bankruptcy or similar distressed status, we could lose our rights to use such intellectual property or our exclusivity with respect to those rights. The same may be the case if the agreements by which we have in-licensed intellectual property are terminated or if a dispute arises in relation to them. As a result, our ability to develop and commercialize the affected product candidates may be adversely affected and we may not be able to prevent competitors from making, using, and selling competing products.

***Third-party claims of intellectual property infringement or misappropriation may prevent or delay our development and commercialization efforts.***

There is a substantial amount of litigation involving patent and other intellectual property rights in the pharmaceutical and biotechnology industries, including patent infringement lawsuits, interferences, oppositions and *inter partes* reexamination proceedings before the government patent offices. Numerous patents and pending patent applications owned by third parties exist in the fields in which we are active. Third parties may assert that we infringe their intellectual property, and patent applications covering our technology or our product candidates could have been filed by others without our knowledge. We may also face a claim of misappropriation if a third party believes that we inappropriately obtained and used trade secrets of such third party. Parties making claims against us may obtain injunctive relief that could effectively prevent us

from further developing or commercializing our product candidates or marketing our product. Defending against claims of patent infringement or misappropriation of trade secrets could be costly and time-consuming, regardless of the outcome. In the event of a successful claim of infringement, we may have to pay substantial damages, pay royalties and incur other significant costs.

During the course of any patent or other intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our technology, product candidates and products, development programs or intellectual property could be diminished.

***We enjoy only limited geographical protection with respect to orphan drug designations and patents and may face difficulties in certain jurisdictions, which may diminish the value of intellectual property rights in those jurisdictions.***

We have not filed for orphan drug designation or patent protection in all national and regional jurisdictions where such protection may be available. In addition, we may decide to abandon national and regional patent applications before grant or to no longer seek orphan drug designation. Finally, the grant proceeding of each patent or orphan drug designation in each jurisdiction is an independent proceeding, and applications might in some jurisdictions be refused, while granted in others. Depending on the jurisdiction, the scope of patent protection or an orphan drug designation may vary for the same drug candidate or technology.

Many countries have compulsory licensing laws under which an owner of exclusivity rights may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of exclusivity rights against government agencies or government contractors. In these countries, the owner of exclusivity rights may have limited remedies, which could materially diminish the value of such exclusivity rights. If we are, or any of our licensors is, forced to grant a license to third parties with respect to any exclusivity rights relevant to our business, our competitive position may be impaired and our business and results of operations may be adversely affected.

***If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.***

We rely on trade secrets, including proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our technology and development processes that involve proprietary know-how, information or technology that is not covered by patents. In addition, we rely on our employees, advisors, third party contractors, consultants, collaboration partners as well as on CROs to develop and manufacture our product and product candidates, which is why we must, at times, share our intellectual property and trade secrets with them.

Trade secrets can be difficult to protect and our competitors may gain access to our trade secrets through legal or illegal means. We cannot be certain that our arrangements to protect trade secrets will be effective and we may not have adequate remedies against misappropriation of trade secrets. Misappropriation, unauthorized disclosure or a competitor's discovery of our trade secrets could materially impair our competitive position or our business.

***We may become involved in lawsuits to protect or enforce our patents and other exclusivity rights, which could be expensive, time-consuming, and unsuccessful.***

Competitors may infringe our intellectual property, the intellectual property of our licensors, or the orphan drug designations that we have achieved. To counter or defend against such claims can be expensive and time-consuming. In an infringement proceeding, a court may decide that a patent owned or in-licensed by us is invalid or unenforceable and/or may refuse to stop the other party from using the technology at issue. An adverse result in any litigation over exclusivity rights could put one or more of our or our licensors' patents at risk of being invalidated or interpreted narrowly or an orphan drug designation of being revoked.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation in many jurisdictions, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our business, financial condition, results of operation or prospects.

**6. Risks related to manufacturing, employment matters, operations, managing growth, corporate structure and financial reporting**

***We have no manufacturing capabilities or capacity of our own and rely on third parties for production of Raxone® and our secondary compound, omigapil. Our dependence on these third parties has the potential to adversely affect our business, results of operations or financial condition.***

We have no manufacturing capabilities or capacity of our own and have outsourced the entire manufacture, formulation, packaging, storage and distribution of Raxone® and our secondary compound, omigapil, to third parties. We currently have no plans to build up or acquire manufacturing capacity and the related know-how of our own. For the production of Raxone®, we rely on a drug substance supplier, with whom we have agreed on a seven-year exclusivity period (subject to exceptions) starting with the first launch of Raxone® in Europe and the U.S., respectively. We currently have one finished drug product supplier, and evaluations to have a second finished drug product supplier are ongoing. If any of our manufacturing agreements is terminated, we may not be able to timely negotiate a new agreement with our current or any other third-party providers, or on acceptable terms, and switching a supplier of the drug substance or the finished drug product is expensive and time-consuming.

The facilities used by our suppliers to manufacture Raxone® (or any future products) are subject to approval and inspections by regulatory authorities. We do not have full control over a supplier's quality control or compliance with laws, regulations or cGMP standards, and any non-compliance could result in sanctions being imposed also on us, including fines, injunctions, civil penalties, delays, suspension, withdrawal or non-grant of market of approvals, seizures or recalls of products, operating restrictions and criminal prosecutions.

***The compounds we use are complex and difficult to manufacture. Only a handful of manufacturers are able to manufacture these compounds, and our manufacturers may experience production problems.***

The manufacturing of our compounds necessitates compliance with regulatory requirements, such as cGMP, and is complex, time-consuming and expensive. Only a handful of manufacturers are able to manufacture idebenone in compliance with all requirements. Manufacturing idebenone involves heavy metal catalysts, the incomplete removal of which in the manufacturing process would result in toxic amounts of these impurities remaining in the drug substance, and non-cGMP synthesis of idebenone may result in other toxic or cancerogenic by-products. Problems with the manufacturing process, even minor deviations from the normal process, could result in contamination, product defects or manufacturing failures that could result in lot failures, product recalls, product liability claims, or insufficient inventory. Regulatory authorities may require us to submit samples of any lot or may require that we do not distribute a lot until the agency authorizes its release. Our contract manufacturers may be unable to achieve adequate quantities and quality of clinical-grade materials, and their supply chain could be interrupted from time to time. Any such problems could materially harm our business, financial condition, results of operations, and prospects.

***The composition of our board of directors is expected to significantly change in April 2017, and there is no assurance that our future board will pursue the same strategy as our existing board.***

Our board of directors (the **Board**) has nominated Elmar Schnee, Philipp Gutzwiller, Patrick Vink (who has been advising the Board since 2016) and Thomas Meier (our Chief Executive Officer (the **CEO**)) for election to the Board at our Annual General Meeting scheduled to be held on April 4, 2017 (see below Section VII.D.1 for more information). Subject to his election to the Board, our CEO is expected to be appointed Delegate of the Board. It is the exclusive responsibility of our Board to, among other things, define our

strategy (including relating to our business, financing and operations), organization and major policies. If the proposed Board members are elected by the Annual General Meeting, there can be no assurance that in the new composition, our Board will continue to pursue our existing strategy and continue our business as currently conducted.

***If we lose the services of any member of the top management or other key members of our management, scientific or commercial staff or if we fail to attract and retain key scientific or other personnel, we may be unable to successfully develop and commercialize our product candidates or market our current product or future products.***

We are highly dependent on the performance and expertise of members of our top management, especially our CEO, whose responsibilities include those of a Chief Scientific Officer, and other key members of our management, scientific and commercial staff. We are a small company with many key functions being carried out by one person only. The loss of the services of any of our key personnel for any reason or our inability to attract new highly qualified and experienced employees could have a material adverse effect on our business, financial condition, results of operations and prospects. Furthermore, we do not currently maintain "key person" insurance for any of our executives or other employees.

Focused experience and know-how in neuromuscular and mitochondrial diseases and the product and product candidates developed by us are rare. To foster retention, we have established employee participation plans, but there is intense competition for skilled personnel. If our product candidates are granted marketing authorizations or if we expand our development activities, we would need to hire additional personnel, which may be difficult to recruit and retain on acceptable terms.

***We will need to grow the size and capabilities of our organization, and we may experience difficulties in managing this growth.***

As of December 31, 2016, we had 80 employees (74.4 full-time equivalent) and we expect our headcount to increase significantly in the near future. Our future financial performance will depend, in part, on our ability to effectively manage any future growth. We will need to expand and effectively manage our organization, personnel, operations and facilities in order to successfully develop and commercialize our product and product candidates. We will only be able to organize operations efficiently and avoid a misallocation of resources if we continue to improve our operational, financial and management controls, reporting systems and procedures. Our management may have to divert a disproportionate amount of its attention away from day-to-day activities in order to manage these growth activities. If we are unable to effectively expand our organization, we may not achieve our development and commercialization goals and our operational efficiency may be materially adversely affected.

***Our and our partners' computer systems may fail or suffer security breaches, which could result in a material disruption of our product development programs.***

Despite the implementation of security measures, our computer systems and those of our current and any future suppliers, CROs and other contractors, consultants and collaborators are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our business operations, whether due to a loss of our trade secrets or other disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in data loss or inappropriate disclosure of confidential or proprietary information or personal data of patients or other persons, our business, results of operations, financial condition or prospects could be materially adversely affected.

## **7. Risks related to general economic and financial market conditions**

***Changes in the macro-economic environment and political developments in Europe, the United States and elsewhere may have a material adverse effect on the Group and may reduce the value of the Bonds.***

Over the past years, there has been a series of political and economic events such as the past global economic financial crisis, sovereign debt and financial crises in several EU countries, the decision of voters in the United Kingdom to leave the EU (commonly known as "Brexit"), the presidential election in the U.S. of 2016 and the conflict in Syria. These events have impacted the global economy at large, the economies and financial situation of governments in many of our current and potential future markets, as well as exchange rates (in particular the euro/Swiss franc rate) and have been associated with, among other things, instability of financial institutions, high market volatility, liquidity problems, limited availability of financing and legal uncertainty. Recession or rising inflation and other effects may also be a consequence of these events. This uncertain macro-economic environment may have a material adverse effect on our business, results of operations, financial condition, prospects, or the market price of our securities. Further, rising inflation may reduce the real value and yield rate of the Bonds, and the fact that inflation has been very low or negative over the past years does not indicate that inflation will continue to be low or negative during the term of the Bonds.

***We are exposed to currency fluctuation risks and other financial risks.***

While we incur costs mainly in Swiss francs, a significant proportion of our costs have to be paid in euros. To the limited extent we have revenue, we receive payments mainly in euros. If and as our business grows, we expect that a significant part of our revenues and a significant part of our expenses will be denominated in euros. Our reporting currency is the Swiss franc and, as a result, financial line items are converted into Swiss francs at applicable foreign exchange rates. Further, we are subject to interest rate risks. Unfavorable developments in the value of the Swiss franc as compared to the euro, in interest rates and in the capital markets could have a material adverse effect on our financial condition and results. For a discussion of our foreign exchange rate, interest rate, credit and liquidity risks please also refer to pages 46 and 47 of our Annual Report 2015 (Annex A of this Prospectus).

## **B. Risks related to the Bonds and the Offering**

***The Bonds are unsecured, structurally subordinated and subordinated to secured indebtedness.***

The Bonds are unsecured and rank equally in right of payment with all of the Issuer's existing and future unsecured, non-privileged indebtedness. The Issuer is the holding company of the Group. In the event of bankruptcy of one or more of the Issuer's subsidiaries, the respective subsidiaries' creditors have preference over the Issuer. Moreover, to the extent that the Issuer pledges or provides security over any of its assets, the respective pledgees or security holders have priority over the other creditors, including the Bondholders, with respect to the distribution of enforcement proceeds.

***The Issuer may redeem the Bonds early under certain circumstances and Bondholders may be exposed to reinvestment risk.***

The Issuer may redeem all, but not only some of the outstanding Bonds at their Principal Amount, together with unpaid accrued interest, if any, at any time after the second anniversary of the Payment Date if the average VWAP of a Share over a certain period of time has been at least 160% of the prevailing Conversion Price, as set out in more detail in Condition 5(b) of the Terms of the Bonds in Section V. During any period when the Issuer may elect to redeem the Bonds, the market value of the relevant Bonds generally is not expected to rise substantially above the price at which they can be redeemed. This may also be the case prior to such period. In the event of an early redemption of the Bonds, Bondholders may be exposed to risks connected to the reinvestment of the proceeds received upon early redemption and may incur additional transaction costs as a consequence of reinvesting such proceeds.

***The Issuer may be unable to redeem the Bonds.***

Upon maturity of the Bonds, in the event of a delisting of the Shares or in other situations, the Bondholders may require the Issuer to redeem all of the outstanding Bonds (see Conditions 5(a), 5(c) 7(d) and 9 of the Terms of the Bonds in Section V). If such an event were to occur, or at maturity of the Bonds, no assurance can be given that the Issuer will have sufficient funds or would be able to arrange financing to pay the redemption amount for all Bonds that are to be redeemed. The Issuer's ability to redeem the Bonds in such event may be limited by law or the terms of other debt instruments. Also, the Issuer may be required to refinance its debt in order to make such payments. See also risk factor "*We may need to obtain substantial additional funding for purposes of our continuing operations and capital expenditures and to meet our obligations under the Bonds. We may not be able to redeem the Bonds or to pay interest thereon when due. Future financing may not be available and may significantly dilute our shareholders (in the case of equity or equity-linked financing) and/or restrict our flexibility to operate or meet the obligations under the Bonds (in the case of debt financing).*" in Section IV.A.1 above.

***There is no assurance that the escrow in relation to interest payments for the first three years of the term of the Bonds will constitute a complete security or secure payment of interest in case of financial distress of the Issuer or the escrow agent.***

While an amount corresponding to the interest payable on the Bonds for the first three years of their term will be put into escrow, to be used for such interest payments (see Section IX.E for more information), there is no assurance that such escrow will constitute a complete security or secure payment of interest in case of financial distress of the Issuer or the escrow agent. Bondholders will not have a direct claim against the escrow agent in relation to such amounts in escrow.

***The Issuer and/or other member of the Group can incur additional debt.***

The Terms of the Bonds (Section V) do not limit the amount of additional indebtedness that the Issuer and/or its subsidiaries can create, incur, assume or guarantee. We may create, incur, assume or guarantee additional indebtedness and such debt may be privileged over the Bonds.

***Bondholders' anti-dilution protection is limited.***

The Conversion Price at which the Bonds may be converted into Shares will be adjusted only in the situations and to the extent provided in the Terms of the Bonds (see, e.g., Condition 7 of the Terms of the Bonds in Section V). There is no requirement that there must be an adjustment for every corporate or other event that may affect the value of the Conversion Rights. Events in respect of which no adjustment must be made may adversely affect the value of the Conversion Rights and the Bonds.

***The possibility of a reset of the Conversion Price affords limited protection against a falling Share price.***

If the average daily VWAP of the Shares during a specified period (the **Reset Period**) prior to the Reset Date (i.e., 12 months after the Payment Date) is lower than the Reference Share Price, the Conversion Price at which the Bonds may be converted into Shares will be adjusted downwards, but not to a level below 75% of the Conversion Price prevailing at the Payment Date (see Condition 6(a)(v) of the Terms of the Bonds in Section V). There is no assurance that the conditions for such reset will be fulfilled. In particular, no such reset will occur if the Shares trade below the Reference Share Price prior to or after the Reset Period, or if the Shares do not trade below the Reference Share Price during the Reset Period. Further, even if such reset occurs, the Conversion Price will not be adjusted to a level below 75% of the Conversion Price, and Bondholders who chose to convert the Bonds before the Reset Date will in any event not be able to benefit from the lower Conversion Price (if any). Also, the market price of the Shares prior to, during or after the Reset Period may be adversely affected by the possibility or occurrence of such reset, respectively, or arbitrage in view of that, and our shareholders would face additional dilution as a result of a downward adjustment of the Conversion Price.

***Upon conversion of the Bonds, Bondholders may be subject to additional expenses or taxes.***

Upon conversion of a Bond, expenses, taxes, stamp, issue, registration, documentary, transfer and other duties may be due by the Bondholders.

***Bondholders have no shareholder rights prior to exercising their Conversion Rights.***

An investor in the Bonds is not a shareholder of the Issuer. No Bondholder (in his capacity as such) has any right to participate in shareholders' meetings, any voting rights, rights to receive dividends or other distributions or any other rights with respect to the Shares unless such Bondholder has exercised his or her Conversion Right and has been recorded in the share register of the Issuer as a shareholder with voting rights in relation to the Shares received upon conversion.

***We have broad discretion in the use of the net proceeds from this Offering and may not use them effectively.***

The management of the Group will have broad discretion in the allocation and use of the net proceeds of this Offering. A failure by us to allocate or use these funds effectively, or to invest them appropriately before they are used, could harm our business. Further, our ultimate use of the net proceeds from this Offering may vary substantially from their currently intended use.

***An active and liquid trading market for the Bonds may not develop.***

The Bonds are a new issue of securities for which there is no established trading market. Application has been made for listing of the Bonds on the SIX Swiss Exchange. However, an active and liquid trading market for the Bonds may not develop. Even if such trading market will develop, it may not provide enough liquidity to allow a Bondholder to trade or sell the Bonds easily, or the Bonds may trade at unfavorable prices. Such trading market may also fail to continue throughout the term of the Bonds. Neither the Issuer nor any of the Lead Managers is under an obligation to provide a bid or offer price for the Bonds. Therefore, Bondholders may not be able to sell the Bonds easily at prices reasonably acceptable to them, or at all, and potential investors should only invest in the Bonds if they can hold them until their Maturity Date.

***The market price of the Bonds may be volatile.***

Bond markets have from time to time experienced substantial price and volume fluctuations. These broad market fluctuations, as well as fluctuations in the market price of the Shares (see also risk factor "*The market price of the Shares has been and is expected to be volatile.*" in Section IV.C), on which the market price of the Bonds is expected to partly depend, may lead to a drop in the market price of the Bonds. The price at which the Bonds will trade will depend upon many factors within and outside of our control. Bondholders may have to sell their Bonds at a substantial discount from the original purchase price and may lose some or all of their initial investment.

***Neither the Issuer nor the Bonds have a credit rating. Even if a credit rating agency were to rate the Bonds, such rating may not reflect all risks.***

The Issuer does not have a credit rating and the Bonds are not expected to be rated. Even if a credit rating agency were to assign a credit rating to the Bonds, such rating may not reflect all risk factors that may affect the value of the Bonds. Further, a credit rating is not a recommendation to buy, sell or hold securities and may be revised, suspended or withdrawn at any time. Such actual or anticipated revision, suspension or withdrawal may adversely affect our financing costs or the market price and trading of the Bonds.

***Bondholders may be exposed to exchange rate risks.***

The settlement currency of the Bonds may not be the currency of the home jurisdiction of an investor. In this case, such Bondholder will be exposed to an exchange rate risk between the settlement currency and the Bondholder's home currency. Exchange rate fluctuations between a Bondholder's home currency and the settlement currency may adversely affect Bondholders who intend to convert proceeds from the sale



of the Bonds into their home currency. As a result, such Bondholders may lose some or all of their initial investment.

***Purchasing Bonds on credit may significantly increase the risk of a loss.***

If a loan was used to finance a Bondholder's acquisition of the Bonds and subsequently an event of default occurs with respect to the Issuer, or if the market price of the Bonds diminishes significantly, such Bondholder may not only face a potential loss on his or her investment, but will also have to repay the loan and pay any interest thereon. Accordingly, any such loan may significantly increase the risk of a loss. Potential investors should not assume that they will be able to repay any such loan or pay any interest thereon from the return on the Bonds.

***A majority or supermajority of Bondholders could modify the Terms and Conditions of the Bonds (Section V) on behalf of all Bondholders.***

Articles 1157 et seq. CO contain provisions for calling meetings of Bondholders to consider matters affecting their interests generally, including, without limitation, modifications of the Terms of the Bonds set out in Section V. These provisions permit defined majorities to bind all Bondholders including Bondholders who did not attend and vote at the relevant meeting and Bondholders who voted in a manner contrary to the majority.

**C. Risks related to the Shares**

***The market price of the Shares has been and is expected to be volatile.***

The market price of the Shares into which the Bonds are convertible has historically been and is expected to be subject to substantial fluctuations depending upon many factors, including the risk factors listed in this Prospectus, but also the price and volume fluctuations affecting securities markets in general. As a result, the Shares may trade at prices significantly below their market price at the date of this Prospectus and the market price of the Bonds, which is expected to partly depend on the market price of the Shares, may fluctuate likewise. The market price of the Shares may not reach or exceed the Conversion Price.

***The trading market for the Shares is not liquid and shareholders may not trade or sell their Shares easily or at all.***

The volume of the trading market for the Shares on the SIX Swiss Exchange has been low and is expected to be low in the future. Therefore, the trading market may not provide enough liquidity to allow shareholders (including Bondholders who have converted their Bonds) to trade or sell their Shares easily or at all. The Issuer is not obliged to provide a bid or offer price for the Shares. Further, the Issuer's market making arrangement with Kepler Cheuvreux SA may be terminated at any time, and even while this arrangement is in place, there is no assurance that shareholders will be able to trade or sell their shares easily or at all.

***Future sales of a substantial number of Shares or derivative instruments by us or our investors could negatively affect the market price of the Shares or the Bonds.***

The Issuer has agreed that, without the prior written consent of the Lead Managers and subject to customary exceptions, it will not, for a period ending 90 calendar days after the Issue Date, sell Shares in the public market or effect certain other transactions in the Shares or related to the Shares (see Section IX.G for more details). Future issues or sales of a substantial number of Shares at any time following the expiry of such lock-up period, as well as any sales of a substantial number of shares by one or more of the Issuer's significant shareholders (none of whom is bound by any lock-up undertakings in connection with the Offering) at any time, could negatively affect the market price of the Shares and, consequently, the market price of the Bonds.

***The Issuer does not expect to pay dividends in the foreseeable future.***

Since its inception, the Issuer has never paid any dividends and it does not anticipate paying dividends in the foreseeable future. Investors cannot rely on dividend income from the Shares that they may receive upon conversion of the Bonds, and any returns on an investment in the Shares will likely depend entirely upon any future appreciation in the price of the Shares.

***If securities or industry analysts do not publish research or publish inaccurate research or unfavorable research about the Group's business, the market price and trading volume of the Shares could decline.***

The trading market for the Shares depends in part on the research and reports that securities or industry analysts publish about the Group or its business. If no or few securities or industry analysts cover the Issuer, the market price for the Shares would be negatively affected. If one or more of the analysts who cover the Issuer downgrades the Shares, publishes incorrect or unfavorable research about the Group's business, ceases to cover the Issuer or fails to publish reports on it regularly, the market price and/or trading volume of the Shares would likely decline.

***The Issuer may not be able to issue Shares out of its conditional or authorized share capital that it may need to be able to deliver Shares to Bondholders upon conversion.***

As of the date hereof, the Issuer may issue up to 650,000 Shares out of its conditional share capital upon conversion of the Bonds (and in accordance with the Terms of the Bonds set out in Section V). The Issuer plans to propose to its shareholders at its Annual General Meeting, which is scheduled to be held on April 4, 2017 (the **AGM**), to increase such conditional capital in such a way as to cover a conversion in full of all Bonds. Should the shareholders not approve such proposed increase with the requisite majority of two thirds of votes represented at the AGM or should such increase not be registered in the commercial register, the Issuer plans to issue a sufficient number of Shares from its authorized capital to a subsidiary or to itself, such shares to be held as reserved shares (*gebundene Vorratsaktien*) until the Bonds are converted or redeemed. Such issuance is subject to a number of legal and regulatory requirements, including successful registration in the commercial register. The issuance of Shares by the Issuer out of its authorized capital may be blocked by the registrar or any shareholder or third party, which may prevent or delay such Share issuance.

***Our articles of association provide for an opting out of the mandatory tender offer rules. As a result, our shareholders would not have the possibility to sell their Shares in the event that a shareholder or group of shareholders acquires more than 33 1/3% of the voting rights in the Issuer. Also, the minimum price rules would not be applicable in any voluntary public tender offer for Shares in the Issuer.***

Our articles of association exempt shareholders from the mandatory tender offer rules under the Federal Act on Financial Market Infrastructures and Market Conduct in Securities and Derivatives Trading of June 19, 2015 (the **FMIA**) and its predecessor. As a result, any shareholder or group of shareholders exceeding the threshold of 33 1/3% of the voting rights (whether exercisable or not) of the Issuer would not be required to make a mandatory public tender offer for all Shares. Accordingly, our shareholders would not have the possibility to sell their Shares in the event that a shareholder or group of shareholders obtains control of the Issuer. Also, voluntary public tender offers may be made at less than the minimum price under the mandatory tender offer rules (*i.e.*, the higher of the pre-offer 60-day volume weighted average price and the highest price paid by the offeror for equity securities within the last 12 months) even if the offeror would, as a result, hold more than 33 1/3% of the voting rights in the Issuer.

## V. TERMS OF THE BONDS

The terms and conditions (each a "**Condition**", and together the "**Terms of the Bonds**") of the 5.00 per cent senior unsecured convertible bonds due 2022 (the "**Bonds**" and each a "**Bond**"), conferring a conversion right with reference to registered shares of Santhera Pharmaceuticals Holding AG, Hammerstrasse 49, 4410 Liestal, Switzerland (the "**Issuer**") in the aggregate principal amount of Swiss Francs ("**CHF**") 60 million, are established pursuant to a Bond Purchase Agreement (the "**Agreement**") among the Issuer on the first part and Bank am Bellevue AG, Seestrasse 16, 8700 Küsnacht, Switzerland ("**BaB**") and Kepler Cheuvreux S.A., 112 avenue Kléber, 75784 Paris Cedex 16, France ("**Kepler**", and together with BaB the "**Joint Bookrunners**") on the second part.

The Terms of the Bonds govern the rights and obligations of the Issuer and of each holder of Bonds (a "**Bondholder**", collectively the "**Bondholders**") in relation to the Bonds and are as follows (defined terms used herein have the meaning ascribed to them in Condition 18):

### 1. Denomination, Form and Delivery of the Bonds

- (a) The aggregate principal amount of the Bonds of CHF 60 million is divided into 12,000 Bonds with denominations of CHF 5,000 (five thousand) each (the "**Principal Amount**").
- (b) The Bonds and all rights in connection therewith are issued in uncertificated form in accordance with article 973c of the Swiss Code of Obligations of 30 March 1911, as amended (the "**CO**") as uncertificated securities (*Wertrechte*) that will be created by the Issuer by means of a registration in its register of uncertificated securities (*Wertrechtbuch*). Such uncertificated securities (*Wertrechte*) will then be entered into the main register (*Hauptregister*) of SIX SIS Ltd ("**SIS**") or any other intermediary in Switzerland recognized for such purposes by the Relevant Exchange (SIS or any such other intermediary, the "**Intermediary**"). Once the uncertificated securities (*Wertrechte*) are registered in the main register (*Hauptregister*) of the Intermediary and entered into the accounts of one or more participants of the Intermediary, the Bonds will constitute intermediated securities (*Bucheffekten*) (the "**Intermediated Securities**") in accordance with the provisions of the Swiss Intermediated Securities Act of 3 October 2008, as amended (*Bucheffektengesetz*) (the "**FISA**").
- (c) So long as the Bonds are in the form of Intermediated Securities, the Bonds may only be transferred or otherwise disposed of in accordance with the provisions of the FISA.
- (d) The records of the Intermediary will determine the number of Bonds held through each participant of the Intermediary. In respect of Bonds held in the form of Intermediated Securities, the Bondholders will be the persons holding the Bonds in a securities account (*Effektenkonto*) which is in their own name or, in the case of intermediaries (*Verwahrungsstellen*), the intermediaries holding the Bonds for their own account in a securities account (*Effektenkonto*) which is in their name.
- (e) The conversion of the uncertificated securities (*Wertrechte*) into a permanent global certificate (*Globalurkunde auf Dauer*) or individually certificated bonds (*Wertpapiere*) is excluded. Neither the Issuer nor the Bondholders nor BaB as paying and conversion agent (the "**Paying and Conversion Agent**") nor any third party shall at any time have the right to effect or demand the conversion of the uncertificated securities (*Wertrechte*) into, or the delivery of a permanent global certificate (*Globalurkunde auf Dauer*) or individually certificated securities (*Wertpapiere*).

### 2. Interest

The Bonds bear interest from (but excluding) the Payment Date at the rate of 5.00 per cent per annum of their Principal Amount, payable semi-annually in arrears on each Interest Amount Payment Date (the CHF amount in respect of each Bond so calculated being the "**Interest Amount**"). Interest on the Bonds is computed on a 30E/360 basis, i.e., on the basis of a year consisting of twelve (12) months of thirty (30) days each.

Each Bond will cease to bear interest (i) when the Conversion Right with respect to such Bond shall have been exercised by the respective Bondholder thereof pursuant to Condition 3, from the Interest Amount

Payment Date (or, if none, the Payment Date) immediately preceding the Conversion Date, or (ii) in all other circumstances from the due date for redemption or repayment of such Bond, provided that if, upon due presentation, delivery of the Shares or payment of any amount due is improperly withheld or refused, such Bond shall continue to bear interest as provided in these Terms of the Bonds. In such case, interest will accumulate until the day on which all Shares and/or all sums due in respect of such Bonds are received by the Paying and Conversion Agent on behalf of the relevant Bondholder.

### 3. Conversion

#### (a) Conversion Right, Conversion Ratio and Conversion Price

- (i) Each Bond in the Principal Amount of CHF 5,000 (five thousand Swiss Francs) will be convertible on any Business Day during the Conversion Period into Shares at the Conversion Ratio.
- (ii) The Conversion Ratio will be determined by dividing CHF 5,000 (five thousand), the Principal Amount, by the Conversion Price prevailing on the Conversion Date. The number of Shares to be delivered upon conversion of one Bond shall be calculated to five decimal places, provided that if more than one Bond is converted at any one time by the same Holder, the number of Shares to be delivered upon conversion will be determined by dividing the aggregate Principal Amount of the Bonds converted by the same Bondholder at any one time by the Conversion Price prevailing at the Conversion Date, such number of Shares to be calculated to five decimal places.
- (iii) Fractions of Shares will not be issued and delivered on conversion. Instead, cash payments in CHF based on the VWAP of a Share on the Relevant Exchange on the Trading Day immediately preceding the relevant Conversion Date will be made in respect thereof (the "**Cash Payment for Fractions**"), except where any individual entitlement would be less than CHF 10.00 (ten), in which case, no such payment shall be required to be made. If the resulting amount of CHF is not an integral multiple of CHF 0.01 (one hundredth of a Swiss Franc), it shall be rounded to the nearest whole or multiple of CHF 0.01 (one hundredth of a Swiss Franc) with 0.005 being rounded upwards.
- (iv) A Conversion Right may not be exercised following the giving of a default notice by the Bondholder Representative pursuant to Condition 9 nor in respect of a Bond which has been redeemed pursuant to Conditions 5, 7(d) or 9.
- (v) Where a Conversion Right is exercised during a Change of Control Period, the provisions in Condition 7(c) shall apply.

#### (b) Conversion Procedures

##### (i) Conversion Notices

To exercise the right to convert all or any of its Bonds pursuant to this Condition 3, a Bondholder must deposit with the Paying and Conversion Agent at its own expense during the Conversion Period a duly completed notice of conversion (the "**Conversion Notice**") in a form satisfactory to the Paying and Conversion Agent together with clearing instructions in a form satisfactory to the Paying and Conversion Agent allowing for the transfer of the relevant Bond(s) through the Intermediary to the Paying and Conversion Agent at the Specified Office.

By depositing the Conversion Notice, a Bondholder is deemed to represent and warrant that (x) it understands that the Shares to be transferred upon conversion of the Bonds have not been and will not be registered under the U.S. Securities Act of 1933 (the "**Securities Act**") and (y) it is not a U.S. person (as defined in Regulation S under the Securities Act ("**Regulation S**")) and is located outside the United States within the meaning of Regulation S, is acquiring the Shares to be transferred upon conversion of the Bonds in an offshore transaction (as defined in Regulation S) in accordance with Rule 903 or 904 of Regulation S and understands that the Shares may not be delivered within the United States upon conversion

of the Bonds and may not be resold in the United States except pursuant to an exemption from the registration requirements of the Securities Act.

A Conversion Notice, once duly completed and deposited as aforesaid, shall be irrevocable. Bonds duly presented and/or transferred for conversion shall be cancelled in their entirety by the Paying and Conversion Agent and, upon delivery of the relevant Shares and the payment of the Cash Payment for Fractions, if any, shall be considered redeemed.

The Conversion Right shall be exercised only in respect of the whole of the Principal Amount of a Bond.

A Conversion Notice shall be deemed to be presented on a Business Day if received in a form satisfactory to the Paying and Conversion Agent before 4.00 p.m. CET on that Business Day at the Specified Office. Any Conversion Notice presented after 4.00 p.m. CET will be deemed to have been received on the following Business Day.

The conversion date in respect of a Bond (the "**Conversion Date**") shall be the date on which a Conversion Notice has been received or deemed to have been received in accordance with this Condition 3(b)(i).

(ii) Delivery of Shares and Cash Payments for Fractions

The Shares to be delivered upon conversion of Bonds in accordance with this Condition 3, if any, will be Shares issued from the conditional capital or reserved Shares to be issued from authorised capital of the Issuer with the same entitlements as the other outstanding Shares, except that the Shares so delivered will not be entitled to any dividend or other distribution declared, paid or made by reference to a Record Date prior to the relevant Conversion Date and except that the voting rights may not be exercised unless the person designated in the Conversion Notice as recipient of the Shares is registered as the holder of the Shares with voting rights in the Issuer's share register.

The Issuer will (x) effect delivery of the Shares and (y) make Cash Payments for Fractions, if any, (i) within five (5) Business Days after the Conversion Date if the Conversion Right was exercised in a Change of Control Period or following the giving of a notice in accordance with Condition 5(b), and (ii) within ten (10) Business Days after the Conversion Date in all other cases, in each case through the Intermediary in accordance with directions given by the relevant Bondholder in the relevant Conversion Notice. At the time of such delivery of the Shares, the then valid share registration rules of the Issuer will apply; the Issuer does not offer any assurance or guarantee that the exercising Bondholder will be accepted as a shareholder with voting rights in its share register.

(iii) Taxes and other Costs

Any Swiss Federal Stamp Duty, if due, as well as the fee of the Relevant Exchange, if any, payable upon the delivery in Switzerland of Shares to the Bondholder upon the conversion of Bonds will be paid or reimbursed by the Issuer. The Issuer will, however, not pay (a) any tax payable in connection with any subsequent sale or transfer of Shares by the respective Bondholder, or (b) any tax or other cost payable in connection with the sale, transfer or delivery of Share(s) in or to a country other than Switzerland.

#### 4. Payments

The amounts required for the payment of the Interest Amounts (after deduction of the then applicable Swiss withholding tax) and the Principal Amount and any other payments in cash to be made under these Terms of the Bonds will be made available in good time in freely disposable CHF, which will be placed at the free disposal of the Paying and Conversion Agent in Switzerland. If the due date for any payment by the Issuer does not fall on a Business Day, the Issuer undertakes to effect payment for value the Business

Day immediately following such due date and Bondholders will not be entitled to any additional sum in relation thereto.

Upon receipt of the funds in Switzerland, the Paying and Conversion Agent will arrange for payment to the Bondholders.

The Issuer undertakes that payments shall be made in freely disposable CHF without collection cost to the Bondholders, and, unless otherwise provided for by applicable law, without any restrictions and whatever the circumstances may be, irrespective of nationality, residence or domicile of the Bondholders and without requiring any affidavit or the fulfilment of any other formality.

The receipt by the Paying and Conversion Agent of funds in CHF in Switzerland from the Issuer shall release the Issuer from its obligations under the Bonds to the extent of the amounts received by the Paying and Conversion Agent.

## 5. Redemption and Purchase

### (a) Repayment at Maturity Date

Unless previously converted, redeemed, or purchased and cancelled as provided below, the Issuer undertakes to repay the Bonds on the Maturity Date, without further notice, at the Principal Amount together with unpaid accrued interest to such date (such repayment of any Bond on the Maturity Date, as well as any early redemption in accordance with this Condition 5, with Condition 7 or with Condition 9, in these Terms of the Bonds being referred to as the "**Redemption**").

### (b) Early Redemption at the Option of the Issuer

Subject to not less than thirty (30) nor more than sixty (60) calendar days' prior notice, the Issuer may redeem all but not only some of the Bonds outstanding at the Principal Amount (together with unpaid accrued interest, if any):

- (i) at any time after the Payment Date and prior to the Maturity Date, if less than fifteen (15) per cent of the aggregate Principal Amount of the Bonds issued pursuant to the Terms of the Bonds are outstanding at the time of the notice; or
- (ii) at any time after the day of the second (2<sup>nd</sup>) anniversary of the Payment Date, if the VWAP of a Share on the Relevant Exchange on each of at least twenty (20) out of thirty (30) consecutive Trading Days ending not earlier than five (5) Trading Days prior to the date the relevant notice of Redemption is given has been at least 160 per cent of the Conversion Price in effect on each such Trading Day, respectively.

### (c) Early Redemption at the Option of the Bondholders in Case of Delisting of Shares

If the Shares are delisted from the Relevant Exchange without being listed on another Relevant Exchange, each Bondholder may, acting in accordance with this Condition 5(c), require the Issuer to redeem all or any of the Bonds held by such Bondholder at their Principal Amount (together with unpaid accrued interest) at the Relevant Put Date.

At the latest on the date the Shares are delisted from the Relevant Exchange, the Issuer shall give notice of that fact (the "**Notice of Delisting**").

To exercise its right pursuant to this paragraph c), the Bondholder must deposit at its own expense a duly completed and signed notice (a "**Put Notice**") in a form satisfactory to the Paying and Conversion Agent during the period starting on the date of the Notice of Delisting and ending sixty (60) calendar days thereafter. A Put Notice shall be irrevocable.

(d) Purchases

The Issuer and any of its Subsidiaries may at any time purchase Bonds at any price in the open market or otherwise. Any purchase shall be made in accordance with applicable laws or regulations, including applicable stock exchange regulations. Such Bonds may be held, resold or, at the option of the Issuer, surrendered to the Paying and Conversion Agent for cancellation in accordance with Condition 5(e) below.

Any Bonds while held by or on behalf of the Issuer or any of its Subsidiaries, shall not entitle their Bondholder to vote at any meetings of the Bondholders and shall not be deemed to be outstanding for the purposes of calculating quorums at meetings of the Bondholders.

(e) Cancellation

All Bonds which are converted, redeemed, or surrendered, shall forthwith be cancelled. All Bonds which are to be cancelled cannot be reissued or resold.

## 6. Adjustments to the Conversion Price

(a) Events leading to adjustments to the Conversion Price

(i) *Increase of capital by means of capitalization of reserves, profits or premiums by distribution of Shares, or division or consolidation of Shares:*

In the event of a change in the Issuer's share capital as a result of capitalization of reserves, profits or premiums, by means of the distribution of Shares, save for a distribution of Shares as a Dividend as set out in Condition 6(a)(iv) below, and in the event of division or consolidation of Shares, the Conversion Price shall be adjusted by multiplying the Conversion Price in force immediately prior to such change by the result of the following formula:

$$N_{Old}/N_{New}$$

where:

$N_{Old}$  is the number of Shares existing before the change in share capital; and

$N_{New}$  is the number of Shares existing after the change in share capital.

Such adjustment shall become effective on the date on which such Shares are distributed or, in the event of division or consolidation of Shares, on the first day the Shares are traded on the new basis on the Relevant Exchange.

(ii) *Issues of Shares or Other Securities by way of conferring subscription or purchase rights:*

If (a) the Issuer grants to holders of Shares any rights or options, warrants or other rights to subscribe for or acquire Shares, Other Securities or securities convertible or exchangeable into Shares or Other Securities, or (b) any third party with the agreement of the Issuer issues to holders of Shares any rights, options or warrants to purchase any Shares, Other Securities or securities convertible or exchangeable into Shares or Other Securities (the rights referred to in (a) and (b) collectively and individually being the "**Purchase Rights**"), the Conversion Price shall be adjusted by multiplying the Conversion Price in force immediately prior to such issue or grant by the result of the following formula:

$$(P_{cum} - R)/P_{cum}$$

where:

$P_{cum}$  is the Current Market Price by reference to whichever is the later of (x) the date on which the Shares are first traded ex-Purchase Rights on the Relevant Exchange and

(y) the Trading Day when the subscription or purchase price for Shares or Other Securities under the Purchase Right is announced, or, if the day the subscription or purchase price is announced is not a Trading Day, the next following Trading Day; and

R is the value of the Purchase Right(s) relating to one Share or Other Security, such value to be calculated as follows:

(A) in the event the Purchase Rights relate to Shares:

$$R = P_{cum} - TERP$$

where:

$$TERP = (Nold \times P_{cum} + Nnew \times (Prights + Div)) / (Nold + Nnew) \text{ and:}$$

TERP is the theoretical ex-Purchase Rights price; and

Nold is the number of Shares existing before the change in share capital; and

Nnew is the number of offered Shares contemplated to be newly issued; and

Prights is the price at which one new Share can be subscribed, exercised or purchased; and

Div is the amount (in CHF) by which the entitlement to Dividends per existing Share exceeds the entitlement to Dividends per new Share, (x) if Dividends have already been proposed to the general meeting of shareholders but not yet paid, based on the proposed amount of the Dividends, or (y) if Dividends have not yet been proposed, based on the Dividends paid in the immediately preceding financial year;

provided, however, that no such adjustment shall be made if the subscription or purchase price at which one new Share can be subscribed or purchased is at least ninety-five (95) per cent of the Current Market Price on whichever is the later of (x) the date on which the Shares are first traded ex-Purchase Rights on the Relevant Exchange or (y) the Trading Day when the subscription or purchase price for the Purchase Right is announced, or, if the day the subscription or purchase price is announced is not a Trading Day, the next following Trading Day;

(B) in the event the Purchase Rights relate to Other Securities or to securities convertible or exchangeable into Shares or Other Securities and where such Purchase Rights are traded on a regulated stock exchange in Switzerland, the European Union, the United Kingdom, the United States of America, Canada or Japan:

$$R = Nrights \times Prights$$

where:

Nrights is the number of Purchase Rights granted per Share; and



Pright is the VWAP of the Purchase Rights on the Relevant Exchange (or, if no dealing is recorded, the arithmetic mean of the bid and offered prices) during the time Purchase Rights are traded, but not longer than the first ten (10) Trading Days.

- (C) in all other cases where neither of the previous paragraphs (A) or (B) is applicable, R will be determined by a Common Expert.

Such adjustment shall become effective

- i. in the case of Condition 6(a)(ii)(A), on the first day on which the Shares are traded ex-Purchase Rights on the Relevant Exchange;
- ii. in the case of Condition 6(a)(ii)(B), five (5) Trading Days after (x) the end of the period during which the Purchase Rights are traded or (y) the tenth (10<sup>th</sup>) Trading Day of the Purchase Rights, whichever is sooner; and
- iii. in the case of Condition 6(a)(ii)(C), on the date determined by the Common Expert.

(iii) *Spin-offs and capital distributions other than Dividends:*

If, in respect of a spin-off or a capital distribution other than Dividends as referred to in Condition 6(a)(iv) below, the Issuer shall issue or distribute to holders of its Shares any assets, evidence of indebtedness of the Issuer, shares or other rights (other than as referred to in Condition 6(a)(ii) above) (the "**Distribution**"), the Conversion Price shall be adjusted as follows:

- (A) In case the Distribution (x) consists of securities that will be traded on a regulated stock exchange in Switzerland, the European Union, the United Kingdom, the United States of America, Canada or Japan, (y) consists of securities that are traded on a regulated stock exchange in Switzerland, the European Union, the United Kingdom, the United States of America, Canada or Japan or (z) has otherwise a value which is determinable by reference to a stock exchange quotation or otherwise, by multiplying the Conversion Price in force immediately prior to such issue or distribution by the result of the following formula:

$$(P_{cum} - D)/P_{cum}$$

where:

$P_{cum}$  is the Current Market Price by reference to the date on which the Shares are first traded ex-Distribution on the Relevant Exchange following the relevant Distribution; and

- D is equal to (i) in case of iii)(A)(x), the current market price of the Distribution (in CHF) on the Relevant Exchange, calculated on a per Share basis, as determined by the Paying and Conversion Agent, or (ii) in case of iii)(A)(y), the current market price of the Distribution (in CHF) on the Relevant Exchange on the date by reference to which  $P_{cum}$  has been determined, calculated on a per Share basis, as determined by the Paying and Conversion Agent or (iii) case of iii)(A)(z), as determined by a Common Expert,

where for purposes of this provision, the current market price (to determine D) in case of iii)(A)(x) shall be deemed to be the average of the VWAPs on the five (5) consecutive Trading Days commencing on the date on which the Shares are first traded ex-Distribution on the Relevant Exchange, and in case of iii)(A)(y) shall be deemed to be the average of the VWAPs on the five (5) consecutive Trading Days

ending on and including the Trading Day preceding the day on which the Shares are first traded ex-Distribution.

- (B) In all other cases and where there is one (but not more than one) Distribution on a given Trading Day, by multiplying the Conversion Price in force immediately prior to such issue or distribution by the result of the following formula:

$P_{\text{after}}/P_{\text{before}}$

where:

$P_{\text{after}}$  is the current market price per Share after the date of such Distribution (the "**Distribution Date**"); and

$P_{\text{before}}$  is the current market price per Share before the Distribution Date;

whereby for purposes of this provision the current market price per Share shall be deemed to be the average of the VWAPs, (x) in the case of  $P_{\text{before}}$ , on the five (5) consecutive Trading Days before the Distribution Date, and (y) in the case of  $P_{\text{after}}$ , on the five (5) consecutive Trading Days after the Distribution Date, as determined by the Paying and Conversion Agent. When calculating the average of the VWAPs the gross dividend amount (or any other entitlement), if any, of any dividend paid (or any other entitlement) during either of the above mentioned periods of five (5) consecutive Trading Days, shall be added back to the VWAPs on each of the Trading Days on which the Shares are traded ex-dividend (or any other entitlement).

- (C) If the Issuer issues or distributes to its shareholders tradable put options as a Dividend with respect to any financial year, the Conversion Price shall be adjusted according to the formula set out in Condition 6(a)(iv).
- (D) In all cases where there is more than one Distribution on a given Trading Day, the Common Expert will determine the necessary adjustment.

Such adjustment shall become effective, in the case of (A)(y), on the date on which the Distribution is made and, in the case of (A)(x) and (B), on the sixth (6<sup>th</sup>) Trading Day after the Distribution Date and, in the case of (A)(z) and (D) as determined by a Common Expert.

(iv) *Dividends:*

If the Issuer pays a Dividend, the Conversion Price shall be adjusted by multiplying the Conversion Price in force immediately prior to such payment by the following fraction:

$(P_{\text{cum}} - D)/P_{\text{cum}}$

where:

$P_{\text{cum}}$  is the Current Market Price with respect to the Effective Date; and

D is the Dividend attributable to one Share as set out below

Any reference to D in the above formula shall be a reference to

- (A) the cash amount in case of a cash dividend or a repayment of paid-in capital;
- (B) an amount as calculated by the following formula in case of a stock dividend in lieu of a cash dividend:

current market price - (current market price x (N<sub>Old</sub>/N<sub>New</sub>))

where:

current market price is the average of the daily VWAP of one Share on each of the five (5) consecutive Trading Days ending on and including the Trading Day immediately prior to the Ex-Date;

N<sub>Old</sub> is the number of Shares existing before the change in share capital; and

N<sub>New</sub> is the number of Shares existing after the change in share capital;

- (C) an amount as calculated by the following formula in case of tradable put options in lieu of a cash dividend (the "**Put Options**"):

current market price x (P/N)

where:

current market price is the average of the daily VWAP of the Put Option on each of the five (5) consecutive Trading Days commencing on the Ex-Date;

P is the number of Put Options to be issued; and

N is the number of Shares existing prior to the Ex-Date.

Such adjustment shall become effective on the Ex-Date or, in case of Put Options according to (C) above, on the sixth (6<sup>th</sup>) Trading Day following the Ex-Date.

- (v) *Reset of Conversion Price:*

If the average of the daily VWAPs of the Shares during 20 consecutive Trading Days immediately preceding the fifth Trading Day prior to the date that is 12 months after the Payment Date (the "**Reset Date**") is lower than the Reference Share Price, the Conversion Price shall be replaced by the higher of (a) 120% of the average of the daily VWAPs of the Shares during the 20 consecutive Trading Days immediately preceding the fifth Trading Day prior to the Reset Date and (b) 75% of the Conversion Price prevailing at the Payment Date.

Such adjustment shall become effective on the Reset Date.

- (b) Calculation of Adjustments

- (i) Each adjustment to be made pursuant to Condition 6(a) shall be calculated by the Paying and Conversion Agent and shall (in the absence of manifest error) be binding on all parties concerned. The Paying and Conversion Agent shall for the purpose of the foregoing provisions only be liable for making, or not making, adjustments or taking, or not taking, any other measures in connection with these Bonds, if and to the extent that it fails to act with due care according to established market practice. The Paying and Conversion Agent may engage the advice or services of any Common Expert whose advice or services it may consider necessary and rely upon any advice so obtained, and the Paying and Conversion Agent shall incur no liability as against the Issuer or the Bondholders in respect of any action taken, or not taken, or suffered to be taken, or not taken, in accordance with such advice and in exercising due care according to established market practice.

- (ii) If in case of any adjustment the resulting Conversion Price is not an integral multiple of CHF 0.01 (one hundredth of a Swiss Franc), it shall be rounded to the nearest whole or multiple of CHF 0.01 (one hundredth of a Swiss Franc) with 0.005 being rounded upwards.
- (iii) The Issuer will procure that a notice is published in the manner described in Condition 10 as soon as practicable after either the date on which any adjustment to the Conversion Price becomes effective or, if no adjustment is required, the date on which it is possible to determine that such is the case.

(c) Retroactive Adjustments

If the Conversion Date in relation to any Bond is (i) before the relevant Record Date for any issue, sale, grant or offer leading to an adjustment pursuant to Condition 6(a)(ii) before publication of the event leading to such Record Date, and (iii) before the relevant adjustment to the Conversion Price becomes effective under Condition 6(a), and (iv) provided that the Shares will be delivered to the converting Bondholder after the Record Date, the Issuer shall (conditional upon the relevant adjustment becoming effective) procure that there shall be issued or paid to the converting Bondholder such an additional cash amount or number of Shares, if applicable (the "**Additional Consideration**") as, together with the cash amounts to be transferred and the Shares delivered or to be delivered, if any, on conversion of the relevant Bond is equal to the consideration (in form of cash amounts or Shares as set out in Condition 3(a)(ii) and (iii)) which would have been required to be delivered on conversion of such Bond if the relevant adjustment to the Conversion Price had in fact been made and become effective prior to the Conversion Date (the "**Retroactive Adjustment**").

Without prejudice to the provisions of Condition 3, upon a Retroactive Adjustment becoming effective in accordance with this Condition 6(c), the delivery of the relevant Additional Consideration shall be made within ten (10) Business Days after the first date it is possible to calculate such adjustment but not earlier than the Record Date. Without prejudice to the foregoing and to mandatory provisions of applicable law, in the event that an issue, sale, grant or offer leading to an adjustment pursuant to Condition 6(a) is effected between the above Conversion Date and the date of delivery of the relevant Additional Consideration, the Issuer shall request a Common Expert to determine the amount of the further consideration to be made to the converting Bondholder, whether in kind or in cash, so that the Bondholder may be substantially treated as if such Bondholder actually held the Additional Consideration on the Conversion Date.

(d) Events not giving rise to Adjustments

No adjustment to the Conversion Price will be made:

- (i) as a result of any issue or distribution of Shares or Other Securities if the pre-emptive right (*Bezugsrecht*) in respect thereof under the CO has been validly excluded by resolution of the general meeting of shareholders or by the board of directors of the Issuer unless a pre-emptive right in respect thereof is granted indirectly to the shareholders by a third party with the agreement of the Issuer; or
- (ii) as a result of any public issue of bonds convertible or exchangeable into Shares or bonds with options to subscribe for Shares, such issue being in connection with a conditional increase of the share capital of the Issuer, irrespective of whether in respect of such issue the advance subscription rights to acquire such bonds (*Vorwegzeichnungsrecht*) have been excluded or not, unless advance subscription rights have been granted to the shareholders of the Issuer and are traded on the Relevant Exchange; or
- (iii) if Shares or Other Securities (including pre-emptive rights, options, warrants or stock appreciation rights in relation to Shares or Other Securities) are issued, offered or granted to, or for the benefit of, members of the board of directors, officers, employees or advisors of the Issuer or of any of its Subsidiaries or of any associated company or to trustees to be held for the benefit of any such person, in any such case pursuant to any employee share or participation scheme of the Issuer or of any of its Subsidiaries; or

- (iv) if an increase in the Conversion Price would result from such adjustment, except in case of an exchange of the Shares for Other Securities or a consolidation of Shares; or
- (v) if the Conversion Price would fall below the nominal value of a Share. In this case, the Conversion Price will be adjusted to the nominal value of a Share and any remaining reduction of the Conversion Price resulting from such adjustment or from any further adjustment will be carried forward and only be applied if and to the extent the nominal value of a Share will be reduced.

(e) Other Events

If the Issuer determines, after consultation with the Paying and Conversion Agent, or the Paying and Conversion Agent determines after consultation with the Issuer, that notwithstanding Condition 6(a) and Condition 6(d) an adjustment should be made to the Conversion Price as a result of one or more events or circumstances not referred to in Condition 6(a) or circumstances including circumstances listed in Condition 6(d) have arisen which have an adverse effect on the right to convert Bonds and no adjustment to the Conversion Price under Condition 6(a) would otherwise arise or is excluded according to Condition 6(d), the Paying and Conversion Agent shall engage the advice or services of a Common Expert to determine as soon as practicable what adjustment, if any, to the Conversion Price or amendment, if any, to the terms of this Condition 6 is fair and reasonable to take account thereof and the date on which such adjustment should take effect. If several events occur which become effective on the same Trading Day and which would lead to an adjustment of the Conversion Price pursuant to Condition 6(a), the decision as to the manner of calculating the adjustment of the Conversion Price shall be taken by the Common Expert. The decision of the Common Expert shall be binding as set forth in Condition 18.16. The Paying and Conversion Agent shall have no responsibility to make any inquiries as to whether or not any event has occurred which might require an adjustment to the Conversion Price or amendment, if any, to the terms of this Condition 6.

(f) Correction of Adjustments

If an adjustment has been made in accordance with Condition 6(a) based on events or circumstances that subsequently are not implemented or are implemented in a manner materially different than anticipated when calculating the adjustment, then the Issuer and the Paying and Conversion Agent shall determine whether and to what extent the adjustment previously made shall be corrected. The Paying and Conversion Agent may engage the services of a Common Expert to determine whether and to what extent a correction shall be made. The decision of the Common Expert shall be binding. The Paying and Conversion Agent shall have no responsibility to make any inquiries as to whether or not any event has occurred which might require correction of an adjustment to the Conversion Price previously made.

## 7. Change of Control

(a) A "Change of Control" occurs when:

- (i) an offer to acquire Shares, whether expressed as a public takeover offer, a merger or similar scheme with regard to such acquisition, or in any other way, is made in circumstances where (A) such offer is available to (aa) all holders of Shares, (bb) all holders of Shares other than the offeror and any persons acting in concert with such offeror, or (cc) all holders of Shares other than persons who are excluded from the offer by reason of being connected with one or more specific jurisdictions (or a combination of the exceptions pursuant to (bb) and (cc)), and (B) such offer having become or been declared unconditional with respect to acceptances, the Issuer becomes aware that the right to cast more than fifty (50) per cent of all the voting rights (whether exercisable or not) of the Issuer has become or will become vested in the offeror and any persons acting in concert with the offeror; or
- (ii) the Issuer consolidates with or merges into any other company, save where, following such consolidation or merger, shareholders of the Issuer immediately prior to such consolidation

or merger have the right to cast at least fifty (50) per cent of the voting rights (whether exercisable or not) of such other company; or

- (iii) the Issuer becomes aware that the right to cast more than fifty (50) per cent of all voting rights (whether exercisable or not) of the Issuer has become unconditionally vested directly or indirectly in any person (or in persons acting in concert with each other in respect of the exercise of such voting rights); or
  - (iv) the legal or beneficial ownership of all or substantially all of the assets owned directly or indirectly by the Issuer is acquired by one or more other persons (other than Subsidiaries).
- (b) Upon a Change of Control, the Issuer shall give notice of the fact that a Change of Control occurred (the "**Change of Control Notice**") to the Bondholders no later than two (2) Trading Days after the occurrence of a Change of Control in the form set out in Condition 10. The Change of Control Notice shall:
- (i) inform the Bondholders of their right to either require redemption of the Bonds pursuant to Condition 7(d) or, if applicable, exercise their Conversion Rights for a period of forty (40) Trading Days (the "**Change of Control Period**") starting on the Trading Day immediately following the date the Change of Control Notice is given, at the adjusted Conversion Price, as further described in Condition 7(c);
  - (ii) specify the date (the "**Change of Control Redemption Date**"), being not more than sixty (60) and not less than fifty-one (51) Trading Days after the date the Change of Control Notice is given, on which the Bonds may be redeemed at the option of the Bondholders pursuant to Condition 7(d);
  - (iii) if Condition 7(c) applies, specify the Conversion Price in effect immediately prior to the Change of Control and the adjusted Conversion Price applicable as a consequence of the Change of Control; and
  - (iv) provide details concerning the Change of Control.
- (c) Adjustment of Conversion Price upon Change of Control

If a Change of Control occurs, the Conversion Price for Bonds converted on a Conversion Date falling within the Change of Control Period shall be adjusted as follows:

$$CP_a = RP \times (1 + (CP \times (1 - c/t)))$$

where:

CP<sub>a</sub> Adjusted Conversion Price

RP Conversion Price prevailing five (5) calendar days before the Change of Control Notice is published, divided by (1 + CP);

CP Initial conversion premium of 20.0 per cent (expressed as a fraction);

c the number of calendar days from and including the date on which the adjusted Conversion Price is applicable to but excluding the seventh (7<sup>th</sup>) Trading Day prior to the Maturity Date; and

t the number of calendar days from and including the Payment Date to but excluding the seventh (7<sup>th</sup>) Trading Day prior to the Maturity Date.

- (d) Early Redemption at the Option of Bondholders upon Change of Control

Upon the occurrence of a Change of Control, the Issuer will, at the option of a Bondholder, redeem such Bondholders' Bond(s) on the Change of Control Redemption Date at their Principal Amount (together with unpaid accrued interest to such date). To exercise such option, a Bondholder must

present, by not later than ten (10) Trading Days prior to the Change of Control Redemption Date, at the Specified Office a duly completed redemption notice in a form satisfactory to the Paying and Conversion Agent (a "**Change of Control Redemption Notice**"), together with clearing instructions in a form satisfactory to the Paying and Conversion Agent allowing for the transfer of the relevant Bond(s) through the Intermediary to the Paying and Conversion Agent. No Change of Control Redemption Notice so deposited may be withdrawn without the consent of the Issuer.

(e) Conversion after the Change of Control Redemption Date

With respect to the Bonds that remain outstanding after the Change of Control Redemption Date, in the case of a Change of Control as defined in Condition 7(a)(ii) and if the Issuer is not the surviving company, the Issuer shall use its commercially reasonable efforts to ensure that each Bond shall be convertible into such shares or other equity securities, including depositary receipts issued for the same and any other consideration (including cash) which such Bondholder would have received in the Change of Control transaction if such Bondholder had exercised its Conversion Rights immediately prior to the date of the Change of Control Notice (and then participated in the Change of Control transaction).

## 8. Status and Negative Pledge

- (a) The Bonds constitute direct, unconditional, and (subject to Condition 8(b)) unsecured obligations of the Issuer and (subject to Condition 8(b)) rank and will rank *pari passu* among themselves and with all other unsecured and unsubordinated obligations of the Issuer, except for such preferences as are provided for by any mandatorily applicable provision of law.
- (b) So long as any Bonds remain outstanding, the Issuer will not, and will procure that no Material Subsidiary will, create or have outstanding any mortgage, charge, pledge, lien or other form of encumbrance or security interest upon the whole or any part of its business, property, assets or revenues, present or future, to secure any Relevant Debt or to secure any guarantee or indemnity in respect of any Relevant Debt unless, at the same time or prior thereto, the Issuer's obligations under the Bonds (i) are secured equally and rateably therewith by such encumbrance or security interest or benefit from a guarantee or indemnity in substantially identical terms thereto, as the case may be or, (ii) have the benefit of such other security, guarantee, indemnity or other arrangement as shall be approved by the Bondholder Representative in its discretion.

For the purposes of this Condition, "**Relevant Debt**" means (i) any present or future indebtedness of the Issuer and its Subsidiaries represented or evidenced by notes, bonds, debentures or other securities which are for the time being, or are capable of being, quoted, listed or ordinarily dealt with on any stock exchange, over-the-counter-market or other securities market and (ii) any financial debt (including, for the avoidance of doubt, bank debt) of the Issuer and its Subsidiaries at any time outstanding exceeding CHF 10 million in the aggregate, other than (x) financial debt secured through or by receivables, and (y) any debt with a security interest over or affecting any asset or property of any company which becomes a Subsidiary after the Payment Date, where the security interest is created prior to the date on which that company becomes a Subsidiary (and with such security interest being limited to encumbering the assets or property acquired).

## 9. Event of Default

The Paying and Conversion Agent in its capacity as bondholder representative (the "**Bondholder Representative**") has the right but not the obligation, on behalf of the Bondholders, to declare all Bonds to be immediately due and repayable at the Principal Amount (together with unpaid accrued interest to such date), by serving a written notice of default upon the Issuer which shall have that effect, but only in case of the occurrence of any of the following events (each an "**Event of Default**"):

- (a) there is a failure by the Issuer (i) to pay the Interest Amount or the Principal Amount when due, or (ii) to deliver Shares and/or to make Cash Payments for Fractions, if and when due, upon conversion of a Bond; and such failure continues for a period of ten (10) Business Days in case of any payment of cash or ten (10) Trading Days in case of delivery of Shares; or

- (b) a default is made by the Issuer in the performance or observance of any material covenant, condition or provision contained in the Terms of the Bonds which is to be performed or observed on its part, the Paying and Conversion Agent considers such default to be materially prejudicial to the interests of the Bondholders, and such default continues for a period of thirty (30) calendar days following the service by the Paying and Conversion Agent on the Issuer of a notice requiring such default to be remedied; or
- (c) any other present or future indebtedness of the Issuer or of any Material Subsidiary for or in respect of monies borrowed or raised from third parties (i.e., excluding any transactions between the Issuer and one or several of its Subsidiaries or among Subsidiaries) is not paid when due or, as the case may be, within any applicable grace period, or becomes due and payable prior to its stated maturity as a result of an event of default (howsoever described), or any security in respect of any such indebtedness becomes enforceable or any guarantee of, or indemnity in respect of, any such indebtedness given by the Issuer or any Material Subsidiary is not honoured when due and called upon or, as the case may be, within any applicable grace period, provided that no such event shall be taken into account for the purposes of this paragraph c) unless the relative indebtedness, either alone or when aggregated with other indebtedness relative to all, if any, other such events which shall have occurred and be continuing shall at any time have an outstanding nominal value of at least CHF 5,000,000 (or its equivalent in another currency); or
- (d) the Issuer or any Material Subsidiary is (or is deemed by law or a court to be) insolvent or bankrupt or unable to pay its debts, stops or suspends payment of all or a material part of its debts, or proposes or applies for a stay of execution; or
- (e) a postponement of payments (*Stillhaltevereinbarung*), a general assignment or an arrangement or composition with or for the benefit of the relevant creditors in respect of any such debts or a moratorium or postponement of payments is agreed or declared in respect of or affecting all or any part of (or of a particular type of) the debts of the Issuer or any Material Subsidiary; or
- (f) the Issuer or one or more Material Subsidiaries alters its or their legal or commercial structure through bankruptcy, liquidation, or disposal of its or their assets, the Issuer changes the objects of the company or its commercial activities or merges with a third party (other than the Issuer or any of its Subsidiaries) and such merger does not constitute a Change of Control, in so far as the relevant action in each of the above scenarios has or may have a material adverse effect on the capacity of the Issuer to meet its obligations in connection with the Bonds then or in the future, unless in the sole opinion of the Bondholder Representative the situation of the Bondholders as a consequence of the security provided or other steps taken by the Issuer provide adequate protection to the Bondholders; or
- (g) a dissolution or merger involving the Issuer as a result of which the Issuer is not the surviving company, unless the successor company assumes all the Issuer's liabilities.

The Issuer shall inform the Bondholder Representative without delay that any event mentioned under paragraphs a) through g) has occurred and provide the Bondholder Representative with all necessary documents. The Issuer accepts responsibility for the information contained in those documents.

If an Event of Default occurs, the Bondholder Representative has the right but not the obligation to serve a written notice of default upon the Issuer, such notice having the effect that the Bonds shall become immediately due and repayable at the Principal Amount (together with unpaid accrued interest) on the day the default notice is given.

## 10. Notices

All notices to Bondholders regarding the Bonds (the "**Notices**") shall be published by the Paying and Conversion Agent on behalf of, and in accordance with directions by and at the expense of the Issuer in due time in a daily newspaper nationally circulated in Switzerland, expected to be the *Neue Zürcher Zeitung*.

Upon the first Trading Day of the Bonds on the Relevant Exchange and for as long as the Bonds are admitted to trading or listed on the Relevant Exchange, all Notices shall be validly published according to the then applicable rules of the Relevant Exchange, in case of SIX Swiss Exchange currently electronically



on its internet website (currently: [http://www.six-swiss-exchange.com/news/official\\_notices/search\\_en.html](http://www.six-swiss-exchange.com/news/official_notices/search_en.html)), save as otherwise required by law, replacing the publication in a daily newspaper.

## **11. Listing**

The Issuer will use its reasonable efforts to have the Bonds listed on the SIX Swiss Exchange and to maintain such listing until the Maturity Date or in case of an early redemption of the Bonds to the date of the early redemption. The Issuer will use all reasonable efforts to have the Shares listed and to maintain a listing for all the issued Shares on the SIX Swiss Exchange or any other Relevant Exchange.

## **12. Statute of Limitations**

Claims for payment of the Principal Amount and for Cash Payments for Fractions, respectively, cease to be enforceable by legal action in accordance with the applicable Swiss statute of limitations (presently after ten (10) years from their relevant due dates for payment). Claims for payments of Interest Amounts cease to be enforceable by legal action in accordance with the applicable Swiss statute of limitations (presently after five (5) years from their relevant due dates for payment).

## **13. Governing Law and Jurisdiction**

The Bonds and these Terms of the Bonds shall in every respect (including without limitation questions of form, content and interpretation) be subject to and governed by substantive Swiss law.

Any dispute arising out of or in connection with the Bonds or these Terms of the Bonds shall be submitted to the exclusive jurisdiction of the courts of the City of Zurich (Zurich 1), Switzerland.

The Issuer shall be discharged by and to the extent of any payment or delivery of Shares made in respect of any Bonds to a person recognized as a creditor by an enforceable judgement of a Swiss court.

## **14. Amendment to these Terms**

The Terms of the Bonds may be amended from time to time by agreement between the Issuer and the Bondholder Representative, acting on behalf of and with effect for all present and future Bondholders, provided that in the sole opinion of the Bondholder Representative such amendment is of a formal, minor or technical nature, is made to correct a manifest error or is not materially prejudicial to the interests of the Bondholders.

Notice of any such amendment shall be published in accordance with Condition 10 above.

Any such amendment shall be binding on the Issuer and the Bondholders in accordance with its terms.

## **15. Role of BaB and Kepler**

BaB acts as Joint Bookrunner and as Listing Agent, will act as Paying and Conversion Agent of this Bond issue and will or may also act as Bondholder Representative, but only in the cases stated explicitly in these Terms of the Bonds. Kepler acts as Joint Bookrunner. In any other cases, neither BaB nor Kepler is obliged to take or to consider any actions on behalf or for the benefit of the Bondholders.

## **16. Severability**

If at any time any one or more of the provisions of the Terms of the Bonds is or becomes unlawful, invalid, illegal or unenforceable in any respect under any law, the validity, legality and enforceability of the remaining provisions shall not be in any way affected or impaired thereby.

## 17. Further Issues

The Issuer reserves the right to issue from time to time further bonds with identical terms as set out in these Terms of the Bonds without the consent of the Bondholders. In such a case such further issue shall form a single series with the then outstanding Bonds and the term "Bonds" shall comprise such additionally issued Bonds.

## 18. Definitions

- 1     **"Additional Consideration"** has the meaning given to it in Condition 6(c);
- 2     **"Agreement"** has the meaning given to it in the preamble;
- 3     **"BaB"** has the meaning given to it in the preamble;
- 4     **"Bond(s)"** has the meaning given to it in the preamble;
- 5     **"Bondholder(s)"** has the meaning given to it in the preamble;
- 6     **"Bondholder Representative"** has the meaning given to it in Condition 9;
- 7     **"Business Day"** means any day (other than Saturday or Sunday) on which banks in Zurich are open for the whole day for business;
- 8     **"Cash Payment for Fractions"** has the meaning given to it in Condition 3(a)(iii);
- 9     **"Change of Control"** has the meaning given to it in Condition 7(a);
- 10    **"Change of Control Notice"** has the meaning given to it in Condition 7(b);
- 11    **"Change of Control Period"** has the meaning given to it in Condition 7(b)(i);
- 12    **"Change of Control Redemption Date"** has the meaning given to it in Condition 7(b)(ii);
- 13    **"Change of Control Redemption Notice"** has the meaning given to it in Condition 7(d);
- 14    **"CHF"** has the meaning given to it in the preamble;
- 15    **"CO"** has the meaning given to it in Condition 1(b);
- 16    **"Common Expert"** means an independent investment bank of international repute or an independent law firm or accounting firm of international repute or an independent financial advisor with relevant expertise of international repute (an **"Expert"**) selected and instructed by the Issuer and the Paying and Conversion Agent by mutual agreement. If the Issuer and the Paying and Conversion Agent do not mutually agree on an Expert within seven (7) days from the beginning of the appointment process, each of the Issuer and the Paying and Conversion Agent shall select an Expert, whereby the so elected Experts shall select together a third Expert. In case the two selected Experts do not mutually agree on a third Expert within seven (7) days after being appointed, each of them shall select another Expert, whereby a Swiss Notary Public appointed by the Paying and Conversion Agent will pick one of these two Experts as third Expert by drawing lots. In the case of the appointment of three Experts references in the Terms of the Bonds to a Common Expert shall be deemed to refer to these three Experts, deciding by majority decision. Decisions of the Common Expert shall be final and binding on the Issuer, the Bondholders and the Paying and Conversion Agent. The Paying and Conversion Agent shall incur no liability against the Issuer or the Bondholders in respect of any action taken, or suffered to be taken, in accordance with such decision and in good faith. The fees and costs of the Common Expert shall be borne by the Issuer;
- 17    **"Condition"** has the meaning given to it in the preamble;
- 18    **"Conversion Date"** has the meaning given to it in Condition 3(b)(i);
- 19    **"Conversion Notice"** has the meaning given to it in Condition 3(b)(i);
- 20    **"Conversion Period"** means the period during which a Bondholder may exercise the Conversion Rights at his option, such period commencing on 17 May 2017 up to and including the earlier of (i) seven (7) Trading Days before the Maturity Date or (ii) in case of early redemption of the Bonds pursuant to Condition 5(b) ten (10) Trading Days prior to the date fixed for early redemption;

- 21 **"Conversion Price"** means CHF 86.4006 subject to adjustments in accordance with Condition 6 or 7(c);
- 22 **"Conversion Ratio"** has the meaning given to it in Condition 3;
- 23 **"Conversion Right"** means the right of a Bondholder to request conversion of any Bond in accordance with the provisions of these Terms of the Bonds;
- 24 **"Current Market Price"** means the average (mean) of the daily VWAP of one Share on each of the five (5) consecutive Trading Days ending on (and including) the Trading Day immediately preceding the date by reference to which such average is calculated, provided that when calculating the average (mean) of the VWAPs the gross dividend amount (or any other entitlement), if any, of any dividend (or any other entitlement) paid during either of the above mentioned period of five (5) consecutive Trading Days, shall be added back to the VWAPs on each of the Trading Days on which the Shares are traded ex-dividend (or any other entitlement);
- 25 **"Distribution"** has the meaning given to it in Condition 6(a)(iii);
- 26 **"Distribution Date"** has the meaning given to it in Condition 6(a)(iii)(B);
- 27 **"Dividend"** means a distribution per Share made by the Issuer to holders of the Shares at any time as (i) a cash dividend, (ii) a repayment of paid-in capital, (iii) a stock dividend in lieu of a cash dividend, or (iv) tradable put options in lieu of a cash dividend;
- 28 **"Effective Date"** means the last date on which the Shares are traded cum-dividend on the Relevant Exchange or, in the case of a purchase, redemption or buy back of Shares or any depositary or other receipts or certificates representing Shares, the date on which such purchase, redemption or buy back is made or in the case of a spin-off, the last date on which the Shares are traded cum-the relevant spin-off on the Relevant Exchange;
- 29 **"Event of Default"** has the meaning given to it in Condition 9;
- 30 **"Ex-Date"** means the first day on which the Shares are traded on the Relevant Exchange without entitlement (ex);
- 31 **"Expert"** shall have the meaning given to it in the definition of Common Expert;
- 32 **"FISA"** has the meaning given to it in Condition 1(b);
- 33 **"Interest Amount"** has the meaning given to it in Condition 2;
- 34 **"Interest Amount Payment Date"** means 17 February and 17 August in each year, from and excluding 17 February 2017 to and including the Maturity Date;
- 35 **"Intermediary"** has the meaning given to it in Condition 1(b);
- 36 **"Intermediated Securities"** has the meaning given to it in Condition 1(b);
- 37 **"Issuer"** has the meaning given to it in the preamble;
- 38 **"Joint Bookrunners"** has the meaning given to it in the preamble;
- 39 **"Kepler"** has the meaning given to it in the preamble;
- 40 **"Listing Agent"** means BaB, appointed as recognized representative pursuant to article 43 of the listing rules of SIX Swiss Exchange to file the listing application (including the application for provisional admission to trading) for the Bonds with SIX Swiss Exchange;
- 41 **"Material Subsidiary"** means any operating Subsidiary of the Issuer whose assets or net sales at any time represent ten (10) per cent or more of the consolidated assets, the consolidated net sales, the consolidated operating result or net result (profit after tax or net loss), as the case may be, of the Issuer and its consolidated Subsidiaries at any time, and for this purpose:
- (a) the assets, net sales, the operating result and the net result (profit after tax or net loss) of any such Subsidiary shall be ascertained by reference to:
    - (i) the financial statement information of such Subsidiary, provided to the Issuer and adjusted for consolidation purposes (and thereby in particular excluding mere intercompany transactions) under generally accepted accounting principles applied by the Issuer, at the date to

which the last audited consolidated annual financial statements of the Issuer and its consolidated Subsidiaries have been prepared;

- (ii) if such corporate body becomes a Subsidiary of the Issuer after that date, the latest financial statements of such Subsidiary adjusted to take into account subsequent acquisitions and disposals or other changes in circumstances and adjustments required for consolidation purposes under generally accepted accounting principles applied by the Issuer;
- (b) the consolidated assets, consolidated net sales, consolidated operating result and net result (profit after tax or net loss) of the Issuer shall be ascertained by reference to the last audited consolidated annual financial statements of the Issuer and its consolidated Subsidiaries; and
- (c) once a subsidiary has become a Material Subsidiary, it shall be considered one until it has been demonstrated to the reasonable satisfaction of the Paying and Conversion Agent that it has ceased to be a Material Subsidiary, a written report from the Issuer's auditors to this effect being sufficient for this purpose.

42 **"Maturity Date"** means 17 February 2022;

43 **"Notices"** has the meaning given to it in Condition 10;

44 **"Notice of Delisting"** has the meaning given to it in Condition 5(c);

45 **"Other Securities"** means equity securities of the Issuer other than Shares;

46 **"Paying and Conversion Agent"** has the meaning given to it in Condition 1(e);

47 **"Payment Date"** means 17 February 2017;

48 **"Principal Amount"** has the meaning given to it in Condition 1(a);

49 **"Purchase Rights"** has the meaning given to it in Condition 6(a)(ii);

50 **"Put Notice"** has the meaning given to it in Condition 5(c);

51 **"Put Options"** has the meaning given to it in Condition 6(a)(iv)(C);

52 **"Record Date"** means the last Business Day prior to the Ex-Date;

53 **"Redemption"** has the meaning given to it in Condition 5(a);

54 **"Reference Share Price"** means CHF 71.9969;

55 **"Regulation S"** has the meaning given to it in Condition 3(b)(i);

56 **"Relevant Debt"** has the meaning given to it in Condition 8(b);

57 **"Relevant Exchange"** means (i) in the case of Shares, the SIX Swiss Exchange or any successor thereof or, if the Shares are no longer admitted to trading on the SIX Swiss Exchange, the principal stock exchange or securities market on which the Shares are traded, and (ii) in the case of other securities, the principal stock exchange or securities market on which such other securities are traded;

58 **"Relevant Put Date"** means the fourteenth (14<sup>th</sup>) day after the expiry of the period of sixty (60) days referred to in Condition 5(c). If such a due date does not fall on a Business Day, the Relevant Put Date shall be on the Business Day immediately following such due date;

59 **"Reset Date"** has the meaning given to it in Condition 6(a)(v);

60 **"Retroactive Adjustment"** has the meaning given to it in Condition 6(c);

61 **"Securities Act"** has the meaning given to it in Condition 3(b)(i);

62 **"Shares"** means issued and fully paid registered shares of currently CHF 1.00 (one Swiss Franc) par value each of the Issuer, or any other shares or stock resulting from any subdivision, consolidation or reclassification of such shares, which as between themselves have no preference in respect of dividends or of amounts payable in the event of any voluntary or involuntary liquidation or dissolution of the Issuer;

63 **"SIS"** has the meaning given to it in Condition 1(b);

- 64     **"SIX Swiss Exchange"** means SIX Swiss Exchange Ltd (or any successor to SIX Swiss Exchange Ltd), or the Swiss stock exchange operated by that company, as the context requires;
- 65     **"Specified Office"** means Bank am Bellevue AG, Corporate Finance, Seestrasse 16, 8700 Küsnacht, Switzerland;
- 66     **"Subsidiary"** of the Issuer means a company the financial statements of which are, in accordance with applicable law or generally accepted accounting principles, fully consolidated with those of the Issuer;
- 67     **"Swiss Federal Stamp Duty"** means (a) the transfer stamp duty that may become due on the transfer of securities if a transfer is made by or through a Swiss securities dealer (*Effekthändler*) within the meaning of the Swiss Stamp Duty Act of 27 June 1973, as amended (*Bundesgesetz über die Stempelabgaben*) and (b) the capital issuance stamp duty becoming due upon the issuance of any new Shares by the Issuer;
- 68     **"Terms of the Bonds"** has the meaning given to it in the preamble;
- 69     **"Trading Day(s)"** means any day (other than a Saturday or Sunday) on which (i) the Relevant Exchange is open for business and Shares may be dealt in or (ii) (if the Shares are not listed or admitted to trading on the Relevant Exchange) closing bid and offered prices are furnished for the Shares; and
- 70     **"VWAP"** means with respect to any Trading Day the volume-weighted average price of one Share (or other relevant security) published by Bloomberg Page HP (setting Weighted Average Line) or, if there is none, by such other source as shall be determined to be appropriate by the Common Expert on such Trading Day, provided that on any such Trading Day on which such price is not available or cannot otherwise be determined as provided above, the volume weighted average price of a Share (or other relevant security) in respect of such Trading Day shall be the VWAP, determined as provided above, on the immediately preceding Trading Day on which the same can be so determined.

## **VI. SANTHERA AND ITS BUSINESS**

### **A. Business overview**

Santhera is a Swiss specialty pharmaceutical company committed to developing medicines to meet the needs of patients living with mitochondrial disorders and other rare diseases.

Santhera is focusing on the development and commercialization of treatments for mitochondrial, neuro-muscular and neuro-ophthalmological diseases that currently lack treatment options, in particular Leber's hereditary optic neuropathy (**LHON**), Duchenne muscular dystrophy (**DMD**), congenital muscular dystrophy (**CMD**) and primary progressive multiple sclerosis (**PPMS**).

Santhera in its present form was founded in September 2004. Its shares have been listed on the SIX Swiss Exchange since November 2006. Santhera's headquarters are located in Liestal, Switzerland, with subsidiaries in Switzerland, Germany, the United Kingdom, Italy, the Netherlands, Liechtenstein, the U.S., Canada and Finland. As of December 31, 2016, Santhera had 80 employees (74.4 full-time equivalent). Santhera expects its headcount to increase significantly in the near future due to the expansion of its operations.

Since 2004, Santhera has developed its pipeline by conducting various clinical studies in Europe and North America. In September 2015, Santhera received Marketing Authorization in the EU for Raxone® to treat patients with LHON, making Raxone®, to Santhera's knowledge, the first and only approved treatment for LHON. Santhera's clinical program for Raxone® continues in the areas of DMD and PPMS. Santhera is also actively investigating omigapil (an investigational product candidate that prevents cell death) in CMD.

### **B. About mitochondrial diseases**

Mitochondria are found within virtually every cell of the body and generate energy required by the cells to function. They are sometimes colloquially referred to as the powerhouse of the cell.

Mitochondrial diseases are often a result of inherited genetic mutations and typically affect organs with high energy requirements, such as the brain, muscles, eye, ear, heart, liver and the gastrointestinal tract. When mitochondria do not produce enough energy, cells within the organ do not function properly, become damaged and eventually die, resulting in the symptoms typically seen in mitochondrial diseases.

### **C. Strategy and pipeline**

Santhera focuses on providing treatment options for disorders that have a severe impact on the lives of the people affected by them.

Santhera's lead compound is Raxone®, an oral formulation of idebenone, which is a synthetic short-chain benzoquinone and cofactor for the enzyme NAD(P)H:quinone oxidoreductase (NQO1). Idebenone has a dual mode of action: it enhances mitochondrial function and acts as a cell-protecting antioxidant. Numerous indications exist in which a defect in the mitochondrial electron transport chain and the increase in oxidative stress caused by such defect is considered to be an underlying cause of the disease. Idebenone's pharmacological properties make it a development candidate of choice to treat such diseases.

Santhera is exploring Raxone®'s clinical and commercial potential in the following indications:

LHON – Commercialization outside the EU by obtaining additional marketing authorizations in select countries.

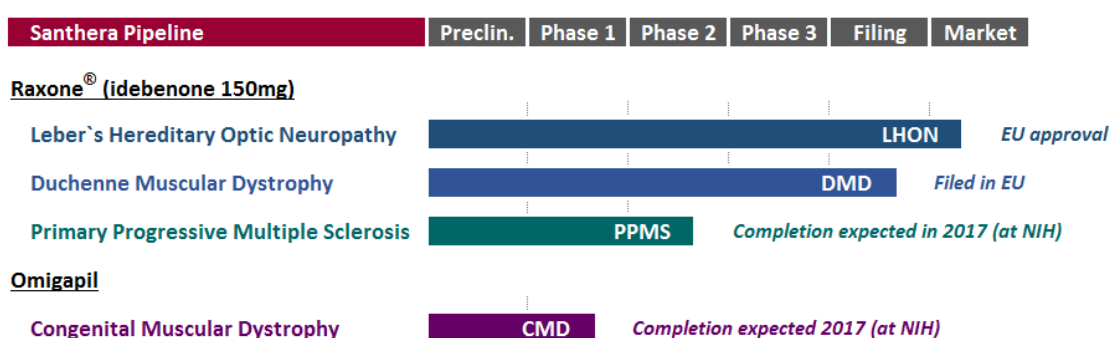
DMD – A phase III clinical trial for treatment of DMD has been completed and another phase III trial in a group of patients with different characteristics is under way. Marketing authorization applications (MAAs) for treatment of DMD in certain patients are under review by the EMA and Swiss-medic.

PPMS – Ongoing phase I/II clinical trial for treatment of PPMS.

Other indications in which the mitochondria play a significant role and where Raxone®'s mode of action could be promising.

In addition to its activities with respect to Raxone®, Santhera is investigating a second compound, omigapil, which is an investigational product candidate that may block cell death pathways. Santhera is currently conducting a phase I clinical trial for omigapil in CMD.

The following figure summarizes Santhera's pipeline:



#### D. Santhera's marketed product: Raxone® in LHON

LHON is a rare, severe hereditary eye disease affecting primarily men in their 20s and 30s and leading to central vision loss in both eyes. Raxone® is, to Santhera's knowledge, the first product approved for the treatment of LHON and received marketing authorization in all 28 EU countries, as well as Norway, Iceland and Liechtenstein, in September 2015.

##### 1. Leber's hereditary optic neuropathy (LHON)

LHON usually affects young, otherwise healthy individuals and is more common in men than women. On average, LHON onsets at an average age between 27 and 34 years. The incidence of LHON has been estimated to be approximately 1 in every 1,000,000 people in Europe.

Loss of central vision occurs in the majority of patients within 1 year of their symptoms becoming apparent. The loss of vision in the first eye is sudden, abrupt, painless and profound. This is typically followed by loss of vision in the other eye 1–3 months later. The rapid loss of vision caused by LHON has a dramatic impact on the quality of life for patients, and is associated with considerable economic and social costs due to productivity loss, lower employment rates, income loss, or costs of care.

LHON is caused by mutations in genes in the mitochondria. When such mutations are present, nerve cells in the retina at the back of the eye do not have enough energy to work properly, leading to the characteristic loss of vision.

##### 2. Treatment of LHON with Raxone®

Raxone® is to Santhera's knowledge the first and only approved treatment for LHON, and is indicated for the treatment of visual impairment in adolescents and adults with LHON.

Raxone® has been shown to help bypassing the deficient mechanism that prevents the mitochondria from working properly. As a result, it may reactivate nerve cells in the retina (retinal ganglion cells) that are still viable but no longer active. This, in turn, can promote recovery of vision in patients with LHON who have already lost vision. Raxone® also works as a cell-protecting antioxidant, preventing damage induced by so-called reactive oxygen species.

Studies suggest that Raxone® can prevent further vision loss and promote clinically relevant recovery of visual acuity in patients with disease duration of up to 5 years. An early diagnosis of LHON offers patients the best chance for the treatment of their condition in the long term. There is a window of opportunity for the optimal treatment of LHON when the retinal ganglion cells are still viable. Clinical data suggest that up to 50% of patients with disease duration of less than 1 year experience a clinically relevant recovery of visual acuity following Raxone® treatment.

Raxone® is available as film-coated tablets containing 150 mg idebenone.



### 3. Clinical Development

Raxone® has demonstrated its efficacy and safety profile in LHON in what is, to Santhera's belief, the largest clinical development program ever undertaken in LHON. The clinical development program included a double-blind, randomized, placebo-controlled study (**RHODOS**), an observational long-term follow-up study (**RHODOS-OFU**), an Expanded Access Program (the **EAP**), and a natural history case record survey (the **CRS**). A number of additional clinical studies in multiple indications also support the safety profile of Raxone®.

RHODOS was, to Santhera's belief, the first and only randomized, placebo-controlled clinical trial to be completed in LHON. RHODOS was conducted in 85 enrolled patients aged 14 to 66 years having all three major mutations causing LHON and with an onset of vision loss within the last 5 years prior to enrollment.

RHODOS-OFU was conducted as a single-visit observational follow-up study in 58 patients who completed the RHODOS trial and who were assessed after a median of 30 months without treatment.

The EAP aimed at providing insight into Raxone®'s therapeutic potential in a real-world setting and was conducted under the Named Patient Program in the EU and the Investigational New Drugs regulations in the U.S. Enrollment was limited to patients presenting for treatment within 1 year of onset of symptoms. Data from 69 patients at 36 centers worldwide were analyzed and reported. The program is still ongoing.



The CRS is a collaboration between Santhera and the European Vision Institute Clinical Research Network (EVICR.net) in which historically documented visual acuity data from untreated patients were collected from participating centers.

#### **4. Efficacy and safety**

In the RHODOS trial, patients treated with RAXONE® on average experienced an improvement of visual acuity with their eye experiencing the most improvement (primary endpoint) by 3 letters on an eye chart, and, when the difference between the best visual acuity in either the left or right eye was measured (main secondary endpoint), by 6 letters, though the result on the primary endpoint was not significant over placebo. In a pre-specified sub-group analysis of the RHODOS data with 8 patients, visual acuity of 0 out of 6 patients deteriorated in the pre-specified way in the treated group, whereas visual acuity of both patients in the placebo group deteriorated. The RHODOS-OFU indicated that the effect of Raxone® may be maintained.

According to data from the EAP and the CRS, 30.6% of (treated) patients in the EAP experienced a clinically relevant recovery after 6 months, compared to 19.1% of (untreated) patients in the CRS. In the EAP, the number of responders increased with longer treatment duration.

An analysis was performed in RHODOS evaluating the proportion of patients who had a clinically relevant recovery of visual acuity in at least one eye. 30.2% of patients experienced clinically relevant recovery of visual acuity (defined as an improvement from being unable to read a single letter on an eye chart to being able to read at least 5 letters, or an improvement by at least 10 letters) compared with 10.3% in the placebo group after 6 months of treatment.

#### **5. Market exclusivity, regulatory status and sales**

Santhera has been granted orphan drug designation for Raxone® for the treatment of LHON in the EU (until September 2025), and the U.S. The product is not patent protected.

Raxone® received marketing authorization from the EMA in all 28 EU countries, as well as Norway, Iceland and Liechtenstein, in September 2015, for the treatment of adolescents and adults with LHON. Raxone® is, to Santhera's knowledge, the first medicine approved for LHON. The marketing authorization was granted under "exceptional circumstances". Such authorization may be given when comprehensive efficacy and safety data cannot be obtained, but it is still appropriate to grant the authorization. In the case of Raxone® in LHON, authorization under "exceptional circumstances" was given because the CHMP was of the view that it was not feasible to generate a comprehensive data set, mainly due to the rarity of LHON. Furthermore, at the time of the CHMP's determination, idebenone was already used to treat LHON patients in clinical practice, which is why neither physicians nor patients were considered to be prepared to participate in a placebo-controlled trial. Under its marketing authorization, Santhera is required to conduct and is currently conducting an additional phase IV clinical trial on the long-term effects and safety of Raxone®, called LEROS, an open label, interventional study. Santhera also maintains and extends its existing CRS. In addition, Santhera is maintaining a registry of LHON patients treated with Raxone® (called PAROS), as required by the EU marketing authorization.

Santhera launched Raxone® for the treatment of LHON in Germany, the largest EU market, in October 2015. In January 2016, Santhera entered into a distribution and supply agreement with Ewopharma to launch Raxone® for the treatment of LHON in eleven countries in Eastern Europe (Bulgaria, Croatia, Czech Republic, Hungary, Poland, Romania, Slovakia and Slovenia) and the Baltics (Estonia, Latvia and Lithuania).

Raxone® in LHON is presently sold in 15 EU countries, with the majority of sales reached in France and Germany. In 2016, the first full year of commercialization of Raxone® in LHON, Santhera reported net sales of CHF 19 million (see Annex C to this Prospectus).

## **6. Competition**

The most advanced program for developing a treatment of LHON is based on gene therapy with an ongoing phase III trial by Gensight Biologics, Paris, France, addressing patients within one year of symptom onset and carrying one of the major mutations causing LHON. A successful proof of concept trial with gene therapy was reported by an academic institution in China on a small number of patients. In addition, Stealth BioTherapeutics, Inc., Newton (Massachusetts), USA, is recruiting patients for a phase II trial in LHON using a peptide antioxidant. Santhera expects all of these approaches to be still several years from filing a marketing authorization application.

### **E. Santhera's lead product candidate: Raxone® in DMD with filed EU and Swiss marketing authorization applications**

Santhera has an ongoing clinical program for Raxone® in DMD, one of the most common and devastating types of inherited degenerative muscle weakness. MAAs for Raxone® in patients with DMD who do not take concomitant steroids is under review by the EMA and Swissmedic. Raxone® in DMD has also been granted fast-track designation by the FDA. Santhera is currently conducting a phase III trial in patients who are using concomitant steroids (called SIDEROS), whose results are expected in 2019.

#### **1. Duchenne muscular dystrophy (DMD)**

DMD results in progressive muscle weakness, starting at young age. DMD is a genetic disease that primarily affects boys with an estimated incidence of up to 1 in 3,500 to 1 in 5,000 live born males worldwide. The average age at which boys will start to show symptoms of DMD is between 3 and 5 years, with patients experiencing progressive weakness of muscles. Patients are commonly unable to walk by their teenage years.

DMD is characterized by a loss of the protein dystrophin, leading to cell damage, uncontrolled influx of calcium, a dysfunction of mitochondria and associated reduced energy production in muscle cells. This results in progressive muscle weakness, loss of muscle tissue and early illness and death due to cardio-respiratory failure. Progressive respiratory muscle weakness leads to restrictive respiratory disease, hypoventilation, ineffective cough, recurrent pulmonary infections, respiratory failure and ultimately the need for daytime ventilation. As respiratory insufficiency develops, mechanical ventilation becomes necessary to prolong survival beyond the late-teenage years.

Currently, glucocorticoids (a form of steroids) are the only available medical treatment that can slow the decline in muscle strength and function, irrespective of the disease-causing mutation. However, the effect is only partial and clinical use is limited by side effects caused by steroids. A recent study showed that up to 42% of DMD patients aged 10 years and older had either never used concomitant steroids or have discontinued their use. Loss of respiratory function with increasing age continues to be a major cause of illness and death in patients with DMD.

#### **2. Clinical development status**

Santhera's clinical development program with Raxone® in DMD started with a phase II randomized, placebo-controlled trial called DELPHI. In May 2014, Santhera completed a phase III, double-blind, placebo-controlled clinical trial called DELOS which randomized 64 patients between 10 and 18 years who were not using concomitant steroids to receive either Raxone® (900 mg/day) or matching placebo. The DELOS trial evaluated the efficacy and safety of Raxone® in delaying the loss of respiratory function in patients with DMD compared with placebo. The DELOS trial met its primary endpoint and demonstrated that Raxone® can slow the loss of respiratory function and reduces bronchopulmonary complications. Adverse events were comparable to placebo.

The results of the DELOS trial have been substantiated by a comparative natural history study showing that the benefit observed in the Raxone®-treated group would not have been expected from the natural course of the disease.

In September 2016, Santhera started another randomized, double-blind, placebo-controlled phase III clinical trial called SIDEROS. The SIDEROS trial aims at assessing the efficacy of Raxone® in slowing the rate of decline of the respiratory function in approximately 260 DMD patients who are using concomitant steroids. If the trial is successful, there may be a potential for a future labeling extension of Raxone® to also treat patients using concomitant steroids. SIDEROS enrolls patients with declining respiratory function on any stable steroid treatment scheme and irrespective of the underlying gene mutation or their current ability to walk. Study participants receive either Raxone® (900 mg/day) or placebo for 78 weeks (18 months). The primary endpoint of the SIDEROS trial is change from baseline to week 78 in forced vital capacity % predicted. Secondary endpoints include changes from baseline in % predicted peak expiratory flow, time to first 10% decline in forced vital capacity and change from baseline in inspiratory flow reserve. Patients completing the SIDEROS trial are expected to be offered the opportunity to enroll in an open label extension study where all patients receive Raxone®. The SIDEROS trial is being conducted at 60 centers in the United States and Europe. It is currently expected that the results of the SIDEROS trial will become available in the second half of 2019.

In addition, Santhera and Parent Project Muscular Dystrophy (PPMD), a U.S. patient advocacy group, conducted what to Santhera's belief is the first-ever patient benefit/risk survey in patients with DMD and caregivers of individuals with DMD. The survey showed that DMD patients and their caregivers placed a high value on treatments that could reduce pulmonary complications.

### 3. Market exclusivity and regulatory status

Santhera has been granted orphan drug designation for Raxone® for the treatment of DMD in the EU, the U.S. and Australia. In addition, Santhera has a method of use patent for Raxone® in DMD, which is expected to expire in March 2027 in the EU and Japan and in December 2027 in the U.S.

The EMA's Committee for Medicinal Products for Human Use (**CHMP**) is currently assessing a MAA for Raxone® in DMD patients with declining respiratory function and who are not taking concomitant steroids. The indication would include patients who previously were treated with steroids or in whom steroid treatment is not desired, not tolerated or contraindicated. The MAA was submitted as a so-called Type II variation of Santhera's existing marketing authorization for LHON and is based data from the phase II DELPHI and the phase III DELOS trials. In June 2016, the EMA confirmed that the MAA was complete and that the review process had begun. Santhera expects an opinion from the CHMP in the first or second quarter of 2017.

Santhera has submitted a MAA for Raxone® for the same indication as in the MAA filed with the EMA to Swissmedic. Swissmedic confirmed in November 2016 that the submission is sufficiently complete to permit substantive review. The standard assessment time is typically 15-18 months.

In the U.S., the FDA has granted fast track designation for Raxone® in DMD in addition to a rare pediatric disease designation. The fast track designation will allow Santhera to request priority review when filing a New Drug Application (**NDA**). In July 2016, the FDA advised Santhera that the results from the SIDEROS trial (which is focused on patients who use concomitant steroids), if positive, should be provided when an NDA is filed for the treatment of DMD patients irrespective of whether they use concomitant steroids or not. The FDA had previously confirmed based on SIDEROS' protocol that the SIDEROS trial has the potential, if successful, to provide the necessary efficacy data along with data from previous trials to support the filing of an NDA for Raxone® in DMD.

The UK's Medicines and Healthcare Products Regulatory Agency (**MHRA**) designated Raxone® for the treatment of DMD in patients with respiratory function decline who do not take concomitant steroids as Promising Innovative Medicine (**PIM**) (a status similar to a breakthrough therapy designation by the FDA) and as suitable candidate for further evaluation under the UK Early Access to Medicines Scheme (**EAMS**) in December 2016. The PIM designation is an early indication that a medicinal product is a promising

candidate for EAMS and gives reassurance that its clinical development is on track by having an early review of its data by the medicines regulator. The next step under the EAMS scheme would be the Scientific Opinion by the MHRA that would describe the benefits and risks of the medicine and support the prescriber and patient to make a decision on using the medicine before its license is approved.

#### **4. Competition**

To date, two treatments for DMD developed by third parties have been approved. The most advanced therapeutic approaches in DMD are directed against the genetic cause of the disease and typically address a subset of patients. PTC Therapeutics, Inc., South Plainfield (New Jersey), USA (**PTC Therapeutics**), obtained a conditional marketing authorization in the EU for its product Translarna™ in 2014 and is also attempting to obtain marketing authorization for Translarna™ from the FDA in the U.S. Sarepta Therapeutics, Cambridge (Massachusetts), USA, obtained a marketing authorization in the U.S. for eteplirsen, an antisense-based oligonucleotide drug, in 2015, and has filed a MAA with the EMA that was validated in December 2016.

Marathon Pharmaceuticals, LLC, Northbrook (Illinois), USA, has filed an NDA in the U.S. for deflazacort, a steroid anti-inflammatory compound that already has been widely used off-label in DMD. A decision by the FDA is expected in early 2017. In addition, there are a number of other small molecule clinical phase II programs addressing muscle weakness in DMD.

#### **F. Santhera's early stage product candidates**

##### **1. Raxone® as phase I/II product candidate in PPMS**

Santhera also explores Raxone® for the treatment of PPMS, which is a subtype of multiple sclerosis (**MS**). Santhera is currently conducting a phase II clinical trial (called IPPoMS). The trial is currently planned to be completed late in 2017 with results expected to be available in late 2017 or early 2018.

##### **a. Primary progressive multiple sclerosis (PPMS)**

MS is an inflammatory and neurodegenerative disorder of the central nervous system that causes a wide range of physical symptoms, such as impaired movement, fatigue, numbness, and pins and needles, as well as problems with memory and understanding. There are two main types of MS: relapsing-remitting MS (**RRMS**) and primary progressive MS (PPMS). In RRMS, patients experience symptoms intermittently (called relapses) and symptoms may disappear completely between attacks, with a slower accumulation of permanent disability than in PPMS. RRMS is more common in women than in men. PPMS is the more aggressive form of MS. Physical disability gets progressively worse over time and patients do not experience periods without symptoms. PPMS affects about 9–15% of patients with MS and is associated with a later age of onset than RRMS. PPMS affects similar proportions of men and women.

In MS, the outer coating of nerve fibers (called myelin) is damaged, preventing the nerves from functioning properly. The causes of MS are unknown, but research has established that dysfunction and oxidative stress of the mitochondria in nerve cells could play a major role, particularly in PPMS.

Extensive research has led to the successful development and approval of a range of treatments for patients with RRMS. Treatment candidates for PPMS developed by third parties are in late development and prior to approval (see Section VI.F.1.c for further information).

##### **b. Clinical development status and market exclusivity**

Santhera is collaborating with the National Institute of Neurological Disorders and Stroke (**NINDS**), an institute within the National Institutes of Health, Bethesda (Maryland), U.S. (the **NIH**), in a phase I/II clinical trial called "Idebenone in Patients with Primary Progressive Multiple Sclerosis" (**IPPoMS**). The IPPoMS trial is investigating the safety, therapeutic efficacy and mechanism of action of Raxone® in PPMS. The trial combines a 12-month observational run-in phase followed by a 24-month double-blind, randomized,

placebo-controlled treatment period and is fully enrolled. Final results of the IPPoMS trial are expected in 2018. Patients who complete this trial are offered participation in a 12-month open label extension study.

Santhera has an exclusive license from the NIH for the use of idebenone in PPMS.

**c. Competition**

The first drug specifically developed for the treatment of PPMS that Santhera expects to potentially come to the market is ocrelizumab by Roche, for which market authorization applications have been filed both in the EU and the U.S. Biogen's Fampyra® (fampridine) is approved for the treatment of walking difficulties in all forms of MS, including PPMS. In addition, a number of treatments of PPMS are currently being developed. The most advanced one is a highly concentrated form of biotin, developed by MedDay Pharmaceuticals, Paris, France, which in Santhera's view has shown promising phase IIb/III data.

**2. Omigapil as phase I product candidate in CMD**

The second compound in Santhera's pipeline is omigapil for the treatment of CMD. Santhera is currently conducting a phase I clinical trial called CALLISTO.

**a. Congenital muscular dystrophy (CMD)**

CMD is a group of inherited neuromuscular conditions that causes progressive and potentially life-threatening loss of muscle tissue, affecting frequently newborns and children. Children born with CMD often have muscle weakness or "floppiness" and can also have stiffness of the joints, hip dislocation and a type of curvature of the spine (known as kyphoscoliosis). Affected patients have difficulties in walking, maintaining stable body posture and lifting objects. These symptoms can be present at birth or develop during childhood or later in life.

The British Muscular Dystrophy Campaign estimates that one in every 20–50,000 children in the United Kingdom is born with CMD. CMD conditions are caused by mutations in proteins required for the muscles, and sometimes the eyes and brain, to work properly. Many types of CMD are stable or progress only slowly, allowing children to acquire new skills and to live a normal lifespan. However, some severe forms of CMD cause respiratory problems that can be life-threatening as they worsen over time.

No approved pharmaceutical treatments are available or in advanced clinical development for CMD and current therapy is only symptomatic (physiotherapy, speech therapy, occupational therapy, respiratory support, scoliosis surgery).

**b. Clinical development status**

Santhera is currently investigating omigapil as a potential treatment for CMD. Omigapil is a so-called deprenyl analogue that may prevent cell death pathways (apoptosis). In preclinical research, Santhera demonstrated that omigapil prevents apoptosis and loss of muscle tissue, ameliorates muscle histology, and increases body weight and survival of a disease-relevant animal model organism for CMD.

Santhera's ongoing CALLISTO phase I clinical trial aims to evaluate the pharmacokinetic profile, safety and tolerability of a new liquid formulation of omigapil in children and adolescents with two subtypes of CMD, called COL6-RD or LAMA2-RD. The CALLISTO trial is also expected to establish the feasibility of conducting disease-relevant clinical assessments for the design of future efficacy trials. The CALLISTO trial is expected to be completed in the second half of 2017.

In August 2016, the FDA granted Santhera an award of USD 246,000 in support of the CALLISTO trial. The grant was awarded through the FDA's Orphan Products Grants Program (OPGP) to support the clinical development of products for use in rare diseases where no current therapy exists. Such grants are intended for clinical studies evaluating the safety and/or effectiveness of products that could either result in, or substantially contribute to, market approval of these products. The CALLISTO trial is being conducted

in collaboration with the NINDS in the United States. It was previously supported by a public-private partnership comprising two patient organizations (the U.S.-based Cure CMD and the Swiss Foundation for Research on Muscle Diseases) and EndoStem, an EU 7th Framework program.

**c. Market exclusivity and regulatory status**

Santhera has a world-wide exclusive license from Novartis to develop and commercialize omigapil. Omigapil has been granted orphan drug designation for CMD in the EU and the U.S.

In May 2016, Santhera received fast track designation from the FDA for omigapil for the treatment of CMD. The FDA's fast track process is designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need for the purpose of getting them to the patient earlier.

**d. Competition**

To Santhera's knowledge, its CALLISTO phase I trial is still the only ongoing clinical trial in CMD. There are a few discovery stage programs reported.

**G. Additional information on Santhera's business**

**1. Material agreements**

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

In September 2013, Santhera entered into an agreement with Takeda Pharmaceutical Company Ltd, Osaka, Japan (**Takeda**) to license back from Takeda all previously granted rights to idebenone in DMD and another indication. In return, Takeda is entitled to a percentage from future licensing and/or sales income generated by Santhera from idebenone in DMD of up to EUR 7.0 million. In addition, Santhera obtained the right to cross-reference Takeda's idebenone data for regulatory use in any indication. If Santhera makes use of such cross-reference right, Takeda would be entitled to a percentage from future licensing and/or sales income generated by Santhera in such indications of up to EUR 3.0 million. Lastly, Takeda is entitled to receive up to EUR 1.0 million as a percentage from future income generated by Santhera to offset Takeda's waiver of a contingent claim for the same amount under an earlier agreement.

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

In March 2005, Santhera entered into an agreement with Katholieke Universiteit Leuven, Leuven, Belgium (**KU Leuven**), under which KU Leuven assigned to Santhera its patents and patent applications relating to the use of idebenone 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 idebenone for the treatment of DMD.

KU Leuven is entitled to a success fee of up to EUR 0.4 million if and when Santhera commercializes any product in a major market, which includes the EU, the U.S. or Japan and certain countries within the EU. In addition, in the event that Santhera commercializes the product itself, KU Leuven is entitled to 5% royalties on net sales. In the event that Santhera grants commercialization rights to a third party, KU Leuven is entitled to 15% of 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 for treatment of CMD on an exclusive world-wide basis and undertook to develop that product candidate. Additional payments would be due to Novartis upon start of a pivotal clinical trial, upon regulatory approval in a major market country, and after reaching certain commercialization milestones. Santhera would also have to pay royalties to Novartis calculated on net sales.

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

In June 2013, Santhera obtained an exclusive world-wide license from the NIH, to its patents and patent applications in the U.S., EU and other jurisdictions for the use of idebenone to treat 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 entitled to a royalty fee of 3% on net sales and 15% of the consideration received by Santhera from any sublicense.

### ***Clinical development, manufacturing and other contracts***

As part of its ordinary course of business, Santhera has entered into several contracts for, e.g., clinical or technical development services and the manufacturing of active pharmaceutical ingredients and finished drug products. Payments of the salaries of our employees in the development department and to our service providers make up most of our development expenses. In order to meet its requirements for market supply, potential launch and inventory risk management purposes (security stock), Santhera entered into commitments for the purchase of active pharmaceutical ingredients in the amount of up to EUR 6.3 million. Part of such order was delivered in 2016 and the remainder is expected to be delivered in early 2017.

## **2. Manufacturing**

Santhera has no internal manufacturing capabilities and relies on third parties for the manufacture, formulation, packaging, storage and distribution of its product and product candidates. See also risk factor "*We have no manufacturing capabilities or capacity of our own and rely on third parties for production of Rax-one® and our secondary compound, omigapil. Our dependence on these third parties has the potential to adversely affect our business, results of operations or financial condition.*" in Section IV.A.6.

## **3. Competition**

Santhera is active in clinical areas where competitive therapeutic or development programs exist. See Sections D.6, E.4, F.1.c and F.2.d for an overview of the competitive landscape for our product and each of our product candidates.

## **4. Recent developments**

Other than as disclosed in this Prospectus, there have been no developments after June 30, 2016, that would materially affect Santhera's business.

## VII. INFORMATION ON THE ISSUER

### A. Name, registered office, incorporation

The Issuer, Santhera Pharmaceutical Holding AG, is a stock corporation (*Aktiengesellschaft*), incorporated under the laws of Switzerland and registered since July 16, 2002, in the commercial register of the Canton of Basel-Landschaft (register number CHE-105.388.338). The current domicile of the Issuer is Liestal and its registered office is at Hammerstrasse 49, 4410 Liestal, Switzerland.

### B. Articles, business purpose

The Issuer's current articles of association (the **Articles**) as at the date of this Prospectus are dated as of May 11, 2016.

The Issuer is a holding company and does not carry out operative activities. The Issuer's business purpose according to the Articles is to acquire, hold, permanently manage, dispose of and finance participations in and outside of Switzerland. The Issuer may establish branches in and outside of Switzerland, may provide security for other group companies and enter into guaranty obligations, and may conduct any business that seems appropriate to foster or is related to its purpose. The Issuer may acquire, manage, exploit commercially and sell real estate and intellectual property in and outside of Switzerland and finance other companies.

### C. Major shareholders

As at January 31, 2017, the shareholders of the Issuer holding at least 3% of its share capital registered in the Commercial Register of the Canton of Basel-Landschaft were, to the Issuer's knowledge, a group of shareholders comprising certain investors affiliated with Iglu Group AG, Switzerland, as well as Ernesto Bertarelli, Donata Guichard-Bertarelli and Maria-Iris Bertarelli (18.84% of voting rights), certain investors affiliated with Consonance Capital Management LP, United States (9.53%), UBS Fund Management (Switzerland) AG (3.11%), and Lagoda Investment Management, L.L.C., United States (3.00%).

### D. Administrative and management bodies

#### 1. Board of directors

The ultimate responsible body for management and supervision of the Issuer is the board of directors (the **Board**). The members of the Board are:

<b>Name</b>	<b>Function</b>
Martin Gertsch	Chairman of the Board, member of the Compensation Committee
Jürg Ambühl	Member of the Board, member of the Compensation Committee

On January 31, 2017, the Issuer announced that its Board had nominated Elmar Schnee, Philipp Gutzwiller, Patrick Vink and Thomas Meier (the Chief Executive Officer of Santhera, see below Section VII.D.2) for election to the Board at the Issuer's Annual General Meeting scheduled to be held on April 4, 2017. Subject to his election to the Board, Thomas Meier is expected to be appointed Delegate of the Board.

**Elmar Schnee** is Chief Operating Officer of MindMaze, a neuro-technology company spun off from the Swiss Federal Institute of Technology in Lausanne (EPFL). Prior to that, he was Chairman, CEO and board member of Cardiorentis in Zug, Switzerland. Previously, he was a General Partner and member of the Executive Board of Merck KGaA, responsible for its worldwide pharmaceutical business. He also led the major restructuring of the business including the acquisition and integration of Serono. Prior to Merck, Elmar Schnee held senior roles as managing director and in marketing, licensing, strategy and business development with UCB Pharma, Sanofi-Synthelabo, Migliara Kaplan and Fisons. He currently serves on



the board of directors of listed Jazz Pharmaceuticals and Stallergenes Greer as well as of several privately held life science companies.

**Philipp Gutzwiller** is Global Head Healthcare at Lloyds Banking Group plc in London. He has accumulated over 15 years of experience as a banker to the broader healthcare industry, advising corporate and private equity clients on the assessment, financing and execution of acquisitions and capital market transactions. He started his career at Roche as a financial controller and later worked as an executive in Roche's corporate mergers and acquisitions team.

**Patrick Vink**, MD, has been an advisor to Santhera's Board since 2016. He advises the life sciences industry and has over 25 years of global industry experience. In his latest assignment, he was employed as Chief Operating Officer at Cubist Pharmaceuticals, overseeing all worldwide commercial and technical operations as well as global alliance management and managing the company's P&L. Previously, Patrick Vink held several senior management positions with Mylan Inc., Novartis Generics / Sandoz, Biogen and Sanofi-Synthelabo. He currently is chairman of the board of privately-held NMD Pharma and Acacia Pharma and a member of the board of listed Concordia International Corp. and several privately held life science companies.

The election of Board members is in the sole power of the shareholders at the Issuer's general meeting of shareholders. Accordingly, there is no assurance that the proposed new members will actually assume office. See also risk factor "*The composition of our board of directors is expected to significantly change in April 2017, and there is no assurance that our future board will pursue the same strategy as our existing board.*" in Section IV.A.6.

The business address of the members of the Board is Santhera Pharmaceuticals Holding AG, Hammerstrasse 49, 4410 Liestal, Switzerland.

## 2. Executive management

The members of the Issuer's executive management (the **Executive Management**) are:

<i><b>Name</b></i>	<i><b>Function</b></i>
Thomas Meier	Chief Executive Officer*
Todd Bazemore	Chief Operating Officer, Santhera USA
Günther Metz	Executive Vice President, Business Development
Christoph Rentsch	Chief Financial Officer
Giovanni Stropoli	Chief Commercial Officer (Europe & Rest of World)
Oliver Strub	Executive Vice President, Group General Counsel & Secretary to the Board
Kristina Sjöblom Nygren	Chief Medical Officer, Head of Development

\* Mr. Meier's responsibilities as CEO include those of a Chief Scientific Officer.

Two members of the Executive Management were appointed in 2016:

**Todd Bazemore** was appointed Chief Operating Officer of Santhera USA in September 2016. He is a biopharmaceutical executive with 22 years of experience across multiple therapeutic areas. Prior to joining Santhera, he served as EVP and Chief Commercial Officer at Dyax Corp. (which was acquired by Shire plc in January of 2016), where he was responsible for global commercial strategy and oversight of all commercial functions. Prior to that, he was at Sunovion Pharmaceuticals (previously Sepracor INC, prior to acquisition by Sumitomo Dainippon Pharma Co., Ltd), where he served in various roles including Vice President of Sales, Vice President of Respiratory Business Unit and Vice President of Market Access and Reimbursement. He began his career in sales at MURO Pharmaceuticals. Mr. Bazemore has a Bachelor's of Science in Health from the University of Massachusetts at Lowell.

**Kristina Sjöblom Nygren** (formerly Kristina Timdahl), MD, was appointed Chief Medical Officer and Head of Development of Santhera as of January 2017. She studied chemistry and biochemistry and graduated

as a medical doctor from the Karolinska Institute, Sweden. She has over 18 years of experience as biopharmaceutical executive in drug development across multiple therapeutic areas, including orphan diseases. During her career she has worked in clinical development roles at Wyeth, AstraZeneca and Biovitrum. Prior to joining Santhera, she served as VP and Head of Clinical Development at Swedish Orphan Biovitrum AB (Sobi), where she led the clinical development of all programs from first in man to commercialization and life cycle management.

The business address of the members of the Board is Santhera Pharmaceuticals Holding AG, Hammerstrasse 49, 4410 Liestal, Switzerland.

#### **E. Auditors**

The Issuer's auditors are appointed on an annual basis. The current auditors are Ernst & Young AG, Aeschengraben 9, 4051 Basel, Switzerland, who have acted as the Issuer's auditors for more than a decade.

#### **F. Dividends and dividend policy**

Since its inception, the Company has never paid any dividends and it does not anticipate paying dividends in the foreseeable future, as it currently intends to retain all available funds and future earnings, if any, primarily to fund the development and commercialization of Raxone® and its product candidates or for other corporate purposes.

#### **G. Notices to shareholders and Bondholders**

In accordance with the Articles, unless personal notification is mandated by law, notices to shareholders are validly made by publication in the Swiss Official Gazette of Commerce (*Schweizerisches Handelsamtsblatt*). In contrast, notices in respect of the Bonds will be published in accordance with the Terms of the Bonds (Section V). Announcements concerning information with significant relevance for the price of the Shares or the Bonds will be made as required and by the means provided by the SIX Swiss Exchange ad-hoc publicity regulations.

#### **H. Legal and regulatory proceedings**

As of the date of this Prospectus, there are no pending or threatened court, arbitral or administrative proceedings that are of material importance to Santhera's assets and liabilities or profits and losses, other than the filings pending before medical product authorities and similar authorities discussed elsewhere in this Prospectus.

## VIII. INFORMATION ON THE ISSUER'S SHARE CAPITAL AND THE SHARES

### A. Capital

#### 1. Capital structure

The share capital of the Issuer as of the date of this Prospectus amounts to CHF 6,279,857 and is divided into 6,279,857 fully paid-up registered shares, each with a par value of CHF 1, which form one single class of shares. The General Meeting of Shareholders may at any time convert registered shares into bearer shares (*Inhaberaktien*) and bearer shares into registered shares.

As of the date of this Prospectus, the Issuer has the following authorized and conditional share capital:

*Authorized share capital:* Article 3a of the Articles provides as follows (convenience translation from the German original):

#### **"Article 3a – Authorized Share Capital**

*The Board of Directors is authorized at any time until May 10, 2018, to increase the Company's share capital by a maximum of CHF 1,500,000 by issuing up to 1,500,000 registered shares with a nominal value of CHF 1.00 each, to be fully paid up. Increases in partial amounts are permitted.*

*The Board of Directors shall define the issue price of new shares, the manner in which they are to be paid up, the time of the issuance of new shares, the conditions for the exercise of the preemptive rights and the beginning of the period of dividend entitlement. In doing so, the Board of Directors may issue new shares through firm underwriting by a bank, bank syndicate or a third party and subsequent offer to the existing shareholders (unless the preemptive rights of the existing shareholders are excluded). The Board of Directors is authorized to permit, restrict or to prohibit trading in the preemptive rights. The Board of Directors may permit preemptive rights that have been granted but not exercised to expire, place them and the shares for which subscription rights have been granted but not exercised, respectively, at market conditions, or use them for other purposes in the interest of the Company.*

*The subscription, the acquisition and each following transfer of the new registered shares are subject to the transfer restrictions set forth in Article 5 of the Articles of Association.*

*The Board of Directors is authorized to restrict or exclude the preemptive rights of the shareholders and to allocate them to third parties if the shares are to be used:*

- (a) for acquisitions of businesses, parts thereof, participations, products, intellectual property rights or licenses, or for investment projects including product development programs, or for the financing or refinancing of such transactions or investment projects by means of a share placement with one or more investors; or*
- (b) for the purposes of participations by strategic partners (including in the case of a public takeover bid) or for expansion of the shareholder constituency in certain investor groups or markets or in connection with the listing of the shares on domestic or foreign stock exchanges, including for the purpose of delivering shares to the participating banks upon exercise of an overallotment option; or*
- (c) for the purposes of participations or remuneration of persons or companies that provide services to the company or one of its subsidiaries; or*
- (d) if the issue price of the new shares is determined in consideration of the market price; or*
- (e) in order to quickly and flexibly raise equity capital by a share placement that could only be achieved with difficulty or on significantly less favorable terms if the preemptive rights of shareholders were maintained; or*

- (f) *for the defense of an actual, threatened or potential takeover bid that the Board of Directors, upon consultation with an independent financial adviser retained by it, has not recommended to the shareholders because the Board of Directors has not found it to be financially fair to the shareholders."*

*Conditional share capital for employee participations:* Article 3b of the Articles provides as follows (convenience translation from the German original):

**"Article 3b – Conditional Share Capital for Employee Participations**

*The share capital may be increased through the issuance of up to 550,000 registered shares, to be fully paid up with a nominal value of CHF 1.00 each, by up to CHF 550,000 through the direct or indirect issuance of shares, options or respective subscription rights to employees and/or members of the Board of Directors of the Company and its affiliates.*

*The preemptive rights as well as the advance subscription rights of the shareholders of the Company are excluded upon the issue of shares, options or subscription rights in respect thereof. The issue of shares, options or subscription rights in respect thereof is conducted according to one or more participation schemes and/or regulations to be issued by the Board of Directors and taking into consideration Article 4 of the Articles of Association.*

*The new shares directly or indirectly acquired by employees or members of the Board of Directors of the Company or its affiliates as part of an employee participation program and any following transfer of such shares shall be subject to the restrictions of Article 5 of the Articles of Association."*

As of the date of this Prospectus, 17,059 Shares have been issued out of such conditional share capital. Accordingly, 532,941 Shares may still be issued under article 3b of the Articles.

*Conditional share capital for financings, mergers and acquisitions:* Article 3c of the Articles provides as follows (convenience translation from the German original):

**"Article 3c – Conditional Share Capital for Financings, Mergers and Acquisitions**

*The share capital of the Company may be increased by up to CHF 650,000 through the issuance of up to 650,000 registered shares, to be fully paid up with a nominal value of CHF 1.00 each, through the exercise or mandatory exercise of options and/or conversion rights granted in connection with bonds, similar debt instruments, notes or other securities or contractual obligations by or of Santhera Pharmaceuticals Holding AG or one of its affiliates, and/or through the exercise of options rights issued by Santhera Pharmaceuticals Holding AG or one of its affiliates (hereinafter collectively, the Financial Instruments). The preemptive rights of the shareholders shall be excluded in connection with the issuance of shares upon the exercise of any Financial Instrument. The respective holders of the Financial Instruments are entitled to subscribe the new shares. The conditions of the Financial Instruments shall be determined by the Board of Directors. The acquisition of registered shares through the exercise of Financial Instruments and the following transfer of the registered shares shall be subject to the transfer restrictions set forth in Article 5 of the articles of association.*

*The Board of Directors shall be authorized to restrict or withdraw the advance subscription rights of the shareholders in connection with the issuance of Financial Instruments,*

- (1) *if the issuance of the Financial Instruments is for purposes of financing or refinancing the acquisition of businesses, parts thereof or participations, cooperations or investments or if it occurs in national or international financial markets (including through private placements);*
- (2) *for purposes of a firm underwriting of the Financial Instruments by a bank or a bank consortium followed by a public offer;*

- (3) *in order to flexibly raise equity capital by a share placement that could only be achieved with difficulty or on significantly less favorable terms if the advance subscription rights of shareholders were maintained.*

*If the advance subscription rights are excluded through a resolution by the Board of Directors, the following shall apply: (i) the Financial Instruments' issue shall be made at the prevailing market conditions (including the standard dilution protection provisions in accordance with market practice), and (ii) the issue of the new shares shall be made pursuant to the relevant conversion or vesting conditions. Conversion or option rights may be exercised during a maximum 10-year period from the date of the respective issue."*

## 2. Options, warrants and incentive compensation

The Issuer has adopted different stock option and other equity-linked plans for the members of its Board, the Executive Management and employees (collectively the **Plans**). Descriptions of the Issuer's Equity Incentive Plan (the **EIP**), its Employee Stock Option Plans (the **ESOPs**) and its Board Stock Option Plans (the **BSOPs**) may be found in Note 17 to the Issuer's Annual Report 2015 (Annex A to this Prospectus).

As of July 1, 2016, the Issuer switched from stock option plans to share appreciation right plans and adopted a Board Share Appreciation Rights Plan (the **BSARP 2016**) for the members of its Board and an Employee Share Appreciation Rights Plan (the **ESARP 2016**) for the members of Executive Management and other employees. The BSARP 2016 and the ESARP 2016 provide for the grant of share appreciation rights (**SAR**). Grants made from July 1, 2016 onwards are only in the form of SAR. A SAR entitles a participant to receive the difference between a reference price (base value) that is equal to the closing share price on the first trading day in July (with respect to SAR granted in 2016) and in January (with respect to SAR granted in 2017) and the Share price at exercise in Shares. SARs vest 2 (25%), 3 (25%) and 4 years (50%) after grant and are exercisable during the entire exercise period (10 years). Upon exercise of a SAR, participants receive the difference between the price of one Share at the time of exercise and the base value (defined upon grant) in Shares. Subsequently, participants may sell their Shares on the open market.

In 2016, the last remaining 1,210 unexercised options under the EIP (which dates from 2006), were exercised. The EIP has thus expired.

The below table provides a summary of the options for Shares outstanding under the Issuer's stock option plans as of December 31, 2016, and December 31, 2015, respectively:

Exercise price range for options (in CHF)	Number outstanding	Weighted average remaining contractual life (years)	2016 number exercisable	Number outstanding	Weighted average remaining contractual life (years)	2015 number exercisable
1.00	0	0	0	1,210	0.86	1,210
from 3.78 to 6.34	33,699	6.66	33,574	42,673	7.44	31,611
from 22.25 to 30.10	4,550	7.48	2,000	6,600	7.43	1,500
from 59.44 to 69.30	18,800	9.23	0	19,788	0.52	19,788
from 82.10 to 114.50	257,116	8.58	753	153,563	9.02	6,303
Total	314,165	8.40	36,327	223,834	7.87	60,412

The below table provides a summary of the SAR outstanding under the BSARP 2016 and the ESARP 2016 as of December 31, 2016:

Base value range of SAR (in CHF)	Number outstanding	Weighted average remaining contractual life (years)	2016 Number exercisable
from 51.75 to 76.50	56,581	9.71	0
Total	56,581	9.71	0

In addition to the above-described instruments, the members of the Executive Management are entitled to receive a short term incentive in cash. The payment of such cash bonus is subject to the retrospective

approval by the annual general meeting of shareholders based on a proposal made to it by the Board. Each member of the Executive Management has a contractually agreed maximum bonus which is expressed as a percentage of his or her base salary, ranging between 25% and 50%. To determine the cash amount to be paid out, the achievement of both corporate and individual goals (0% to 100%) is multiplied by a defined factor, *i.e.*, 70% and 90% (CEO) with respect to the achievement of corporate goals and 30% and 10% (CEO) with respect to the achievement of individual goals.

### **3. Treasury shares**

As of December 31, 2016, the Company held 3,616 Shares in treasury in connection with a market making agreement with Kepler Cheuvreux SA.

### **4. Asset transfer and contributions in kind**

Pursuant to an asset transfer agreement (*Vermögensübertragungsvertrag*) dated August 11, 2004, the Issuer transferred assets in the amount of CHF 1,299,086 and liabilities in the amount of CHF 827,280 to Santhera Pharmaceuticals (Schweiz) GmbH, Liestal, in consideration of one quota in the amount of CHF 124,000 in Santhera Pharmaceuticals (Schweiz) GmbH, Liestal.

On the occasion of the capital increase of June 14, 2005, and pursuant to contribution agreements dated June 14, 2005, the Issuer took over an aggregate of 149,825 preference shares series (B) in Santhera Pharmaceuticals (Deutschland) AG, in Heidelberg (Germany), at an aggregate price of CHF 656,170, in consideration of 131,234 preference shares series (B) in the Issuer with a nominal value of CHF 1.00.

On the occasion of the authorized capital increase of September 29, 2009, pursuant to the authorization resolution of April 21, 2009, and pursuant to an agreement on contributions in kind dated September 25, 2009, the Issuer took over participations at an aggregate price of CHF 105,973, in consideration of which 105,973 registered shares in the Issuer with a nominal value of CHF 1.00 were issued.

## **B. The Shares**

### **1. General description**

The Shares are fully paid-up registered shares with a par value of CHF 1 each. By decision of the shareholders' meeting, registered shares may be converted into bearer shares and vice versa.

The Shares rank *pari passu* in all respects with each other, including in respect of entitlements to dividends, liquidation proceeds and pre-emptive rights.

Only persons registered in the share register are recognized as shareholders by the Issuer.

### **2. Form of Shares**

The Shares are issued in the form of uncertificated securities (*Wertrechte*) within the meaning of article 973c CO and are maintained as book-entry securities (*Bucheffekten*) within the meaning of the Swiss Federal Intermediated Securities Act (**FISA**; *Bucheffektengesetz*).

### **3. Transfer restrictions**

The Shares are freely transferable and the Issuer recognizes acquirers of Shares as shareholders with voting rights and records them as such in the share register, provided that they declare that they acquired the Shares in their own name and for their own account. Registration in the share register is made upon request. The Board may record persons (including individuals or entities acting in concert) who do not explicitly declare in their registration request that they hold Shares for their own account and who have entered into a nominee agreement with the Issuer (**Nominees**) in the share register with the right to vote

up to 2% of the share capital (as recorded in the commercial register). Shares held by a Nominee in excess of 2% of the share capital may be recorded with voting rights if the respective Nominee discloses the names, addresses and number of Shares of persons for whose account it holds such Shares. Since January 1, 2016, the Board has granted no exceptions to these rules.

#### **4. Voting at shareholders' meetings**

Subject to the restrictions described above, each Share carries one vote at the Issuer's shareholders' meetings. Voting rights may be exercised only after a shareholder has been recorded in the Issuer's share register as a shareholder with voting rights. Only shareholders, usufructuaries or nominees recorded with voting rights in the Issuer's share register may exercise a shareholder's voting and related rights on its behalf.

#### **5. Opting out of mandatory tender offer rules**

Under the Federal Act on Financial Market Infrastructures and Market Conduct in Securities and Derivatives Trading of June 19, 2015 (the **FMIA**), and its predecessor, any person who acquires shares of a company whose shares are listed on a Swiss stock exchange, whether directly or indirectly or acting in concert with third parties, and, as a result, exceeds the threshold of 33 1/3% of the voting rights (whether exercisable or not) of such company, must submit a public tender offer to acquire 100% of the listed equity securities of such company, subject to certain exceptions. The FMIA allows companies to waive this requirement or raise the relevant threshold to up to 49% ("opting-out" and "opting-up", respectively) in their articles of association.

Santhera has opted out of the mandatory tender offer rules in its Articles. The shareholders' meeting may resolve to opt in again.

#### **6. Listing**

The existing Shares are listed on the SIX Swiss Exchange in accordance with the International Reporting Standard.

#### **7. Share price information**

Information on past performance of the Shares is available at:  
<http://www.santhera.com/investors-and-media/investor-toolbox>.

#### **8. Security number, ISIN, common code and ticker symbol of the Shares**

Swiss security number:	002714864
ISIN:	CH0027148649
Common Code	026905214
SIX Swiss Exchange ticker symbol	SANN

## IX. DESCRIPTION OF THE OFFERING AND GENERAL INFORMATION

### A. Authorization

The issue of the Bonds and the issuance and delivery of Shares by the Issuer upon conversion of the Bonds was authorized by a resolution of the Board, passed on February 9, 2017.

### B. Issue and sale of the Bonds and underwriting

On February 10, 2017, the Issuer entered into a bond purchase agreement with the Lead Managers (the **Bond Purchase Agreement**) and on the same date, the Issuer entered into a paying and conversion agency agreement with Bank am Bellevue AG (referred to in this capacity as the **Paying and Conversion Agent**).

Pursuant to the terms of the Bond Purchase Agreement, the Lead Managers agreed to purchase and the Issuer agreed to sell the Bonds to the Lead Managers with the following quotas:

Lead Managers	% of aggregate Principal Amount	Aggregate Principal Amount	Number of Bonds	% of capital and voting rights upon conversion (rounded)*
Bank am Bellevue AG Seestrasse 16 8700 Küsnacht Switzerland	50 %	CHF 30,000,000	6,000	5.54 %
Kepler Cheuvreux SA 112 avenue Kléber 75784 Paris Cedex 16 France	50 %	CHF 30,000,000	6,000	5.54 %
Total	100 %	CHF 60,000,000	12,000	11.09 %

\* Based on the 6,262,798 Shares recorded in the Commercial Register of the Canton of Basel-Landschaft as of the date of this Prospectus.

The issue and sale of the Bonds shall be completed on the Settlement Date. Completion is subject to the satisfaction of certain conditions precedent and the right of the Lead Managers to terminate the Bond Purchase Agreement upon the occurrence of certain events.

### C. Source of Shares to be delivered upon conversion

The Shares to be delivered upon conversion of the Bonds are expected to be created as new Shares out of the Issuer's current conditional capital and, to the extent that such conditional capital should not be sufficient, the Issuer plans to propose to its shareholders to increase such conditional capital at its Annual General Meeting scheduled to be held on April 4, 2017, in such a way as to cover a conversion in full of all Bonds. Should the shareholders not approve such proposed increase, the Issuer plans to issue a sufficient number of Shares from its authorized capital to a subsidiary or to itself, such shares to be held as treasury shares until the Bonds are converted or redeemed. In the latter case, such unused Shares are planned to either be sold on the market or canceled.

### D. Use of net proceeds

Out of the net proceeds from the Offering, an amount corresponding to the interest payable on the Bonds for the first three years of their term will be put into escrow to be used for such interest payments (see Section IX.E). The remainder of the net proceeds, amounting to approximately CHF 49 million, is expected to be used primarily to fund the commercialization of Raxone® in the currently approved indication, to prepare the market entry and commercial launch in subsequent indications, for investment into further clinical trials of Raxone® and other product candidates and for other corporate purposes. The Lead Managers shall not have any responsibility for, or be obliged to concern themselves with, the application of the net proceeds from the Offering.



## **E. Escrow**

On the Payment Date the Issuer shall transfer to an account (the **Escrow Account**) with an escrow agent a sum equal to the full amount of interest payable on the Bonds on each of the first six Interest Payment Dates. Amounts standing to the credit of the Escrow Account may not be withdrawn other than as provided below.

Where Bonds are redeemed early, have been converted or are purchased and canceled, in any such case prior to third anniversary of the Payment Date, then (provided that an Event of Default or Potential Event of Default shall not have occurred and be continuing) there shall be released to the Issuer from the Escrow Account an amount equal to the interest that would otherwise have been paid in respect of the relevant Bonds on all Interest Payment Dates falling on or after the relevant redemption date (less any accrued interest paid in respect of such redemption), conversion date or relevant date of purchase and cancellation, as the case may be, up to and including the Interest Payment Date falling on third anniversary of the Payment Date.

Where a payment of interest is to be made in respect of the Bonds on or prior to third anniversary of the Payment Date, then there shall be released from the Escrow Account for payment to the relevant Bondholders an amount equal to such interest, as the case may be.

Any interest accrued on amounts standing to the credit of the Escrow Account pursuant to arrangements between the Issuer and the Escrow Agent will, provided that an Event of Default or Potential Event of Default shall not have occurred and be continuing, be released to the Issuer for its own account. Any negative interest accrued and debited to the Escrow Account shall be exclusively borne by the Issuer.

## **F. Sanctions on capital movements imposed by Switzerland**

Payments (including, without limitation, coupon and dividend payments) and the delivery of securities by Swiss companies to certain countries such as the Republic of Iraq, the Islamic Republic of Iran, the Central African Republic, Lebanon, Libya, Sudan, the Democratic Republic of Congo, Myanmar (Burma), Somalia, Syria, Guinea, Guinea-Bissau, Eritrea, Zimbabwe, Belarus, the Democratic People's Republic of Korea (North Korea), Yemen, Burundi, the Republic of South Sudan, to certain persons and organizations with connections to Osama bin Laden, the "Al-Qaeda" group or the Taliban, to certain persons in connection with the assassination of Rafik Hariri or to circumvent international sanctions in connection with the situation in Ukraine are currently restricted pursuant to sanctions imposed by the Swiss government.

## **G. Lock-up**

The Issuer has agreed with the Lead Managers, subject to customary exceptions, that it will not, for a period ending 90 calendar days after the Issue Date, without the prior written consent of the Lead Managers, (i) issue, offer, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, pledge, or otherwise transfer or dispose of (or publicly announce any such issuance, offer, sale or disposal), directly or indirectly, or file with the Securities and Exchange Commission a registration statement under the Securities Act relating to, any shares or any securities convertible into or exchangeable or exercisable for shares or warrants or other rights to purchase any Shares, or (ii) enter into any swap, hedge or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the Shares, whether any such transaction described in section (i) or (ii) above is to be settled by delivery of Shares or other securities of the Issuer, in cash or otherwise.

## **H. Listing agent**

In accordance with article 43 of the Listing Rules of the SIX Swiss Exchange, Bank am Bellevue AG was appointed by the Issuer as representative to lodge the listing application with regard to the Bonds with the SIX Swiss Exchange.

## **I. Availability of documents**

Copies of this Prospectus are available free of charge at Bank am Bellevue AG, Seestrasse 16, 8700 Küsnacht (Canton of Zurich), Switzerland (telephone number: +41 44 267 67 67; facsimile number: +41 44 267 67 50; email: [prospectus@bellevue.ch](mailto:prospectus@bellevue.ch)), during regular business hours.

For the entire duration of the Bonds, the annual and interim reports of the Issuer will be available free of charge at the Issuer's website at <http://www.santhera.com/investors-and-media/investor-toolbox/financial-reports>.

## **J. Recent material developments**

Other than as disclosed in this Prospectus, there has been no material change in the assets and liabilities, financial position or profits and losses of the Issuer since June 30, 2016. Please note the risk factor "*We may need to obtain substantial additional funding for purposes of our continuing operations and capital expenditures and to meet our obligations under the Bonds. We may not be able to redeem the Bonds or to pay interest thereon when due. Future financing may not be available and may significantly dilute our shareholders (in the case of equity or equity-linked financing) and/or restrict our flexibility to operate or meet the obligations under the Bonds (in the case of debt financing).*" in Section IV.A.1 and the risk factor "*The Issuer may be unable to redeem the Bonds.*" in Section IV.B concerning the Issuer's ability to fulfill its obligations.

## **K. Responsibility statement**

The Issuer accepts responsibility for all information contained in this Prospectus and hereby confirms that to the best of its knowledge the information stated herein is correct and no material facts or circumstances have been omitted.

## **X. SWISS TAXATION**

*The following discussion is a summary of certain material Swiss tax considerations. The discussion is based on legislation as of the date of this Prospectus. It does not aim to be a comprehensive description of all the Swiss tax considerations that may be relevant for a decision to invest in Bonds. The tax treatment for each investor depends on the particular situation. All investors are advised to consult with their professional tax advisors as to the respective Swiss tax consequences of the purchase, ownership, disposition, lapse, exercise or redemption of Bonds in the light of their particular circumstances.*

### **A. Taxation of the Bonds**

#### **1. Swiss federal withholding tax**

Each payment of interest on the Bonds as well as payments which qualify as interest for Swiss withholding tax purposes (such as a potential issue discount or repayment premium, but not the repayment of principal) will be subject to deduction of 35% Swiss federal withholding tax (*Verrechnungssteuer*) by the Issuer.

A holder of a Bond who resides in Switzerland and who is the beneficial owner of a taxable payment on the Bond at the time such payment is due and, in the case of a holder who is an individual holding the Bond privately, duly reports the gross taxable payment in his or her tax return, and, in the case of a holder who is a legal entity, or who is an individual holding the Bond as part of a business situated in Switzerland for which he or she is required to keep accounting books, includes such payment as earnings in the income statement, is entitled to a full refund of or a full tax credit for the Swiss federal withholding tax, provided that certain other conditions are met.

A holder of a Bond who is resident outside Switzerland and who during the taxation year has not engaged in a trade or business carried on through a permanent establishment or fixed place of business in Switzerland and at the time a taxable payment on the Bond is due is the beneficial owner of the taxable payment may be able to claim a full or partial refund of the Swiss federal withholding tax by virtue of the provisions of a double taxation treaty, if any, between Switzerland and the country of residence of the holder.

#### **2. Swiss stamp duties**

The issuance and sale of the Bonds on the Issue Date will not be subject to Swiss federal securities turnover tax (*Umsatzabgabe*) (primary market).

Secondary market dealings in Bonds may be subject to the Swiss securities turnover tax at a rate of up to 0.15% of the purchase price of the Bonds, but only if a securities dealer in Switzerland or Liechtenstein, as defined in the Swiss Federal Act on Stamp Duties (*Bundesgesetz über die Stempelabgaben*), is a party or an intermediary to the transaction and no exemption applies. An exemption applies, *inter alia*, for each party to a transaction in Bonds that is not resident in Switzerland or Liechtenstein.

#### **3. Swiss income taxation on principal or interest**

##### **a. Bonds held by non-Swiss holders**

Payments of interest and repayment of principal by the Issuer to, and gain realized on the sale or redemption of Bonds by, a holder of a Bond who is not a resident of Switzerland and who during the current taxation year has not engaged in a trade or business through a permanent establishment in Switzerland to which such Bond is attributable will not be subject to any Swiss federal, cantonal or communal income tax in respect of such Bonds.

**b. Bonds held as private assets by Swiss holders**

Individuals who are resident in Switzerland and who hold Bonds as private assets are required to include all payments of interest (including discount, if any) on such Bonds in their personal income tax return for the relevant tax period and will be taxable on any net taxable income for such tax period.

The Bonds should be classified as "classical" convertible bonds (*klassische Wandelanleihe*) as described in Circular No. 15 issued by the Swiss Federal Tax Administration on February 7, 2007, for Swiss federal income tax purposes. In most cantons, the tax treatment for cantonal and municipal income tax will correspond to the Swiss federal tax treatment. Consequently, a capital gain is a tax-free private capital gain. Conversely, a loss on the Bonds is a non-tax-deductible private capital loss.

**c. Bonds held as Swiss business assets (including by private persons classified as professional securities dealers)**

Individuals who hold Bonds as part of a business in Switzerland and Swiss resident corporate taxpayers and corporate taxpayers resident abroad holding Bonds as part of a permanent establishment in Switzerland are required to recognize the payments of interest and any gain realized on the sale or redemption of Bonds and any loss on the Bonds in their income statement for the respective tax period and will be taxable on any net taxable earnings for such period. The same taxation treatment also applies to Swiss resident individuals who, for income tax purposes, are classified as "professional securities dealers" for reasons of, *inter alia*, frequent dealings or leveraged investments in shares or other securities.

**B. Taxation of the Shares**

**1. Non-resident shareholders**

Shareholders who are not resident in Switzerland for tax purposes and who, during the respective taxation year, have not engaged in a trade or business carried on through a permanent establishment or fixed place of business located in Switzerland for tax purposes who are not subject to corporate or individual income taxation in Switzerland for any other reason (all such shareholders, **Non-Resident Shareholders**), will not be subject to any Swiss federal, cantonal and communal income tax on dividends (or repayments of nominal value) paid to them with respect to Shares.

**2. Resident private shareholders and domestic commercial shareholders**

Shareholders who are Swiss residents (all such shareholders, **Resident Private Shareholders**) and who hold Shares as private assets are required to include dividends (but not repayments of the nominal value of qualifying additional paid-in capital (*Kapitaleinlagereserven*) of Shares) in their personal income tax returns and are subject to Swiss federal, cantonal and communal income tax on any net taxable income for the relevant taxation period. Capital gains resulting from the sale or other disposition of Shares are not subject to Swiss federal, cantonal and communal income tax and, conversely, capital losses are not tax-deductible for Resident Private Shareholders.

Corporate and individual shareholders who hold Shares as part of a trade or business carried on in Switzerland or through a permanent establishment or fixed place of business located in Switzerland for tax purposes are required to recognize dividends (and repayment of nominal value) received on Shares and capital gains or losses realized on the sale or other disposition of Shares in their income statement for the respective taxation period and are subject to Swiss federal, cantonal and communal individual or corporate income tax, as the case may be, on any net taxable earnings for such taxation period. The same taxation treatment also applies to Swiss-resident private individuals who, for income tax purposes, are classified as "professional securities dealers" for reasons including frequent dealing, or leveraged investments, in shares and other securities (all shareholders referred to in this paragraph, **Domestic Commercial Shareholders**). Domestic Commercial Shareholders who are corporate taxpayers may be eligible for dividend relief (*Beteiligungsabzug*) in respect of dividends (and repayments of nominal value on Shares) if Shares held by them as part of a Swiss business have an aggregate market value of at least CHF 1 million.

### 3. Swiss federal withholding tax

Dividends (if any) paid on Shares that are not a repayment of the nominal value of qualifying equity reserves from capital contributions (*Kapitaleinlagereserven*) of Shares are, with their gross amount, subject to Swiss federal withholding tax (*Verrechnungssteuer*) at a rate of 35%. The Issuer is required to withhold the Swiss federal withholding tax from such dividends and remit it to the Swiss Federal Tax Administration.

The Swiss federal withholding tax on a dividend will be refundable in full to a Resident Private Shareholder and to a Domestic Commercial Shareholder who, in each case, among other things, as a condition to a refund, duly reports the dividend in his or her individual income tax return as income or recognizes the dividend in his or her income statement as earnings, as applicable.

A Non-Resident Shareholder may be entitled to a partial refund of the Swiss federal withholding tax on a dividend if such Non-Resident Shareholder's country of residence for tax purposes has entered into a bilateral treaty for the avoidance of double taxation with Switzerland and the conditions of such treaty are met. Such shareholders should be aware that the procedures for claiming treaty benefits (and the time required for obtaining a refund) might differ from country to country.

### 4. Swiss federal stamp taxes

The issuance of Shares upon Conversion is subject to 1% issuance stamp duty (*Emissionsabgabe*).

A transfer of Shares in a secondary market transaction where a bank or another securities dealer in Switzerland (as defined in the Swiss Federal Stamp Tax Act) acts as an intermediary or is a party to the transaction may be subject to Swiss securities transfer tax at an aggregate rate of up to 0.15% of the consideration paid for such Shares.

## C. Automatic exchange of information

On November 19, 2014, Switzerland signed the Multilateral Competent Authority Agreement, which is based on article 6 of the OECD/Council of Europe administrative assistance convention and is intended to ensure the uniform implementation of automatic exchange of information (the **AEOI**). The Federal Act on the International Automatic Exchange of Information in Tax Matters (the **AEOI Act**) entered into force on January 1, 2017. The AEOI Act is the legal basis for the implementation of the AEOI standard in Switzerland.

The AEOI is being introduced in Switzerland through bilateral agreements or multilateral agreements. The agreements have, and will be, concluded on the basis of guaranteed reciprocity, compliance with the principle of specialty (*i.e.*, the information exchanged may only be used to assess and levy taxes (and for criminal tax proceedings)) and adequate data protection.

Based on such multilateral agreements and bilateral agreements and the implementing laws of Switzerland, Switzerland will begin to collect data in respect of financial assets, including, as the case may be, Bonds or Shares, held in, and income derived thereon and credited to, accounts or deposits with a paying agent in Switzerland for the benefit of individuals resident in a EU member state or in a treaty state from, depending on the effective date of the respective agreement, 2017 or 2018, as the case may be, and begin to exchange such data in 2018 or 2019, as the case may be.

## **XI. ANNEXES**

**Annex A      Santhera Annual Report 2015**

**Annex B      Santhera Interim Condensed Report January to June 2016**

**Annex C      "Santhera Reports Preliminary Key Financial Figures for 2016 and Provides Corporate Update", press release of January 26, 2017**



# Annual Report **2015**

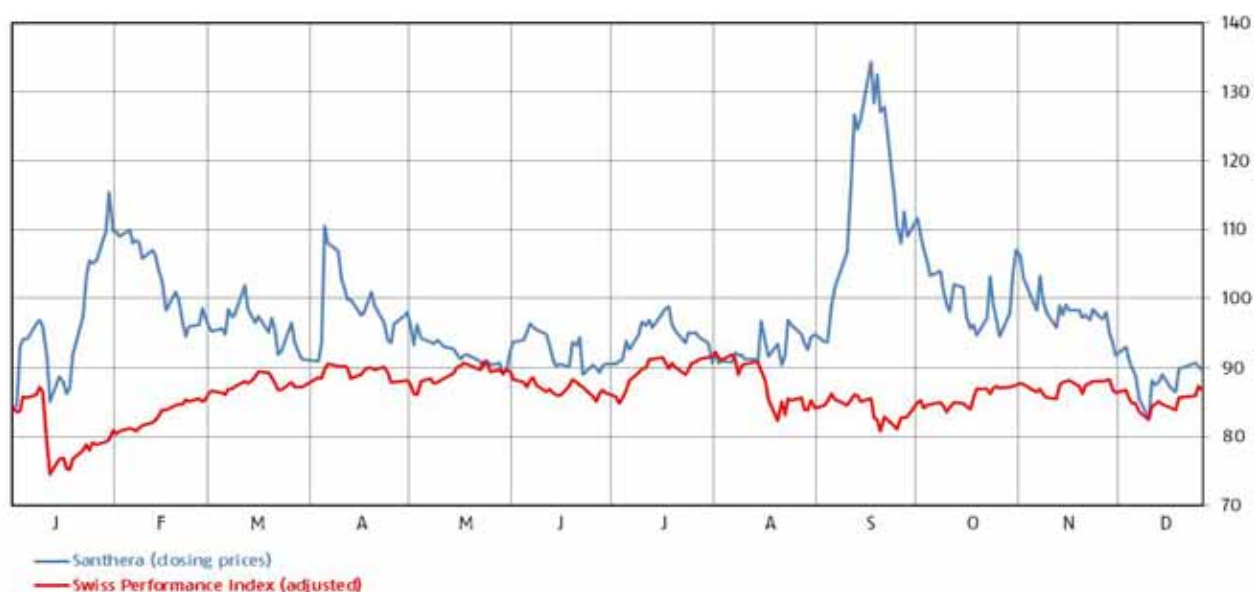


## Financial Key Figures

IFRS consolidated, in CHF thousands	2015	2014
Net sales	<b>4,321</b>	2,591
Operating expenses*	<b>35</b>	-10,860
Operating result*	<b>3,173</b>	-7,935
Net result*	<b>5,949</b>	-7,952
Basic earnings/loss per share (in CHF)	<b>1.11</b>	-1.69
Diluted earnings/loss per share (in CHF)	<b>1.08</b>	-1.69
Cash and cash equivalents at December 31	<b>76,859</b>	17,435
Net change in cash and cash equivalents	<b>59,424</b>	12,391

\* including reversal impairment on intangible assets and inventory of TCHF 27,104

## Share Price Development in 2015



High	CHF 134.40 (September 21, 2015)
Low	CHF 82.60 (December 12, 2015)
Share price performance in 2015	+5.5%
Share price at year-end	CHF 89.70
Market capitalization at year-end	CHF 562 million
Average volume	21,784 shares/day
(based on closing share prices)	



## Contents

Letter to Our Shareholders .....	3
Financial and Operations Highlights: Santhera Strengthened Operationally and Financially and Transitions to a Commercial Company .....	5
Pipeline Highlights: Santhera with Significant Progress in All Clinical Programs .....	7
Consolidated Financial Statements .....	10
Statutory Financial Statements .....	52
Compensation Report .....	65
Corporate Governance Report .....	78
Forward-looking Statements .....	92

# Letter to Our Shareholders

Dear Shareholders,

Of the many milestones Santhera reached in 2015, there is one that stands out: Commercialization! On September 9, the European Commission granted marketing authorization for our lead product Raxone® for the treatment of Leber's hereditary optic neuropathy (**LHON**) in all 28 EU member states, as well as Norway, Iceland and Liechtenstein. Shortly afterwards, on October 1, we launched Raxone in Germany, the first and largest EU market. By Q1 2016, sales were reported primarily for Germany and France, but first sales were also realized in Austria and Switzerland.

The positive market uptake was also reflected in the Company's financial performance: 2015 turned out to be the most successful financial year so far for Santhera. Net sales rose by 67% year-on-year to CHF 4.3 million driven by strong Raxone sales. The Company achieved a positive operating result and a positive net result of CHF 5.9 million influenced by a revaluation of intangible assets and inventory. The progress and prospects of Santhera were also met with excitement from shareholders and investors which enabled us to raise a total of CHF 82.4 million in 2015 in two tranches.

We also saw great progress in the development programs, especially with Raxone in its second indication, Duchenne muscular dystrophy (**DMD**). In April, a paper published in the *The Lancet*, one of the most prestigious medical journals worldwide, validated the positive findings of the pivotal phase III trial (**DELOS**) in DMD. This trial demonstrated the statistically significant and clinically relevant efficacy of Raxone treatment in preserving respiratory function, the loss of which is a main cause of death in this disease.

Last year, we further intensified collaborations with international research groups and patient organizations. For example, we are closely collaborating with the Cooperative International Neuromuscular Research Group (**CINRG**) to compare outcomes of the DELOS trial with natural history data. We are also pleased about our excellent working relationship with patient communities. For example, we have completed a patient and caregiver survey conducted jointly with Parent Project Muscular Dystrophy (**PPMD**), one of the largest and most impactful DMD patient organizations.

Santhera's near-term priorities are the continued commercial rollout of Raxone for the treatment of LHON across Europe. In parallel, the Company intensified preparations for regulatory filings for Raxone in DMD. In Europe, Santhera plans to submit a variation of the existing marketing authorization (**MA**) for Raxone already indicated for the treatment of LHON, while in the US we plan to submit a New Drug Application (**NDA**) to the FDA under the Fast-Track Designation granted last year.

We also continue to explore the use of Raxone in a third indication, primary progressive multiple sclerosis (**PPMS**), where we collaborate with the US National Institutes of Health (**NIH**) in a phase II clinical trial.

Additionally, we are furthering the clinical development of our second compound, omigapil, currently in a phase I (**CALLISTO**) trial, also at the NIH, for the treatment of congenital muscular dystrophies (**CMD**). This program is also supported by several patient organizations.

Our strong cash position (CHF 69.4 as of March 31, 2016) allows us to advance our development programs, support our transition to a fully integrated specialty pharmaceutical company and successfully launch Raxone in additional countries and indications following approval.

Operationally, Santhera's organization was further strengthened by the appointment of professionals to the Company's Executive Management. We are delighted that we can attract and rely on highly talented individuals, and we believe that the strength of the leadership team will enable us to build sustainable growth and long-term success for Santhera. By evolving our organization, we secure the in-house expertise needed to realize the full potential of the lead product Raxone and to build and advance Santhera's pipeline.

We remain fully committed to advancing Santhera as a specialty pharma company dedicated to the development and commercialization of urgently needed therapies to improve the lives of patients suffering from orphan mitochondrial and neuromuscular diseases.

Reaching the current position of Santhera demanded extraordinary efforts from all of us. We would like to thank every team member wholeheartedly for having taken on these challenges with determination and high commitment. Last year, the confidence placed in us by our shareholders began to pay off. Now we move forward as a commercial company, with sales in the first-ever approved treatment of a mitochondrial disease (**LHON**) and a strategy to obtain approval for DMD. We have the funds available to execute on these plans, while we continue pursuing our ongoing clinical programs with Raxone for PPMS and omigapil for CMD.

We appreciate the backing from you, our shareholders, and continue to be grateful for the fortitude, talent and dedication of our employees, the support offered by patient and research organizations and the courage of patients and their families participating in our trials.



Martin Gertsch  
Chairman



Thomas Meier  
Chief Executive Officer

## FINANCIAL AND OPERATIONS HIGHLIGHTS

# Santhera Strengthened Operationally and Financially and Transitions to a Commercial Company

**Top-line growth driven by increasing sales of Raxone following market approval.** Net revenue from product sales in 2015 reached CHF 4.3 million, a 67% increase compared to the previous year (2014: CHF 2.6 million). Net revenues in Q4 were CHF 1.9 million, representing 44% of reported annual revenue and a 136% increase over the average quarterly net sale for Q1–Q3 2015.

Strong top-line growth

Raxone for LHON was launched in Germany on October 1, 2015, and is continued to be sold in France under a temporary use permission until final grant of pricing and reimbursement. In addition, first sales are in the meantime also reported from Austria and Switzerland.

In January 2016, Santhera entered into a distribution and supply agreement with Ewopharma to launch Raxone for the treatment of LHON in eleven countries in Eastern Europe (Bulgaria, Croatia, Czech Republic, Hungary, Poland, Romania, Slovakia and Slovenia) and the Baltics (Estonia, Latvia and Lithuania). The agreement with Ewopharma represents an important step for Santhera and underscores its commitment to making Raxone available to patients across all EU member states.

**Positive operating result for 2015.** Development expenses increased to CHF 10.5 million (2014: CHF 5.9 million) due to costs associated with regulatory filings and study preparation. The launch preparations and market entry for LHON in Europe resulted in higher marketing and sales expenses of CHF 8.4 million (2014: CHF 0.6 million) as well as increased general and administrative expenses of CHF 8.2 million (2014: CHF 4.4 million). Approval of Raxone for LHON allowed for the reversal of a previous impairment charge of CHF 27.1 million (related to LHON development costs) and led to an improvement of the underlying operating result from CHF –23.9 to CHF 3.2 million (2014: CHF –7.9 million).

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

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

**Strong cash position.** As of December 31, 2015, Santhera had cash and cash equivalents of CHF 76.9 million (2014: CHF 17.4 million), which corresponds to a net year-on-year increase of CHF 59.4 million (2014: CHF 12.4 million). Santhera believes that, with this strong cash position and increased income from product sales expected in 2016, it has sufficient financial flexibility to support the development and commercialization of the current pipeline.

**Financial strength secures development and commercialization plans**

**Strengthening the organization.** Santhera added to the Executive Leadership Team, with the appointment of senior staff members Nicholas Coppard, PhD (SVP Head Development); Günther Metz, PhD (SVP Business Development); Oliver Strub (General Counsel and Secretary to the Board); Giovanni Stropoli (Chief Commercial Officer for Europe and Rest of World) and Christoph Rentsch (CFO) all reporting to the Company's CEO Thomas Meier, PhD. By year-end 2015, Santhera had 59 employees, corresponding to 53.3 full-time equivalents (end of March 2016: 64 employees corresponding to 58.4 full-time equivalents).

## PIPELINE HIGHLIGHTS

# Santhera with Significant Progress in All Clinical Programs

Santhera's lead compound is Raxone, an oral formulation of idebenone, which is a synthetic short-chain benzoquinone and cofactor for the enzyme NAD(P)H:quinone oxidoreductase (**NQO1**). The drug has a dual mode of action: idebenone enhances mitochondrial function and acts as a cell-protecting antioxidant. Numerous indications exist in which a defect in the mitochondrial electron transport chain and increase in oxidative stress is considered to be an underlying cause of the disease. Idebenone's pharmacological properties make it a development candidate of choice to treat such diseases.

Santhera is exploring Raxone's clinical and commercial potential, evaluating it in multiple mitochondrial and neuromuscular indications. In parallel, Santhera advanced the clinical development for omigapil, the second compound. The Company plans to expand its franchise in orphan indications in which treatments are scarce and regulators worldwide grant incentives to spur drug development.

### **Raxone is the first product approved for the treatment of LHON**

Raxone received marketing authorization in all 28 EU countries, as well as Norway, Iceland and Liechtenstein, in 2015, for the treatment of visual impairment in adolescent and adult patients with Leber's hereditary optic neuropathy. LHON is a rare, heritable, mitochondrial disease that leads to rapid, profound and, if untreated, usually permanent blindness in otherwise healthy patients. Raxone is the first approved therapy in the world for LHON and any mitochondrial disease.

**Raxone mitigates vision loss and promotes recovery of visual acuity in LHON**

The Company launched Raxone for LHON first in Germany, the largest EU market, and currently reports initial sales from other countries. Raxone is presently also sold in France under a temporary use permission until reimbursement is granted.

### **Preparations for regulatory filings for Raxone in DMD**

Santhera has an ongoing clinical program for Raxone in Duchenne muscular dystrophy (**DMD**), one of the most common and devastating types of inherited degenerative muscle weakness. Raxone can be used in DMD patients with any mutational or disease status.

Statistically significant and clinically relevant results of the successful phase III trial (**DEL05**) show that Raxone slows the loss of respiratory function, a common cause of morbidity and mortality, in DMD patients without concomitant glucocorticoid steroid therapy. Santhera and the leading US patient advocacy group Parent Project Muscular Dystrophy (**PPMD**) announced results of the first-ever patient benefit/risk survey in patients with DMD and caregivers of individuals with DMD. Participants prioritized treatment options that address cardiovascular and pulmonary complications of the disease. Data from this survey will be used as part of the Company's regulatory submissions as supportive evidence of the perceived therapeutic benefits of Raxone in DMD.

In the EU, Santhera plans to file for a Marketing Authorization Application (**MAA**) in DMD as a variation of the marketing approval granted for LHON. In the United States, the Company was granted Fast Track Designation and Rare Pediatric Disease Designation by the FDA last year. The Fast Track Designation for idebenone in DMD will allow us to request priority review when we file the planned New Drug Application (**NDA**).

**Raxone slows the loss of respiratory function, a frequent cause of mortality in DMD**

Given the clear medical need to address respiratory function decline in DMD patients, Santhera has decided to initiate a new clinical trial with Raxone in patients using glucocorticoid steroids (**SIDEROS**). A successful outcome of this trial will offer the potential for a future labeling extension to also treat patients using steroids.

In addition, Santhera has started to develop a novel oral transmucosal formulation for idebenone.

#### **Raxone in primary progressive multiple sclerosis (PPMS)**

Santhera also explores Raxone for the treatment of primary progressive multiple sclerosis (**PPMS**), a subtype of MS, in which patients suffer from a slow, but steady, functional decline with none of the distinct episodes of either acute relapse or regeneration that characterize the more common MS forms. We are collaborating with the National Institute of Neurological Disorders and Stroke (**NINDS**), part of the US National Institutes of Health, in a double-blind, placebo-controlled phase II trial investigating the efficacy of Raxone in PPMS (**IPPoMS**). The trial which combines a one-year observational run-in phase followed by a two-year placebo-controlled intervention period is fully enrolled. Final results of the IPPoMS trial in Raxone's third indication PPMS are expected late in 2017. Patients who complete this trial are offered participation in a one-year open label extension study.



### Santhera advances clinical program for second compound, omigapil, in congenital muscular dystrophies (CMD)

The second compound in Santhera's pipeline is omigapil for the treatment of congenital muscular dystrophies (CMD). CMD are inherited, severe neuromuscular diseases characterized by different forms of progressive and ultimately devastating loss of muscle tissue, frequently affecting young children. Currently, no treatment is available to slow down or stop progression of the disease. The clinical development of omigapil in the phase I trial (**CALLISTO**) is supported by a public-private partnership, including the NINDS, EndoStem (as part of the EU 7th Framework Program), and two patient organizations in Switzerland and the US. The study investigates the safety, tolerability and pharmacokinetic profile of a new liquid formulation of omigapil in pediatric and adolescent patients with CMD. The trial is expected to be completed in 2017.

**Omigapil – first investigational drug for CMD**



# Consolidated Financial Statements

## Contents

Consolidated Balance Sheet .....	12
Consolidated Income Statement .....	13
Consolidated Statement of Comprehensive Income .....	14
Consolidated Cash Flow Statement .....	15
Consolidated Statement of Changes in Equity .....	16
Notes to the Consolidated Financial Statements .....	17
1 General Information .....	17
2 Summary of Significant Accounting Policies .....	17
3 Critical Accounting Estimates, Assumptions and Judgments .....	26
4 Exchange Rates of Principal Currencies .....	26
5 Tangible Assets .....	27
6 Intangible Assets .....	28
7 Impairment Test for Intangible Assets .....	29
8 Prepaid Expenses and Accrued Income .....	30
9 Inventories .....	30
10 Trade and Other Receivables .....	30
11 Cash and Cash Equivalents .....	31
12 Share Capital .....	31
13 Deferred Taxes .....	33
14 Trade and Other Payables .....	34
15 Accrued Expenses .....	34
16 Commitments and Contingent Liabilities .....	34
17 Stock Option Plans .....	36
18 Segment and Geographic Information .....	39
19 Other Operating Income .....	40
20 Operating Expenses by Nature .....	40

21	Employee Expenses and Benefits .....	41
22	Financial Income/Expenses .....	44
23	Income Taxes .....	44
24	Earnings/Loss per Share .....	45
25	Related Party Transactions .....	45
26	Risk Management Objectives and Policies .....	46
27	Events After the Reporting Date .....	49
	Report of the Statutory Auditor on the Consolidated Financial Statements .....	50

## Consolidated Balance Sheet

	In CHF thousands	Notes	31.12.2015	31.12.2014 Restated <sup>1</sup>
<b>Assets</b>				
Tangible assets		5	398	132
Intangible assets		6	29,559	4,274
Financial assets long-term			190	85
Deferred tax assets		13	3,061	0
<b>Noncurrent assets</b>			<b>33,208</b>	<b>4,491</b>
Prepaid expenses and accrued income		8	1,513	376
Inventories		9	3,441	0
Trade and other receivables		10	2,131	720
Cash and cash equivalents		11	76,859	17,435
<b>Current assets</b>			<b>83,944</b>	<b>18,531</b>
<b>Total assets</b>			<b>117,152</b>	<b>23,022</b>
<b>Equity and liabilities</b>				
Share capital		12	6,263	4,974
Capital reserves and share premium			377,031	293,650
Retained earnings			-273,133	-279,083
Employee benefit reserve			-2,958	-1,287
Treasury shares		12	-177	-177
Other components of equity			-779	-762
<b>Total equity</b>			<b>106,247</b>	<b>17,315</b>
Pension liabilities		21	3,957	2,680
<b>Total noncurrent liabilities</b>			<b>3,957</b>	<b>2,680</b>
Trade and other payables		14	3,666	2,166
Accrued expenses		15	3,282	861
<b>Total current liabilities</b>			<b>6,948</b>	<b>3,027</b>
<b>Total liabilities</b>			<b>10,905</b>	<b>5,707</b>
<b>Total equity and liabilities</b>			<b>117,152</b>	<b>23,022</b>

<sup>1</sup> Some positions have been restated, see note 2 "Correction of errors".

## Consolidated Income Statement

For the year ended December 31, in CHF thousands	Notes	2015	2014 Restated <sup>1</sup>
Net sales	18	4,321	2,591
Cost of goods sold		-1,371	-199
Other operating income	19	188	533
Development	20	16,651	-5,876
<i>Of which Development expenses</i>	20	-10,453	-5,876
<i>Of which reversal impairment on intangible assets and inventory</i>	20	27,104	0
Marketing and sales	20	-8,356	-580
General and administrative	20	-8,244	-4,395
Other operating expenses	20	-16	-9
<b>Operating expenses</b>	<b>20</b>	<b>35</b>	<b>-10,860</b>
<b>Operating result</b>		<b>3,173</b>	<b>-7,935</b>
Financial income	22	416	54
Financial expenses	22	-655	-69
<b>Result before taxes</b>		<b>2,934</b>	<b>-7,950</b>
Income taxes	23	3,015	-2
<b>Net result</b>		<b>5,949</b>	<b>-7,952</b>
Basic earnings/loss per share (in CHF)	24	1.11	-1.69
Diluted earnings/loss per share (in CHF)	24	1.08	-1.69

<sup>1</sup> Some positions have been restated, see note 2 "Correction of errors".

## Consolidated Statement of Comprehensive Income

For the year ended December 31, in CHF thousands	Notes	2015	2014 Restated <sup>1</sup>
<b>Net result</b>		<b>5,949</b>	<b>-7,952</b>
<i>Items never to be reclassified to net income in subsequent periods:</i>			
Actuarial gains/(losses) on defined benefit plans	21	-1,671	-1,692
<i>Items to be reclassified to net income in subsequent periods:</i>			
Currency translation differences		-16	5
<b>Other comprehensive result</b>		<b>-1,687</b>	<b>-1,687</b>
<b>Total comprehensive result</b>		<b>4,262</b>	<b>-9,639</b>

<sup>1</sup> Some positions have been restated, see note 2 "Correction of errors".

## Consolidated Cash Flow Statement

For the year ended December 31, in CHF thousands	Notes	2015	2014 Restated <sup>1</sup>
Result before taxes		<b>2,934</b>	<b>-7,950</b>
Depreciation of tangible assets	5	85	66
Reversal of impairment on intangible assets	2, 6	-26,157	0
Amortization of intangible assets	6	1,037	9
Expenses for share options	17, 20	2,040	1,177
Change in pension liabilities	21	-394	-9
Change in deferred taxes	13	-3,061	0
Taxes paid		-46	-2
Change in net working capital		942	634
Total financial result	22	239	15
Interest received	22	2	4
Interest paid	22	-11	-7
<b>Cash flow from operating activities</b>		<b>-22,390</b>	<b>-6,063</b>
Investments in tangible assets	5	-350	-160
Investments in intangible assets	6	-165	-47
Investments in other financial assets		-104	0
<b>Cash flow from investing activities</b>		<b>-619</b>	<b>-207</b>
Capital increases from options exercised	12	2,127	3,247
Proceeds from sale of treasury shares SEDA <sup>2</sup>	12	0	1,444
Capital increase private placement	12	54,870	1,000
Capital increase	12	27,576	13,294
Cost of issuance of share capital		-1,943	-324
<b>Cash flow from financing activities</b>		<b>82,630</b>	<b>18,661</b>
Effects of exchange rate changes on cash and cash equivalents		-197	0
<b>Net increase/(decrease) in cash and cash equivalents</b>		<b>59,424</b>	<b>12,391</b>
Cash and cash equivalents at January 1		17,435	5,044
<b>Cash and cash equivalents at December 31</b>		<b>76,859</b>	<b>17,435</b>

<sup>1</sup> Some positions have been restated, see note 2 "Correction of errors".

<sup>2</sup> 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	Em- ployee benefit reserve	Treas- ury shares	Trans- lation differ- ences	Total
<b>Balance at January 1, 2014 (as previously reported)</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>
Correction	2	0	0	-5,827	0	0	5,837	10
<b>Balance at January 1, 2014 (after correction<sup>1</sup>)</b>		<b>3,934</b>	<b>274,896</b>	<b>-271,131</b>	<b>405</b>	<b>-221</b>	<b>-767</b>	<b>7,116</b>
Net result <sup>1</sup>		0	0	-7,952	0	0	0	-7,952
Other comprehensive result	21	0	0	0	-1,692	0	5	-1,687
<b>Total comprehensive result for the period</b>		<b>0</b>	<b>0</b>	<b>-7,952</b>	<b>-1,692</b>	<b>0</b>	<b>5</b>	<b>-9,639</b>
Share-based payment transactions <sup>1</sup>	17, 20	0	1,177	0	0	0	0	1,177
Capital increase from options exercise	12	197	3,050	0	0	0	0	3,247
Capital increase SEDA <sup>2</sup>	12	355	1,045	0	0	44	0	1,444
Capital increase private placement	12	288	712	0	0	0	0	1,000
Capital increase	12	200	13,094	0	0	0	0	13,294
Cost of issuance of share capital		0	-324	0	0	0	0	-324
<b>Balance at December 31, 2014<sup>1</sup></b>		<b>4,974</b>	<b>293,650</b>	<b>-279,083</b>	<b>-1,287</b>	<b>-177</b>	<b>-762</b>	<b>17,315</b>
<b>Balance at January 1, 2015</b>		<b>4,974</b>	<b>293,650</b>	<b>-279,083</b>	<b>-1,287</b>	<b>-177</b>	<b>-762</b>	<b>17,315</b>
Net result		0	0	5,949	0	0	0	5,949
Other comprehensive result	21	0	0	0	-1,671	0	-16	-1,687
<b>Total comprehensive result for the period</b>		<b>0</b>	<b>0</b>	<b>5,949</b>	<b>-1,671</b>	<b>0</b>	<b>-16</b>	<b>4,262</b>
Share-based payment transactions	17, 20	0	2,040	0	0	0	0	2,040
Capital increase from options exercise	12	399	1,728	0	0	0	0	2,127
Capital increase private placement	12	590	54,280	0	0	0	0	54,870
Capital increase	12	300	27,276	0	0	0	0	27,576
Cost of issuance of share capital		0	-1,943	0	0	0	0	-1,943
<b>Balance at December 31, 2015</b>		<b>6,263</b>	<b>377,031</b>	<b>-273,134</b>	<b>-2,958</b>	<b>-177</b>	<b>-778</b>	<b>106,247</b>

<sup>1</sup> Some positions have been restated, see note 2 "Correction of errors".

<sup>2</sup> 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 11, 2016. They are subject to approval by the Annual Shareholders' Meeting (**ASM**) on May 11, 2016.

## 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.



## 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 accounts further include the wholly owned subsidiaries of Santhera Pharmaceuticals (Schweiz) AG: Santhera Pharmaceuticals (Liechtenstein) AG, Ruggell, Fürstentum Liechtenstein; Santhera (Italy) S.r.l., Milano, Italy; Santhera (Germany) GmbH, Munich, Germany; Santhera (Netherlands) B.V., Nieuwegein, The Netherlands; and Santhera (UK) Limited, London, United Kingdom.

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.

## Correction of errors

In the context of the annual impairment testing for its intangible assets, Santhera became aware that the previously impaired intangible asset "Raxone/Catena" had been reported in EUR rather than CHF, generating exchange differences in other comprehensive income that had accumulated in other components of equity over the years to CHF 5.8 million.

The comparative figures for the year 2014 were corrected retrospectively in accordance with IAS 8. The correction of the error did not have an impact on the consolidated income statement and consolidated cash flow statement. The overall net impact on the consolidated balance sheet was considered not material and no third balance sheet as at January 1, 2014, has been presented.

In the context of the preparation of the compensation report 2015, Santhera became aware that part of the expenses for employee stock options granted in 2015 should have been accounted for in the year 2014. Although these options were only granted in 2015, they formed part of the bonus award to employees for the year ended December 31, 2014, and employees had been rendering services in 2014 in expectation of the annual bonus allocation. Executive management determined that the award should have been expensed starting from 2014 until the date of vesting.

The comparative figures for the year 2014 were corrected retrospectively in accordance with IAS 8. The correction of this error did not have a net impact on the consolidated balance sheet, consolidated cash flow statement and consolidated statement of changes in equity. The overall impact on the consolidated income statement of 2014 is an increase of operating expenses of TCHF 418.

The impact on the relevant positions of the Group's prior year consolidated balance sheet, income statement and consolidated statement of comprehensive income is shown below:

### Consolidated balance sheet

In CHF thousands	January 1, 2014 reported	Intangible assets	Employee stock options	January 1, 2014 restated
Assets:				
Intangible assets	4,225	10	-	4,235
Equity:				
Retained earnings	-265,304	-5,827	-	-271,131
Other components of equity	-6,604	5,837	-	-767
Total equity	7,106	10	-	7,116

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

	2014 reported	Intangible assets	Employee stock options	2014 restated
Development	-5,695	-	-181	-5,876
Marketing and sales	-574	-	-6	-580
General and administrative	-4,164	-	-231	-4,395
Operating expenses	-10,442	-	-418	-10,860
Operating result	-7,517	-	-418	-7,935
Result before taxes	-7,532	-	-418	-7,950
Net result	-7,534	-	-418	-7,952
Currency translation differences	-62	67	-	5
Total comprehensive result	-9,288	67	-418	-9,639

### Consolidated balance sheet

In CHF thousands	December 31, 2014 reported	Intangible assets	Employee stock options	December 31, 2014 restated
Assets:				
Intangible assets	4,197	77	-	4,274
Equity:				
Capital reserves and share premium	293,232	-	418	293,650
Retained earnings	-272,838	-5,827	-418	-279,083
Other components of equity	-6,666	5,904	-	-762
Total equity	17,238	77	-	17,315

## Changes in accounting policies

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

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

- IAS 19 (Amendments) Defined Benefit Plans: Employee Contributions (effective July 1, 2014)
- Annual Improvements (2011–2013 Cycle/2010–2012 Cycle) (effective July 1, 2014)

The IASB has issued a number of amendments to existing standards as well as new standards and interpretations which will become effective in future periods. Many of these changes are not relevant for Santhera or are currently not expected to have a material impact on Santhera's accounting policies or financial performance but may lead to additional disclosures. The most important change relates to IFRS 15 Revenue from Contracts with Customers and IFRS 16 Leases.

The Group is currently evaluating the impact of these changes on the Group's financial reporting:

- IFRS 9 (2014) Financial Instruments (effective January 1, 2018)
- IFRS 15 Revenue from Contracts with Customers (effective January 1, 2018)
- IFRS 16 Leases (effective January 1, 2019)
- IAS 1 (Amendments) Disclosure Initiative (effective January 1, 2016)
- IAS 7 (Amendments) Disclosure Initiative (effective January 1, 2017)
- IAS 16 and IAS 38 (Amendments) Clarification of Acceptable Methods of Depreciation and Amortization (effective January 1, 2016)
- Annual Improvements (2012–2014 Cycle) (effective January 1, 2016)

## Segment reporting

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

## Foreign currency translations

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

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

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

### **Intangible assets**

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

#### **Patents**

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

#### **IT software**

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

### **Tangible assets**

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

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

### **Impairment of assets**

Assets include intangible assets not yet available for use, intangible assets with finite useful lives and tangible assets. In general and in accordance with the terms of IFRS, assets not in use are capitalized at cost in the balance sheet and reviewed for impairment at least annually. Impairment testing is performed at the same time every year or whenever there is an indication that the asset may be impaired. A change to finite useful life is accounted for as a change in an accounting estimate for the respective asset. Testing for indicators of impairment is done at the end of each reporting period.

### **Trade and other receivables**

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

### **Inventories**

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

### **Financial assets**

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

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

This category has two subcategories: financial assets held for trading and those designated at fair value through profit or loss upon initial recognition. A financial asset is classified in this category if acquired principally for the purpose of selling in the short term. 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.

### **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 in the capital reserves and share premium as a deduction, net of tax, from the proceeds.

## Financial liabilities

Santhera classifies its financial liabilities into two categories:

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

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

### *Other liabilities measured at amortized costs*

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

## Income taxes

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

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

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

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

## Earnings/loss per share

Basic earnings/loss per share are calculated by dividing the net profit/loss attributable to owners of ordinary Shares of the Company by the weighted average number of Shares outstanding during the reporting period. Diluted earnings per share are calculated by dividing the net profit attributable to owners of ordinary Shares of the Company by the weighted average number of shares issued and outstanding during the reporting period adjusted for Shares held as treasury shares (purchased at market) and the number of potential shares from stock option plans.

## Employee benefits

### *Post-retirement benefits*

Santhera operates both defined benefit and defined contribution pension schemes.

- Defined benefit scheme:

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

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

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

- Defined contribution schemes:

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

### *Share-based compensation*

Santhera has established several stock option plans to align the long-term interests of the members of the Board, the Executive Management, employees and selected consultants who are eligible to participate. Options granted under all plans are equity-settled. The fair value of employee stock options is determined at the grant date and recognized as personnel expense over the period Santhera receives services for each award. Where stock option awards are modified as a minimum, the expenses are recognized as if no terms had been modified; modifications which increase the fair value of options are expensed additionally. Unless determined otherwise by the Board, terminations of employment by the employer are treated as forfeiture and any previously accumulated share-based payment expenses for unvested awards are reversed.

## **Provisions**

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

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

## **Revenue recognition**

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

### *Revenue from out-licensing*

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

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

Such revenue is recognized in accordance with respective agreements.

### *Revenue from royalties*

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

### *Interest income*

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

## **Development / intangible assets**

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



### 3 Critical Accounting Estimates, Assumptions and Judgments

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

- Measurement and impairment testing of intangible assets, see note 7 *"Impairment Test for Intangible Assets"*.
- Measurement and impairment testing of inventory, see note 9 *"Inventories"*.
- Personnel expenses from share-based payments in accordance with IFRS 2, i.e. estimates regarding the valuation of employee stock options when granted or modified, see note 17 *"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 21 *"Employee Expenses and Benefits"*.

### 4 Exchange Rates of Principal Currencies

	Income statement in CHF average rates		Balance sheet in CHF year-end rates	
	2015	2014	2015	2014
1 Euro (EUR)	1.0681	1.2146	1.0826	1.2028
1 US dollar (USD)	0.9624	0.9152	0.9927	0.9895
1 British pound (GBP) <sup>1</sup>	1.4708	n/a	1.4694	n/a
1 Canadian dollar (CAD)	0.7534	0.8287	0.7157	0.8510

<sup>1</sup> Since annual reporting 2015.

## 5 Tangible Assets

In CHF thousands	Equipment	IT hardware	Leasehold improvements	2015
<b>Cost</b>				
At January 1	185	334	42	561
Additions	61	286	3	350
Disposals	-22	-53	0	-75
Exchange differences	1	0	0	1
<b>At December 31</b>	<b>225</b>	<b>567</b>	<b>45</b>	<b>837</b>
<b>Accumulated depreciation and impairment losses</b>				
At January 1	177	211	41	429
Additions	11	73	1	85
Disposals	-22	-53	0	-75
Exchange differences	0	0	0	0
<b>At December 31</b>	<b>166</b>	<b>231</b>	<b>42</b>	<b>439</b>
<b>Net book value</b>	<b>59</b>	<b>336</b>	<b>3</b>	<b>398</b>

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

## 6 Intangible Assets

In CHF thousands	Raxone/ Catena	Fipamezole	IT software/ patents	2015
<b>Cost</b>				
At January 1	30,387	3,918	312	<b>34,617</b>
Additions	0	0	165	<b>165</b>
<b>At December 31</b>	<b>30,387</b>	<b>3,918</b>	<b>477</b>	<b>34,782</b>
<b>Accumulated amortization and impairment losses</b>				
At January 1	26,157	3,918	268	<b>30,343</b>
Additions	1,013	0	24	<b>1,037</b>
Reversal impairment	-26,157	0	0	<b>-26,157</b>
<b>At December 31</b>	<b>1,013</b>	<b>3,918</b>	<b>292</b>	<b>5,223</b>
<b>Net book value</b>	<b>29,374</b>	<b>0</b>	<b>185</b>	<b>29,559</b>

In CHF thousands	Raxone/ Catena	Fipamezole	IT software/ patents	2014
<b>Cost</b>				
At January 1 (after correction)	30,387	3,918	292	<b>34,597</b>
Additions	0	0	47	<b>47</b>
Disposals	0	0	-28	<b>-28</b>
Exchange differences	0	0	1	<b>1</b>
<b>At December 31</b>	<b>30,387</b>	<b>3,918</b>	<b>312</b>	<b>34,617</b>
<b>Accumulated amortization and impairment losses</b>				
At January 1 (after correction)	26,157	3,918	287	<b>30,362</b>
Additions	0	0	9	<b>9</b>
Disposals	0	0	-28	<b>-28</b>
Exchange differences	0	0	0	<b>0</b>
<b>At December 31</b>	<b>26,157</b>	<b>3,918</b>	<b>268</b>	<b>30,343</b>
<b>Net book value</b>	<b>4,230</b>	<b>0</b>	<b>44</b>	<b>4,274</b>

<sup>1</sup> Some positions have been corrected, see note 2 "Correction of errors".

As a result of receiving the European marketing authorization in September 2015, Santhera determined the recoverable amount of its previously impaired intangible asset "Raxone/Catena". This resulted in a reversal of impairment of CHF 26.2 million which has been recorded under Development expenses (see note 7 "Impairment Testing of Intangible Assets").

## 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. If there are indications that an impairment loss recognized in a previous period no longer exists or may have decreased, the recoverable amount of the asset or cash-generating unit is determined.

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, 2015, the market capitalization of Santhera was above the book value of its equity and therefore not indicating a potential impairment of the intangible assets.

Raxone/Catena forms the basis of the Raxone/Catena development projects. The intangible asset was previously impaired in 2012.

Santhera's main intangible asset was not available for use at the beginning of the reporting period and did not generate cash flows on a stand-alone basis. Based on the European marketing authorization, received in September 2015, an impairment test was performed which resulted in the full reversal of the previous impairments and an increase in the carrying amount of the intangible asset to its recoverable amount of CHF 29.4 million. At the same time the intangible asset formerly not available for use was transformed into an asset available for use with a finite useful live of 10 years. Amortization of the asset began in September 2015.

Management used the risk-adjusted Net Present Value (**rNPV**) model taking into consideration the expected cumulative probability of reaching the market to calculate recoverable amount. This is a customary model for the valuation of pharmaceutical intangibles. The rNPV model considers the net cash flows over the expected lifetime of the products based on the lifetime of the underlying intellectual property or the market exclusivity granted through orphan drug protection. For the purpose of estimating these cash flows, Santhera made estimates about the expected revenues based on estimated market size and patient numbers, expected market penetration rates, product pricing and project- or product-related costs. Santhera's strategic focus is on LHON and DMD. Since LHON is the most advanced program with a market authorization in the EU, received in 2015, the impairment test for 2015 is entirely based on project cash flows derived from this program in Europe (equal treatment end of 2014).

The key assumptions for the tests were as follows:

	2015	2014
Discount rate (WACC)	15%	15%
Market growth rate (terminal value)	0%	0%
Probability of reaching market	100%	>50%
Period of projected cash flows	5 years	5 years

## 8 Prepaid Expenses and Accrued Income

	In CHF thousands	2015	2014
Prepayments		1,467	47
Accrued income		0	323
Other accruals		46	6
<b>Total at December 31</b>		<b>1,513</b>	<b>376</b>

## 9 Inventories

	In CHF thousands	2015	2014
Raw material (active pharmaceutical ingredients)		1,552	0
Semi-finished goods		1,551	0
Finished goods		338	0
<b>Total at December 31</b>		<b>3,441</b>	<b>0</b>

Due to the marketing authorization received in 2015 for LHON in the EU, a reversal of impairment in the amount of TCHF 947 was recognized under development expenses (TCHF 164 less than reported in the interim reporting 2015 due to reconsiderations).

## 10 Trade and Other Receivables

	In CHF thousands	2015	2014
Trade receivables		1,466	610
Other receivables		665	110
<b>Total at December 31</b>		<b>2,131</b>	<b>720</b>

Trade receivables in 2015 mainly result from product sales, see note 18 *“Segment and Geographic Information”*. Other receivables consist mainly of amounts due from the government for tax reimbursements (e.g. VAT). 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, 2015, and 2014.

## 11 Cash and Cash Equivalents

	In CHF thousands	2015	2014
Cash at banks and on hand			
In CHF		69,570	16,416
In EUR		6,270	724
In GBP		772	0
In USD		191	267
In CAD		56	28
<b>Total at December 31</b>		<b>76,859</b>	<b>17,435</b>

Short-term money market deposits

In CHF	45,000	10,002
--------	--------	--------

## 12 Share Capital

### Ordinary share capital

As of January 1, 2014, the share capital amounted to CHF 3,934,049, divided into 3,934,049 Shares at a nominal value of CHF 1 each. During 2014, 197,126 Shares were issued from conditional capital upon the exercise of stock options under the EIP, BSOP 2011, ESOP 2004, ESOP 2008 and ESOP 2010. 355,000 additional Shares were issued from conditional capital under the Standby Equity Distribution Agreement (**SEDA**) (see below). 288,317 Shares were issued from authorized capital for a private placement and 200,000 Shares were issued from conditional capital for sale by an independent broker. As a result, as of December 31, 2014, the share capital amounted to CHF 4,974,492, divided into 4,974,492 Shares at a nominal value of CHF 1 each.

During 2015, 398,306 Shares were issued from conditional capital upon the exercise of stock options. 590,000 Shares were issued from authorized capital for a private placement (accelerated bookbuilding) and 300,000 Shares were issued from conditional capital for sale by an independent broker. As a result, as of December 31, 2015, the share capital amounted to CHF 6,262,798, divided into 6,262,798 Shares at a nominal value of CHF 1 each.

### *Standby Equity Distribution Agreement*

In October 2013, Santhera entered into a SEDA with Yorkville Advisors Global Master SPV Ltd., New York, US (**YA Global**). Under the terms of the agreement, YA Global has committed to provide up to CHF 10 million in equity financing during a period of three years. The SEDA has been established in order to support the funding of Santhera's operations. It remains at the sole discretion of the Company to determine the timing of the funding. During 2015 no draws were made. During 2014, Santhera drew a total of CHF 1.4 million from YA Global for which 399,425 Shares were delivered. The remaining amount for equity financing with YA Global amounts to CHF 8.1 million.

*Treasury shares*

In connection with the liquidation of Oy Juvantia Pharma, Turku, Finland (**Juvantia**), a company acquired in 2009, Santhera received 8,028 Shares from former Juvantia shareholders. These treasury shares serve as pledge from the former owners of Juvantia for compensation of a potential tax claim related to pre-acquisition activities of Juvantia. Final tax assessment by the Finnish authorities is expected to be obtained mid- to end 2016.

**Authorized share capital**

On the occasion of the ASM on May 11, 2015, the shareholders approved an extension of the authorized share capital of the Company. The Board is authorized to increase the share capital at any time until May 11, 2017, through the issuance of up to 1,500,000 Shares with a nominal value of CHF 1 each.

On December 2, 2015, 590,000 Shares were issued in an accelerated bookbuilding process. As a result, as of December 31, 2015, the Board is authorized to increase the share capital at any time until May 11, 2017, through the issuance of up to 910,000 Shares with a nominal value of CHF 1 each. An increase in partial amounts is permitted. For each such increase, the Board has to determine the issue price, the type of payment, the date of issuance of new Shares, the conditions for the exercise of pre-emptive rights and the beginning date for dividend entitlement.

**Conditional share capital**

At the ASM on May 11, 2015, the shareholders additionally approved a maximum increase of the share capital by an aggregate amount of CHF 800,000 (2014: CHF 800,000) through the issuance of a maximum of 800,000 (2014: 800,000) 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.

In addition, the shareholders approved a maximum increase of the share capital by an aggregate amount of CHF 950,000 (2014: CHF 600,000) through the issuance of a maximum of 950,000 (2014: 600,000) Shares with a nominal value of CHF 1 per Share by the exercise of option and/or conversion rights which can be granted in connection with the issuance of bonds, similar obligations or other financial instruments by the Company or another Group company, and/or by the exercise of options which are granted by the Company or another Group company. In the case of the issue of bonds, similar obligations or other financial instruments linked with option and/or conversion rights, and in the case of the issue of option rights, the pre-emptive right of shareholders is excluded.

As of December 31, 2015, the Company had a conditional share capital, pursuant to the above provisions, whereby the share capital may be increased by

- a maximum amount of CHF 401,694 (2014: CHF 604,029) through the issuance of up to 401,694 (2014: 604,029) Shares, under the exclusion of shareholders' pre-emptive rights, for option rights being exercised under the Company's stock option plans, see note 17 "*Stock Option Plans*"; and
- a maximum amount of CHF 650,000 (2014: CHF 600,000) by issuing up to 650,000 (2014: 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	2015	2014
Temporary differences on inventory		3,061	0
<b>Deferred tax assets recognized</b>		<b>3,061</b>	<b>0</b>
Temporary differences on intangible assets		5,167	831
Tax loss carryforwards		-5,167	-831
<b>Deferred tax liabilities recognized</b>		<b>0</b>	<b>0</b>
Tax loss carryforwards		269,696	317,170
Of which recorded		-25,834	-4,153
<b>Of which unrecorded</b>		<b>243,862</b>	<b>313,017</b>
Expiring in			
1 year		9,738	47,276
2 years		5,832	9,738
3 years		22,671	5,832
4 years		177,282	22,671
5 years		0	188,257
More than 5 years		0	11,265
Without expiration		28,339	27,978
<b>Total unrecorded tax loss carryforwards</b>		<b>243,862</b>	<b>313,017</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 3,957 per December 31, 2015, and TCHF 2,680 per December 31, 2014, respectively).



## 14 Trade and Other Payables

	In CHF thousands	2015	2014
Trade payables		3,290	1,654
Other payables (nonfinancial)		376	512
<b>Total at December 31</b>		<b>3,666</b>	<b>2,166</b>

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

## 15 Accrued Expenses

	In CHF thousands	2015	2014
Development programs		700	422
Liabilities to employees		905	137
Accruals for pricing and reimbursement		673	0
Accrued marketing and sales expenses		671	38
Expenses for audit, consulting and other		333	264
<b>Total at December 31</b>		<b>3,282</b>	<b>861</b>

## 16 Commitments and Contingent Liabilities

### Commitments

#### *Commitment for operating lease (non-cancellable)*

	In CHF thousands	2015	2014
Within 1 year		398	125
After 1 year through to 5 years		278	0
After 5 years		15	0
<b>Total at December 31</b>		<b>691</b>	<b>125</b>

### Contingent liabilities

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

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

Takeda is eligible to receive up to EUR 1.0 million as a percentage from future income generated by Santhera to offset this waiver.

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

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

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

#### *License agreement with Novartis*

On June 30, 2007, Santhera entered into an agreement with Novartis Pharma AG, Basel, Switzerland (**Novartis**), under which it in-licensed *omigapil*. Santhera develops *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.

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

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

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

As part of its ordinary course of business, Santhera has entered into several contracts for e.g. clinical or technical development services. Commitments are within current market prices and can be terminated at the Company's discretion.

In order to meet its requirements for market supply, potential launch and inventory risk management purposes (security stock), Santhera entered into commitments for the purchase of active pharmaceutical ingredients in the amount of up to EUR 6.3 million (to be delivered in 2016).

### **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.

## 17 Stock Option Plans

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

### Executive Incentive Plan (EIP)

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

*Options outstanding, exercised or forfeited under the EIP*

Number of options				2015				2014
Plan	Exer- cised	Forfeit- ed	Expired	Out- standing	Exer- cised	Forfeit- ed	Expired	Out- standing
EIP	790	0	0	1,210	42,598	0	0	2,000

### Employee Stock Option Plans

The Company adopted the ESOP 2004, ESOP 2008, ESOP 2010 and ESOP 2015 (collectively the **ESOPs**) to provide incentives to members of the Board, the Executive Management and employees helping to ensure their commitment to Santhera over the long term. Since January 1, 2015, new grants have been allocated under the ESOP 2015. Option grants are made from time to time at the discretion of the Board or as contractually agreed with employees. The ESOPs 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. In general, 50% of the stock options vest on the second anniversary, 25% on the third anniversary and the remaining 25% on the fourth anniversary of the grant date. At the end of the option term, i.e. after a period of 10 years as from the grant date, unexercised stock options expire without value. Subject to the provisions of the ESOP 2004, vested stock options of employees leaving the Company in good faith do not lapse. Under the ESOP 2008 and ESOP 2010 vested stock options of employees leaving the Company in good faith expire six months after the termination date of the employment. Under the ESOP 2015 vested stock options of employees leaving the Company in good faith do not expire. Unvested stock options of employees leaving the Company are forfeited under all stock option plans.

*Options outstanding, exercised, forfeited or expired under ESOPs*

Number of options					2015
	Exercised	Granted	Forfeited	Expired	Outstanding
ESOP 2004	9,045	0	0	0	26,091
ESOP 2008	0	0	0	0	1,500
ESOP 2010	358,971	0	2,700	0	47,773
ESOP 2015	0	142,260	2,000	0	140,260
<b>Total</b>	<b>368,016</b>	<b>142,260</b>	<b>4,700</b>	<b>0</b>	<b>215,624</b>

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

**Board Stock Option Plans**

The Company adopted the BSOP 2011 and BSOP 2015 (collectively the **BSOPs**) to provide incentives to members of the Board. Since January 1, 2015, new grants have been made under the BSOP 2015. 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, or b) the closing share price on the SIX at each grant date. In general, 50% of the stock options vest on the second anniversary, 25% on the third anniversary and the remaining 25% on the fourth anniversary of the grant date. At the end of the option term, i.e. after a period of 10 years as from the grant date, unexercised stock options expire without value. Under the BSOP 2011 vested stock options of Board members leaving the Board in good faith expire six months after the termination date of them being a member of the Board while unvested stock options of Board members leaving the Board in good faith are forfeited. Under the BSOP 2015 vested and unvested stock options of Board members leaving the Board in good faith do not expire.

*Options outstanding, exercised, forfeited or expired under BSOPs*

Number of options	<b>2015</b>				
	Exercised	Granted	Forfeited	Expired	Outstanding
BSOP 2011	29,500	0	0	0	0
BSOP 2015	0	7,000	0	0	7,000
<b>Total</b>	<b>29,500</b>	<b>7,000</b>	<b>0</b>	<b>0</b>	<b>7,000</b>

Number of options	<b>2014</b>				
	Exercised	Granted	Forfeited	Expired	Outstanding
BSOP 2011	34,000	29,500	0	0	29,500

As of December 31, 2015, 177,860 stock options (2014: 126,449) are available for future grants under the ESOP 2015 and/or the BSOP 2015.

**Fair value calculations for stock options granted**

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

	<b>2015</b>	<b>2014</b>
Market price of stock	CHF 80.20 to 138.90	CHF 3.46 to 104.90
Exercise prices	CHF 83.00 to 133.08	CHF 4.23 to 101.00
Weighted average fair value of options granted	CHF 40.12	CHF 2.93
Expected volatility <sup>1</sup>	43% to 46%	50% to 53%
CHF risk-free interest rate	-0.10% to 0.38% p.a.	0.71% to 0.98% p.a.
Option term <sup>2</sup>	10 years	10 years
Expected dividend yield	0%	0%

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

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

**Number of stock options outstanding and exercisable**

Number of options	<b>2015</b>	<b>2014</b>
<b>Outstanding at January 1</b>	<b>477,580</b>	<b>323,421</b>
Granted	149,260	362,300
Exercised <sup>1</sup>	-398,306	-197,126
Forfeited	-4,700	-5,800
Expired	0	-5,215
<b>Outstanding at December 31</b>	<b>223,834</b>	<b>477,580</b>
<b>Exercisable at December 31</b>	<b>60,412</b>	<b>98,655</b>

<sup>1</sup> The average closing share price of options exercised during the reporting period 2015 was CHF 95.40 (2014: CHF 47.40).

The value of stock options granted is recognized as personnel expense over the period Santhera receives services. In 2015, stock option grants resulted in personnel expenses of TCHF 1,528 (TCHF 277 related to Development, TCHF 580 related to Marketing & Sales (M&S) and TCHF 671 to General & Administration (G&A)) and in 2014, such grants resulted in personnel expenses of TCHF 759 (TCHF 386 related to Development, TCHF 26 related to M&S and TCHF 347 to G&A). In the first quarter of 2016, Santhera allocated 90,730 stock options which form part of the bonus award to employees for the year ended December 31, 2015. Although these stock options were not legally granted in 2015, Executive Management considers it appropriate to recognize expenses in 2015 as employees have been rendering services in 2015 in expectation of the annual bonus allocation. Personnel expenses in 2015 for this amounted to TCHF 512 (TCHF 108 related to Development, TCHF 244 related to M&S and TCHF 160 related to G&A). In the first quarter of 2015, Santhera allocated 39,760 stock options which formed part of the bonus award to employees for the year ended December 31, 2014. Personnel expenses in 2014 for this amounted to TCHF 418 (TCHF 181 related to Development, TCHF 6 related to M&S and TCHF 231 related to G&A) (see note 2 "Correction of errors").

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

#### Terms of options outstanding at December 31

Exercise price range for options (in CHF)	Number outstand- ing	Weighted average remaining contractu- al life (years)	2015 Number exercisa- ble	Number outstand- ing	Weighted average remaining contractu- al life (years)	2014 Number exercisa- ble
1.00	1,210	0.86	1,210	2,000	1.85	2,000
from 3.78 to 6.34	42,673	7.44	31,611	428,644	8.75	60,019
from 22.25 to 30.10	6,600	7.43	1,500	11,800	8.90	1,500
from 59.44 to 60.25	19,788	0.52	19,788	28,833	1.62	28,833
from 82.58 to 114.50	153,563	9.02	6,303	6,303	1.89	6,303
<b>Total</b>	<b>223,834</b>	<b>7.87</b>	<b>60,412</b>	<b>477,580</b>	<b>8.20</b>	<b>98,655</b>

## 18 Segment and Geographic Information

### Segment information

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

## Geographic information

### *Net sales*

	In CHF thousands	2015	2014
EU		4,321	2,548
Rest of the world		0	43
<b>Total</b>		<b>4,321</b>	<b>2,591</b>

In 2015, net sales of Raxone/Catena were generated after European marketing authorization in LHON and under special programs (e.g. the French temporary authorization for use as well as international Named Patient Programs) in the amount of CHF 4.3 million. In 2014 net sales of Raxone/Catena amounted to CHF 2.6 million, mainly in the EU.

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

	In CHF thousands	2015	2014
			<b>Restated</b>
Switzerland		29,876	4,403
EU		80	0
North America		1	3
<b>Total</b>		<b>29,957</b>	<b>4,406</b>

## 19 Other Operating Income

This position consists primarily of reimbursements from scientific programs.

## 20 Operating Expenses by Nature

	In CHF thousands	2015	2014
			<b>Restated</b>
External Development expenses		-6,341	-3,168
Reversal of impairment of intangible asset		26,157	0
Reversal of impairment on inventories		947	0
Patent and license expenses		-222	-229
Marketing expenses		-3,870	-446
Employee expenses		-13,105	-5,165
Of which non-cash-relevant expenses for share-based payments		-2,040	-1,177
Other administrative expenses		-2,999	-1,517
Depreciation, amortization and impairment		-110	-75
Lease expenses		-406	-251
Other operating expenses		-16	-9
<b>Total operating expenses</b>		<b>35</b>	<b>-10,860</b>

## 21 Employee Expenses and Benefits

### Employee expenses

	In CHF thousands	2015	2014 Restated
Wages and salaries		-6,435	-3,002
Social security and other personnel-related expenses <sup>1</sup>		-4,630	-986
Of which non-cash-relevant adjustments of pension fund		394	9
Share-based payments		-2,040	-1,177
<b>Total employee costs</b>		<b>-13,105</b>	<b>-5,165</b>
<hr/>			
<b>Average number of full-time equivalents<sup>2</sup></b>		<b>31.4</b>	<b>13.8</b>
<b>Full-time equivalents at year-end</b>		<b>53.3</b>	<b>14.7</b>
<b>Total headcount at year-end</b>		<b>59</b>	<b>18</b>

<sup>1</sup> Thereof TCHF 18 were expensed for defined contribution plans in North America and some EU countries (2014: TCHF 3).

The increase to the previous period results from higher social security expenses on option exercises.

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

### Termination benefits

In 2015 and 2014, 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 the employer. Contributions to the plans are such that the employee contributes 40% and the employer the rest. Contributions are computed as percentage of the salary, depending on age. In order to manage these risks, Santhera entered into an agreement with AXA Foundation for occupational benefits (AXA foundation). The AXA foundation is responsible for the governance of the plan; the board is composed of an equal number of representatives from the employers and employees chosen from all affiliated companies. AXA foundation has set up investment guidelines, defining in particular the strategic allocation with margins. AXA foundation has reinsured its risks (investment risk, mortality risk, etc.) with AXA Life Ltd, Winterthur, Switzerland (AXA). AXA manages the savings capital/investments on behalf of AXA foundation. The accumulated savings capital is allocated to each insured individual and consists of annual contributions, savings 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	2015	2014
<b>Present value of obligation, January 1</b>		<b>7,747</b>	<b>4,176</b>
Current employer service cost		704	297
Past service cost <sup>1</sup>		-656	-89
Interest cost		76	94
Employee contributions		267	138
Benefits paid / transfer payments		6,074	1,524
Insurance premiums		-142	-75
Remeasurements <sup>2</sup>		1,727	1,682
<b>Present value of obligation, December 31</b>		<b>15,797</b>	<b>7,747</b>

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

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

	In CHF thousands	2015	2014
Actuarial (gain)/loss due to changes in financial assumptions		170	1,604
Actuarial (gain)/loss due to experience adjustments		1,557	78
<b>Subtotal (gain)/loss</b>		<b>1,727</b>	<b>1,682</b>
(Return)/loss on plan assets (excluding interest income)		-56	10
<b>Total remeasurements in other comprehensive income (gain)/loss</b>		<b>1,671</b>	<b>1,692</b>

*Changes in plan assets*

	In CHF thousands	2015	2014
<b>Fair value of assets, January 1</b>		<b>5,067</b>	<b>3,179</b>
Interest income on assets		55	77
Employer contributions		463	234
Employee contributions		267	138
Benefits paid / transfer payments		6,074	1,524
Insurance premiums		-142	-75
Remeasurements (return/(loss) on plan assets (excluding interest income))		56	-10
<b>Fair value of assets, December 31</b>		<b>11,840</b>	<b>5,067</b>

*Net defined benefit asset/(obligation)*

	In CHF thousands	2015	2014
Present value of obligation, December 31		15,797	7,747
Fair value of assets, December 31		11,840	5,067
<b>Net defined asset/(obligation)</b>		<b>-3,957</b>	<b>-2,680</b>

*Asset breakdown*

Assets of the defined benefit plan are not quoted since AXA fully insures them. Therefore the entire amount of TCHF 9,499 (2014: TCHF 5,067) 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 %	2015	2014
Discount rate		0.90	1.05
Expected future salary increases		1.50	1.50

*Sensitivity analysis for 2015:*

In CHF thousands	Defined benefit obligation		Gross service cost	
	Increase assumption	Decrease assumption	Increase assumption	Decrease assumption
Discount rate +/-0.25%	-537	578	-73	78
Salary increase +0.25%	84	-	-1	-
Live expectancy +1 year	245	-	20	-

*Sensitivity analysis for 2014:*

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

*Mortality rate:*

Life expectancy at age 65	2015	2014
Male	21.59	21.49
Female	24.06	23.96

The expected employer contributions for fiscal year 2016 amount to approximately TCHF 568 (2014: TCHF 256). No benefit obligations for pensioners exist at December 31, 2015 (2014: none). The duration of the plan liabilities calculated is 20.8 years as per December 31, 2015 (2014: 20.8 years).

## 22 Financial Income/Expenses

### Financial income

	In CHF thousands	2015	2014
Interests on cash and cash equivalents		2	4
Realized and unrealized foreign exchange gains		414	50
<b>Total</b>		<b>416</b>	<b>54</b>

### Financial expenses

	In CHF thousands	2014	2014
Interest expenses		-11	-7
Realized and unrealized foreign exchange losses		-644	-62
<b>Total</b>		<b>-655</b>	<b>-69</b>

## 23 Income Taxes

	In CHF thousands	2015	2014 Restated
Current income tax income/(expense)		-46	-2
Deferred tax income/(expense)		3,061	0
<b>Total</b>		<b>3,015</b>	<b>-2</b>

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

	In CHF thousands	2015	2014
Result before taxes		2,934	-7,950
Tax (expense)/income at expected group tax rate of 20% <sup>1</sup>		-587	1,590
Effect of tax rate difference group versus local		-2,413	0
Effect of non-deductible expenses		-12	0
Utilization of previously unrecognized tax losses		7,376	0
Recognition of DTA on previously unrecognized tax losses		4,336	0
Unrecognized deferred taxes		-5,685	-1,592
Effective tax income/(expense)		3,015	-2

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

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

## 24 Earnings/Loss per Share

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

	2015	2014 Restated
Net result attributable to shareholders (in CHF)	5,949,239	-7,951,925
Weighted average number of shares issued and outstanding	5,343,089	4,704,000
<b>Basic net result per share (in CHF)</b>	<b>1.11</b>	<b>-1.69</b>

Diluted earnings per share are calculated by dividing the net profit attributable to owners of ordinary Shares of the Company by the weighted average number of Shares issued and outstanding during the reporting period adjusted for Shares held as treasury shares (purchased at market) and the number of potential shares from stock option plans. For 2014 no diluted net result was calculated since the exercise of stock options would have been anti-dilutive.

	2015	2014
Net result attributable to shareholders (in CHF)	5,949,239	n/a
Weighted average number of shares issued and outstanding	5,343,089	n/a
Additional shares of potential option exercise	140,441	n/a
Adjusted weighted average number of shares issued and outstanding	5,483,530	n/a
<b>Diluted net result per share (in CHF)</b>	<b>1.08</b>	<b>n/a</b>

## 25 Related Party Transactions

### Board and Executive Management compensation

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

	In CHF thousands	2015	2014 Restated
Compensation, wages and salaries		2,043	504
Post-employment benefits (pension fund contributions)		211	35
Share-based payment expenses (fair value according to IFRS 2)		855	431

#### *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.

In 2015, 29,500 stock options were exercised by members of the Board (2014: 24,000 stock options exercised). 211,394 stock options were exercised by the Executive Management (2014: 23,895 stock options exercised).

## 26 Risk Management Objectives and Policies

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

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

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

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

### Foreign exchange rate risk

Santhera holds cash amounts in four major currencies CHF, EUR, USD, GBP and CAD to cover the majority of future expected expenses. In addition, in order to reduce its foreign exchange rate exposure, Santhera occasionally enters into derivative currency contracts (forwards, options, structured derivatives) to hedge against additional major foreign currency exchange rate fluctuations. Evaluations based on market values were performed regularly. Any fair value changes of such currency positions are recorded accordingly in the income statement. Santhera's primary exposure to financial risk is due to fluctuation of exchange rates between CHF, EUR, USD, GBP and CAD. No derivative currency contracts are outstanding as of December 31, 2015 and 2014.

The following table demonstrates the sensitivity to a reasonable possible change in the EUR 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>EUR positions</b>		
<b>2015</b>	+10%	-608
	-10%	608
<b>2014</b>	+5%	-17
	-20%	67

### 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 2015, variances of +/-50 basis points were calculated, resulting in fluctuations of +/- TCHF 384 before tax (end of 2014: +/-50 basis points resulting in fluctuations of +/-TCHF 87 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 or entered with customers or 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*

<b>Year ended December 31, 2015</b> 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	2,609	0	0	0	2,609	2,609
Trade payables	0	3,291	0	0	0	3,291	3,291
<b>Total</b>	<b>0</b>	<b>5,900</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>5,900</b>	<b>5,900</b>

<b>Year ended December 31, 2014</b> 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	861	0	0	0	861	861
Trade payables	0	1,654	0	0	0	1,654	1,654
<b>Total</b>	<b>0</b>	<b>2,515</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>2,515</b>	<b>2,515</b>

**Categories of financial instruments**

<b>Year ended December 31, 2015</b> In CHF thousands	Book value	Loans and receivables	Other liabilities at amortized cost
<b>Assets</b>			
Financial assets long-term	190	190	0
Trade receivables	1,466	1,466	0
Other receivables	49	49	0
Cash and cash equivalents	76,859	76,859	0
<b>Total</b>	<b>78,564</b>	<b>78,564</b>	<b>0</b>
<b>Liabilities</b>			
Trade payables	3,291	0	3,291
<b>Total</b>	<b>3,291</b>	<b>0</b>	<b>3,291</b>

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

### Capital management

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

The funds raised in various private financing rounds, the private placement in 2008, 2014 and 2015, SEDA, the sale of Shares by an independent broker as well as funds generated through product sales and revenue from licensing enabled the Group to be adequately financed.

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

## 27 Events After the Reporting Date

None



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

Basel, April 11, 2016

As statutory auditor, we have audited the consolidated financial statements of Santhera Pharmaceuticals Holding AG, which comprise the consolidated balance sheet, consolidated income statement, consolidated statement of comprehensive income, consolidated cash flow statement, consolidated statement of changes in equity and notes (pages 12 to 49), for the year ended 31 December 2015.

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

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

### **Auditor's responsibility**

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

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

## **Opinion**

In our opinion, the consolidated financial statements for the year ended 31 December 2015 give a true and fair view of the financial position, the results of operations and the cash flows in accordance with IFRS and comply with Swiss law.

## **Report on other legal requirements**

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

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

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

Ernst & Young Ltd

/s/ Jolanda Dolente  
Licensed audit expert  
(Auditor in charge)

/s/ Nicole Riggenschach  
Licensed audit expert

# Statutory Financial Statements of Santhera Pharmaceuticals Holding AG

## Contents

Balance Sheet .....	53
Income Statement .....	54
Notes to the Statutory Financial Statements .....	55
1    Introduction .....	55
2    Principles .....	55
3    Information on Balance Sheet and Income Statement Items .....	56
4    Other Information .....	58
Proposals of the Board of Directors to the Annual Shareholders' Meeting .....	62
Report of the Statutory Auditor on the Financial Statements .....	64

## Balance Sheet

	As of December 31, in CHF thousands	Notes	2015	2014
<b>Assets</b>				
Cash and cash equivalents			61,256	6,953
Other receivables from third parties			43	8
Other receivables from shareholdings			287	415
Prepaid expenses and accrued income			180	23
Treasury shares			0	177
<b>Current assets</b>			<b>61,766</b>	<b>7,576</b>
Loans to shareholdings		3.1	0	0
Investments in shareholding		3.2	59	0
<b>Noncurrent assets</b>			<b>59</b>	<b>0</b>
<b>Total assets</b>			<b>61,825</b>	<b>7,576</b>
<b>Liabilities and equity</b>				
Trade accounts payable to third parties			154	68
Other accounts payable to third parties			188	447
Other accounts payable to shareholdings			188	49
Accrued expenses			297	171
<b>Current liabilities</b>			<b>827</b>	<b>735</b>
<b>Total liabilities</b>			<b>827</b>	<b>735</b>
Share capital		3.3	6,263	4,974
<i>Reserves from capital contributions</i>			<i>57,083</i>	<i>3,049</i>
<i>Other capital reserves</i>			<i>2,891</i>	<i>916</i>
Statutory capital reserves			59,974	3,965
<i>Reserves for treasury shares</i>			<i>0</i>	<i>177</i>
Statutory retained earnings			0	177
<i>Accumulated result</i>			<i>-5,557</i>	<i>-2,593</i>
<i>Results carried forward</i>			<i>-2,593</i>	<i>-1,503</i>
<i>Net result for the period</i>			<i>-2,964</i>	<i>-1,090</i>
<i>Other voluntary reserves (free reserves)</i>			<i>495</i>	<i>318</i>
Voluntary accumulated result and other reserves			-5,062	-2,275
Treasury shares		3.4	-177	0
<b>Total equity</b>			<b>60,998</b>	<b>6,841</b>
<b>Total liabilities and equity</b>			<b>61,825</b>	<b>7,576</b>

## Income Statement

For the year ended December 31, in CHF thousands	Notes	2015	2014
Income from shareholdings	3.5	1,970	1,203
Other operating income		1	1
<b>Total operating income</b>		<b>1,971</b>	<b>1,204</b>
General and administrative expenses	3.6	-3,322	-1,463
Employee costs		-1,656	-845
Other operating expenses		-2	-2
<b>Total operating expenses</b>		<b>-4,980</b>	<b>-2,310</b>
<b>Operating result</b>		<b>-3,009</b>	<b>-1,106</b>
Financial income		21	31
Financial expenses		-35	-15
<b>Financial result</b>		<b>-14</b>	<b>16</b>
Reversal on allowance of investment		59	0
<b>Result before taxes</b>		<b>-2,964</b>	<b>-1,090</b>
Direct taxes		0	0
<b>Net result</b>		<b>-2,964</b>	<b>-1,090</b>

## Notes to the Statutory Financial Statements

### 1 Introduction

Santhera Pharmaceuticals Holding AG (the Company or Santhera) is the parent company of Santhera Group. The Company has its registered offices at Hammerstrasse 49 in 4410 Liestal, Switzerland.

### 2 Principles

#### General

Beginning in the year ended December 31, 2015, the statutory financial statements of the Company are prepared in accordance with the general accepted accounting principles as set out in art. 957 to art. 963b, of the Swiss Code of Obligations (CO), which became effective since January 1, 2013, and required implementation in relation to the year ended December 31, 2015. In accordance with the transitional regulations for the implementation of the CO the presentation of the prior-year financial statements was not adjusted to conform to the current presentation. Since Santhera prepares consolidated financial statements in accordance with International Financial Reporting Standards (IAASB), a recognized accounting standard, the Company has, in accordance with the CO, elected to forego presenting the statement of cash flows, the additional disclosures and the management report otherwise required by the CO.

#### Cash

Santhera holds cash balances, denominated mainly in Swiss francs (CHF) which include cash deposited in demand bank accounts, money market investment accounts and other liquid investments and interest earned on such cash balances.

#### Current assets and liabilities

Current assets are recorded at historical cost less adjustments for impairment of value and current liabilities at historical cost.

#### Loans to shareholdings

These are valued at their acquisition cost adjusted for impairment losses.

#### Investments in shareholdings

Investments in shareholdings are recorded at acquisition cost less adjustments for impairment of value. We evaluate our investments in subsidiaries for impairment annually and record an impairment loss when the carrying amount of such assets exceeds the fair value. We estimate fair value of our investments using a variety of valuation methods (e.g. income approach).

## Treasury shares

Treasury shares are recognized at acquisition cost and deducted from shareholders equity at the time of acquisition. In case of a resale, the gain or loss is recognized through the income statement as financial income or financial expenses.

## Related parties

In the meaning of the New Swiss Accounting Law, we consider related parties to be only shareholders, direct and indirect subsidiaries (shareholdings) and the board of directors.

# 3 Information on Balance Sheet and Income Statement Items

## 3.1 Loans to shareholdings

Loans to shareholdings are fully impaired to CHF 0 and consist of subordinated loans to Santhera Pharmaceuticals (Schweiz) AG. These loans were primarily related to fund the research and development activities of Santhera Group (December 31, 2015: CHF 172.4 million; December 31, 2014: CHF 172.4 million). The recoverability of these loans is not ensured. The fair value of Santhera Pharmaceuticals (Schweiz) AG and the long-term recoverability of these loans depend on the future market success of the developed and launched products (Raxone in LHON) and successful filings in other indications (Raxone in DMD).

## 3.2 Investments in shareholdings

In 2015 and 2014 the following companies are direct subsidiaries of Santhera Pharmaceuticals Holding AG (100% ownership and 100% voting rights):

	Share capital at December 31	2015	2014
Santhera Pharmaceuticals (Schweiz) AG Liestal, Switzerland	CHF	125,000	125,000
Santhera Pharmaceuticals (Deutschland) GmbH Lörrach, Germany	EUR	25,000	25,000
Santhera Pharmaceuticals (USA), Inc. Charlestown, US	USD	1,000	1,000
Santhera Pharmaceuticals (Canada), Inc. Montréal, Canada	CAD	1,000	1,000
Oy Santhera Pharmaceuticals (Finland) Ltd Helsinki, Finland	EUR	2,500	2,500

Santhera Pharmaceuticals (Schweiz) AG is the primary operational entity while Santhera Pharmaceuticals (Deutschland) GmbH holds the market authorization for the EU. Oy Santhera Pharmaceuticals (Finland) Ltd is not employing any personnel.

In 2015 the following companies, which are 100% direct subsidiaries (100% voting rights) of Santhera Pharmaceuticals (Schweiz) AG, were founded:

	Share capital at December 31	2015	2014
Santhera Pharmaceuticals (Liechtenstein) AG Ruggell, Fürstentum Liechtenstein	CHF	50,000	n/a
Santhera (Italy) S.r.l. Milano, Italy	EUR	50,000	n/a
Santhera (Germany) GmbH Munich, Germany	EUR	50,000	n/a
Santhera (Netherlands) B.V. Nieuwegein, The Netherlands	EUR	50,000	n/a
Santhera (UK) Limited London, United Kingdom	GBP	50,000	n/a

### 3.3 Share capital

During 2015, the share capital was increased by a total amount of CHF 1,288,306 to CHF 6,262,798 as of December 31, 2015 (2014: CHF 4,974,492): The increase consisted of three parts: i) increase through the exercise of 398,306 employee stock options (from conditional capital); ii) increase through an accelerated bookbuilding of 590,000 Shares (from authorized capital) and iii) the increase through the issuance of 300,000 Shares for the sale by an independent broker (from conditional capital).

### 3.4 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, 2015, the number of shares remained unchanged at 8,028.

### 3.5 Income from shareholdings

Income from shareholdings represents reimbursement for management services provided by the Company to its major shareholdings Santhera Pharmaceuticals (Schweiz) AG.

### 3.6 General and administrative expenses

	In CHF thousands	2015	2014
Administrative expenses		712	759
Consulting expenses		667	324
Expenses in connection with capital increases		1,943	380
<b>Total</b>		<b>3,322</b>	<b>1,463</b>



## 4 Other Information

### 4.1 Full-time equivalents

The number of full-time equivalents at period end was not above 10.

### 4.2 Significant shareholders (>2%)

Pursuant to information from the Company's share register and reporting of participations made to the Company in accordance with applicable stock exchange regulation, the following shareholders owned 2% or more of the Company's share capital as registered in the commercial register most recently at February 11, 2016 (6,262,798 shares at February 11, 2016; 4,578,521 shares at December 31, 2014):

	2015 Shares <sup>1</sup>	2015 %	2014 Shares	2014 %
Iglu Group, Switzerland	671,858	10.7	712,670	15.6
Consonance Capital Management, US	625,457	10.0	275,000	6.0
Bertarelli Ernesto, Donata and Maria-Iris, Switzerland	545,777	8.7	545,777	11.9
Union Asset Management Holding AG	326,838	5.2	n/a	n/a
Lagoda Investments Management, LLC, US	187,888	3.0	n/a	n/a
Visum Balanced Master Fund, Ltd., US	179,574	2.9	n/a	n/a
UBS Fund Management (Luxembourg) S.A.	167,203	2.7	n/a	n/a
RTW Investments, LTD, US	140,354	2.2	140,354	3.1
NGN Capital, Germany and US	n/a	n/a	137,409	3.0

<sup>1</sup> Including disclosures until March 30, 2016

<sup>2</sup> Formerly Ares Life Sciences, Switzerland

### 4.3 Disclosure of shares and stock options held by members of the Board and Executive Management (and their respective related party)

*As of December 31, 2015:*

	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	38,109	0	3,000	3,000
Jürg Ambühl	30,000	0	4,000	4,000
<i>Executive Management</i>				
Thomas Meier, CEO	72,902	0	12,250	12,250
Nicholas Coppard, SVP Head Development <sup>1</sup>	1	0	9,000	9,000
Günther Metz, SVP Business Development <sup>1</sup>	0	11,000	5,000	16,000
Christoph Rentsch, Chief Financial Officer <sup>2</sup>	0	0	15,000	15,000
Giovanni Stropoli, Chief Commercial Officer Europe and Rest of World <sup>1</sup>	400	0	15,000	15,000
Oliver Strub, SVP General Counsel and Secretary to the Board <sup>1</sup>	0	10,000	5,000	15,000

<sup>1</sup> Joined the Executive Management February 1, 2015.

<sup>2</sup> Joined the Executive Management July 1, 2015.

*As of December 31, 2014:*

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

#### 4.4. Disclosure of the allocation of stock options for Board of Directors, Executive Management and employees of Santhera Group

	2015	2015	2014	2014
	Quantity	Value (in TCHF) <sup>1</sup>	Quantity	Value (in TCHF) <sup>1</sup>
Board of Directors	7,000	282	29,500	116
Executive Management	53,500	2,094	52,000	93
Employees of Santhera Group	88,760	3,612	280,800	854
<b>Total</b>	<b>149,260</b>	<b>5,988</b>	<b>362,300</b>	<b>1,063</b>

<sup>1</sup> Value of the options calculated in accordance with the Hull-White model at the date of allocation in accordance with the terms of the award. 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. For information about the underlying stock option plans, see note 17 "Stock Option Plans" in the consolidated financial statements. For information about the Company's compensation procedures, consult the Corporate Governance Report and the Compensation Report.

On January 1, 2016, 90,730 options were granted to employees of Santhera. These options are part of the bonus award for the year 2015 to employees of the Group. These options were granted under ESOP 2015 (see note 17 "Stock Option Plans").

	Quantity	Value (in TCHF) <sup>1</sup>
Executive Management	30,550	623
Employees of Santhera Group	60,180	1,226
<b>Total</b>	<b>90,730</b>	<b>1,849</b>

<sup>1</sup> Value of the options calculated in accordance with the Hull-White model at the date of allocation in accordance with the terms of the award. 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. For information about the underlying stock option plans, see note 17 "Stock Option Plans" in the consolidated financial statements. For information about the Company's compensation procedures, consult the Corporate Governance Report and the Compensation Report.

#### 4.5 Contingencies and guarantees

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

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

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

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

##### *Declaration of liability towards Arval Deutschland GmbH*

The Company guarantees to pay for the liabilities of its subsidiary Santhera (Germany) GmbH for contractual duties and obligations.

#### **4.6 Standby Equity Distribution Agreement**

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

#### **4.7 Events After the Reporting Date**

None

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

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

	In CHF	2015	2014
Result carried forward		-2,592,681	-1,502,786
Net result of the year		-2,963,843	-1,089,895
<b>Accumulated result</b>		<b>-5,556,524</b>	<b>-2,592,681</b>
<b>Result to be carried forward</b>		<b>-5,556,524</b>	<b>-2,592,681</b>

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

	In CHF
Reserves from capital contribution at December 31, 2014	3,049,462
Re-allocation to other capital reserves (legal reserves) following final tax Assessment	-32,149
Share premium of option exercise during 2015	1,728,555
Share premium of capital increase December 2015	52,336,612
<b>Reserves from capital contribution</b>	<b>57,082,480</b>
Transfer from reserves from capital contribution to other voluntary reserves (free reserves)	-50,000,000
<b>Reserves from capital contribution</b>	<b>7,082,480</b>

Subject to approval by the Annual Shareholders' Meeting, the other voluntary reserves (free reserves) develop as follows:

	In CHF
Other voluntary reserves (free reserves) at December 31, 2014	318,098
New presentation of reserve for treasury shares	176,616
Transfer from reserves from capital contribution	50,000,000
<b>Free reserves</b>	<b>50,494,714</b>

## Report of the Statutory Auditor on the Financial Statements

Basel, April 11, 2016

As statutory auditor, we have audited the financial statements of Santhera Pharmaceuticals Holding AG, which comprise the balance sheet, income statement and notes (pages 53 to 61), for the year ended 31 December 2015.

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

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

### **Auditor's responsibility**

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

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

### **Opinion**

In our opinion, the financial statements for the year ended 31 December 2015 comply with Swiss law and the company's articles of incorporation.

### **Report on other legal requirements**

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

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

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

Ernst & Young Ltd

/s/ Jolanda Dolente  
Licensed audit expert  
(Auditor in charge)

/s/ Nicole Riggenschach  
Licensed audit expert

# Compensation Report

## Contents

Introduction .....	66
The Role and Powers of the Compensation Committee .....	67
Approval of Compensation by the ASM .....	67
Board of Directors Compensation .....	68
Executive Management Compensation .....	70
Loans and Credits .....	74
Compensation of Former Members of the Board and Executive Management .....	74
Shareholdings of Members of the Board and Executive Management .....	76
Report of the Statutory Auditor on the Compensation Report .....	77



## Introduction

This Compensation Report (**Report**) describes the principles of the compensation system of Santhera's Board of Directors (**Board**) and Executive Management (**EM**) members and how the respective decisions are made. Furthermore, the Report discloses the compensation attributable to the Board and EM in the respective year, as well as shareholdings of the members of the Board and EM members.

Santhera's compensation policy is designed to attract, motivate and retain talent in order to support the achievement of the Company's financial and strategic objectives and also to ensure that the total compensation package is fair and competitive. 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 management are aligned with the interests of the Company and its shareholders. The Company's compensation system does not set any unintended enticements or contain any components that could be counterproductive to the objectives of the compensation system. In addition, compensation elements are focused on rewarding the delivery of outstanding and sustainable results without inappropriate risk-taking.

On an ongoing basis, the Compensation Committee (**CC**) reviews and monitors Santhera's compensation policy in light of the Company's business strategy, corporate goals and values, in order to ensure the alignment of employee interests with those of the shareholders. There were no changes in the compensation policy for the Board and EM members in 2015. For the financial year 2016, some changes to the variable compensation design for the Board will be proposed to the shareholders for the 2016 ASM.

At the last Annual Shareholders' Meeting (ASM), the shareholders of Santhera have adopted substantial amendments to the Company's Articles of Incorporation (**Articles**) in compliance with the "Ordinance against Excessive Compensation at Listed Companies" (**OaEC**). The Articles of Santhera include rules on the principles applicable to performance-related pay and to the allocation of equity securities, convertible rights and options (art. 27), additional amounts for payments to Executive Committee members appointed after the vote on pay at the shareholders' meeting (art. 26), loans, credit facilities and post-employment benefits for the Executive Committee and Board (art. 29) and the vote on pay at the shareholders' meeting (art. 25). With regard to binding approval of the maximum total executive compensation, the current Articles provide for a compensation period that starts on July 1 of a given year and ends on June 30 of the following year. Based on the experience of the last ASM, the Board has decided to propose two changes with regard to the voting procedures on executive compensation, which will be reflected in the Articles:

1. To align the compensation period to be approved on with the reporting period from January 1 to December 31.
2. To change the voting procedure on the variable compensation (cash bonus and long-term incentive plan; currently stock options) for the EM to a retrospective approval for the previous financial year.

The Board believes, the compensation provisions for the Board and EM members serve the best interests of Santhera's shareholders.

## The Role and Powers of the Compensation Committee

The CC currently consists of the two members of the Board. The CC annually reviews the compensation system of the members of the Board and EM and ensures that the Company's regulations and Articles of Incorporation remain in compliance with requirements of the OaEC, the SIX Swiss Exchange, as well as Swiss and international best corporate governance practices.

According to the Company's Articles, the role of the CC assists the Board with the:





- Determination and review of remuneration policies and guidelines
- Determination and review of performance objectives
- Proposals to the ASM concerning the compensation of the Board of Directors and of Executive Management
- Resolution of other compensation related matters


The Board may assign other tasks to the CC.

## Approval of Compensation by the ASM

With regard to binding approval of the maximum total executive compensation, the current Articles provide for a compensation period that starts on July 1 of a given year and ends on June 30 of the following year. Based on the experience of the last ASM, the Board has decided to propose two changes with regard to the voting procedures on executive compensation, which will be reflected in the Articles of Incorporation:

1. To align the compensation period to be approved on with the reporting period from January 1 to December 31.
2. To change the voting procedure on the variable compensation for the EM to a retrospective approval for the previous year.

	Previous year	Current year	Next year
Advisory vote on the Compensation Report	Compensation Framework		
Total Board Compensation (AGM to AGM)		 Compensation Period	
Fixed EM Compensation (following year)			Compensation Period
Variable EM Compensation (previous year)	Compensation Period		

 Voting at ASM

With those changes, the voting on compensation looks as follows:

1. Consultative vote on the Compensation Report for the previous financial year by the shareholders to express their opinion on the effectively paid compensation to the Board and EM for the previous year.
2. The maximum total amount of the fixed compensation for the Board of Directors for the period from the current until the next Annual Shareholders' Meeting.
3. The maximum total amount of the fixed compensation for the Executive Management for the period from January 1 to December 31 of the following year.
4. The maximum total amount of the variable compensation for the Executive Management for the period from January 1 to December 31 of the previous year.

### **Voting procedure at the 2016 ASM**

As 2016 is a transition year, the Board will propose the following votes on compensation for the shareholder approval:

1. Consultative vote on the Compensation Report 2015.
2. The maximum total amount of the fixed compensation for the Board of Directors for the period until the 2017 ASM.
3. The maximum total amount of the fixed compensation for the Executive Management for the period from January 1 to December 31, 2016.
4. The maximum total amount of the fixed compensation for the Executive Management for the period from January 1 to December 31, 2017.

The invitation to the ASM contains the text of the proposed revisions and the explanations there-to in more detail.

## **Board of Directors Compensation**

The compensation for members of the Board currently consists of:

- Annual cash fees
- Annual grant of stock options

Both components do not depend on the achievement of corporate goals or the individual performance of a Board member. Additionally, the Company assumes the payment of employer's social security contributions due on these amounts. Board members do not receive any variable compensation.

### **Annual cash fees**

Since 2015, the annual cash fees for the Chairman were increased to CHF 75,000 (previously: CHF 45,000). As there are currently only two Board members who share the entire Board workload mostly equally, there was a decision to bring the compensation of the other Board member in line with that of the Chairman. Thus, the annual cash fees for the other Board member were increased to CHF 65,000 (previously: CHF 32,000). No additional cash fees are paid for work in the Board committees.

## Stock options

At the 2015 ASM, the shareholders approved a total maximum amount of CHF 330,000 to be granted in options for the period until the 2016 ASM. In accordance with the Board Stock Option Plan (**BSOP 2015**), the grant of 3,000 options was made to each Board member as of June 1, 2015. The exercise price is equal to the closing price of Santhera's share on the first trading day in June 2015 and amounted to CHF 90.75 (2014: CHF 22.25). According to BSOP 2015, 50% of the options vest after a period of 2 years from the grant date, 25% vest after 3 years from the grant date, and 25% vest after 4 years from the grant date. During such vesting periods, stock options may lapse subject to certain conditions as defined by the BSOP. The term of the stock option grant is 10 years. For more information about the underlying Plan, see note 17 "Stock Option Plans" in the consolidated financial statements.

In accordance with the previous option plan regulations and the Company's Group Directive GD-14 (Non-executive Board Member Compensation Policy), Jürg Ambühl received 1,000 options as of January 1, 2015, with an exercise price of CHF 84.10. This was the last grant under this plan.

## Disclosure of compensation of members of the Board for the financial years 2015 and 2014 (audited)

In CHF	Annual cash fees	Stock options <sup>1</sup>	Social security <sup>1,2</sup>	Total compensation	Number of stock options granted
<b>2015</b>					
Martin Gertsch	75,000	121,320	15,340	211,660	3,000
Jürg Ambühl	65,000	160,410	15,594	241,004	4,000
<b>Total</b>	<b>140,000</b>	<b>281,730</b>	<b>30,934</b>	<b>452,664</b>	<b>7,000</b>
<b>2014</b>					
Martin Gertsch	45,000	90,450	10,564	146,014	16,500
Jürg Ambühl	32,000	25,330	3,776	61,106	13,000
<b>Total</b>	<b>77,000</b>	<b>115,780</b>	<b>14,340</b>	<b>207,120</b>	<b>29,500</b>

<sup>1</sup> Reflects value of share-based payments in accordance with IFRS 2 at grant, i.e. the value of unvested stock options attributable at grant. The tax value of such stock options is CHF 0 until stock options are exercised. Such stock option values are theoretical values and do not reflect income tax values and do also take into consideration certain vesting provisions.

<sup>2</sup> To be in line with the market practice, the Board has decided to disclose the social security from 2015 onwards not on exercised but on the fair value of allocated options. For all options held by Board members as of December 31, 2015, the social security contribution is CHF 0 since the options are not in-the-money. The total value of social security payments on options exercised by members of the Board during 2015 is CHF 192,523 (2014: CHF 38,516).

## Comparison of the approved and paid Board compensation

At the 2015 ASM, the shareholders approved a maximum total amount of fixed compensation for the Board of CHF 154,000 for the period from the ASM 2015 to the ASM 2016. In addition, the shareholders approved the allocation of 6,000 options with an estimated value of CHF 330,000 (including employer's social security contribution).

Based on the payments made already in 2015 and the amounts forecasted to be paid in 2016 until the ASM, the actual amount of compensation for the Board for this period amounts to CHF 452,664, which is in line with the approved amount.

The table below represents the approved maximum compensation for the Board as well as the actual amounts paid in 2015 and still payable in 2016.

	Approved May 12, 2015 – May 11, 2016	Paid/payable May 12, 2015 – May 11, 2016
Board fees (CHF)	154,000	149,523
Stock options <sup>1</sup> (CHF)	330,000	261,080
<b>Total (CHF)</b>	<b>484,000</b>	<b>410,603</b>
Stock options (number)	6,000	6,000

<sup>1</sup> The shareholders approved the allocation of a total of 6,000 options, and 6,000 options were granted to the Board.

### Outlook for Board compensation

The Board will submit to the 2016 ASM the total unchanged maximum amount of CHF 484,000 for the period until the next ASM. This maximum amount is gross and consists of:

- Board annual fees of CHF 242,000.
- Stock options with a value of CHF 242,000.

With the above motions, the Board proposes to introduce two changes: a decrease of the value of the options to 50% of the total compensation (64% in the previous period) and to use a value in CHF as a basis for the calculation of the number of options to be allocated rather than the allocation of a fix number of options.

To calculate the number of options to be allocated, the above mentioned amount would be divided by the fair value of the options at the date of their grant, July 1, 2016. The fair value is calculated based on the share price on the first trading day of the month immediately following the ASM, then applying the Hull-White model (excluding employers' social security contribution)

### Executive Management Compensation

The compensation for members of the Board currently consists of:

- Fixed compensation.
- Variable compensation:
  - Annual bonus paid in cash.
  - Annual grant of stock options.

#### Fixed compensation

The fixed compensation for the EM members includes base salary, social security contributions and payments to the pension fund by the Company. The base salary takes into account the position, responsibilities, experience and skills of an individual EM member. Base salaries are reviewed annually by the CC, taking into account individual performance and the results of the external benchmarking.

In 2015, the Company had engaged a reputable compensation and performance expert firm located in Switzerland to benchmark the compensation level and structure for the members of EM. The analysis included compensation data of the comparable Pharma/Biopharma companies, among which several US-based companies that have their international headquarters in Switzerland. The Board came to the conclusion that currently only minor adjustments to the EM base salary were required in order for Santhera to remain a competitive employer.

### Annual cash bonus

The annual cash bonus for 2015 was based on the achievement of Company and individual goals and has been paid in February 2016. The target bonus, i.e. cash bonus to be paid if 100% of corporate and individual objectives are met, is determined individually for each EM member as percentage of the base salary, ranging from 15% to 33%. According to the external benchmarking, the target bonuses continued to be in the lower range of the peer group.

The weightings of the corporate and individual goals are individual for each EM member and vary depending on the position. In general, the higher the position of an employee, the more weight is put on the achievement of corporate goals rather than on individual goals. For the Chief Executive Officer (CEO), the weighting of the achievement of corporate goals has been 90% and for the other Executives 70%. The final payout is capped at 100% of the target bonus.

### Calculation of the individual annual bonus for EM members



The Board determined that the actual target achievement of the 2015 corporate goals was 75%. The actual achievement of individual goals by members of the EM ranged between 75% and 95%.

### Stock options

Under the Employee Stock Option Plan (**ESOP 2015**), members of the EM receive an annual grant of a certain number of stock options which is determined by the Board, taking into account the achievement of Company and individual goals. For the allocation of these options for the 2015 goal achievements, the exercise price is equal to the closing price of Santhera's share on the first trading day in January 2016 and amounted to CHF 89.45 (previous year: CHF 84.10). According to the ESOP 2015, 50% of the options vest after a period of 2 years from the grant date, 25% vest after 3 years from the grant date, and 25% vest after 4 years from the grant date. During such vesting periods, stock options may lapse subject to certain conditions as defined by the Plan.

The term of the stock option grant is 10 years. For more information about the underlying Plan, see note 17 "Stock Option Plans" in the consolidated financial statements. According to the results of the external benchmarking, the equity-based compensation level appeared to be in line with the market.

#### Disclosure of compensation of members of the Executive Management for the years 2015 and 2014 (audited)

In CHF	Base salary	Cash bonus	Stock options <sup>1</sup>	Social security and pension <sup>1,2</sup>	Total compensation	Number of stock options granted
<b>2015</b>						
Giovanni Stropoli, CCO EU & RoW	302,500	50,930	688,815	122,629	1,164,874	20,565
Other 5 members of EM	1,323,924	225,960	1,135,895	411,750	3,097,529	39,985
<b>Total</b>	<b>1,626,424</b>	<b>276,890</b>	<b>1,824,710</b>	<b>534,379</b>	<b>4,262,403</b>	<b>60,550</b>
<b>2014</b>						
Thomas Meier, CEO <sup>3</sup>	332,947	94,000	415,390	108,133	950,470	60,500
<b>Total</b>	<b>332,947</b>	<b>94,000</b>	<b>415,390</b>	<b>108,133</b>	<b>950,470</b>	<b>60,500</b>

<sup>1</sup> Reflects value of share-based payments in accordance with IFRS 2 at grant, i.e. the value of unvested stock options attributable at grant; tax value of such stock options is CHF 0 until stock options are exercised. Such stock option values are theoretical values and do not reflect income tax values and do also take into consideration certain vesting provisions.

<sup>2</sup> To be in line with the market practice, the Board has decided to disclose the social security from 2015 onwards not on exercised but on the fair value of allocated options. For all options held by EM members as of December 31, 2015, the social security contributions amount to CHF 174,490. The total amount of social security payments on options exercised by members of EM during 2015 is CHF 1,461,173 (2014: CHF 6,160).

<sup>3</sup> In the 2014 compensation report, 8,500 Options allocated to the CEO as of January 1, 2015, for the 2014 goal achievement had not been included based on an erroneous classification of such allocation. The restatement made hereinabove results in a difference of the value of stock options of CHF 322,830 in 2014, and of social security and pension payments of CHF 31,570. Accordingly, the total compensation for 2014 as disclosed in the 2014 compensation report amounted to CHF 602,230; the difference to the restated total amount is CHF 348,240.

#### Comparison of the approved and paid EM compensation

At the 2015 ASM, shareholders approved a maximum total compensation for the EM as follows: CHF 1,900,000 for the fixed compensation in cash; CHF 600,000 for the variable short-term compensation, consisting of a bonus; and a total maximum amount of CHF 1,750,000 for the variable long-term compensation, i.e. for a maximum of 30,500 options to be issued.

	<b>Approved</b> <b>July 1, 2015 – June 30, 2016</b>	<b>Paid/payable</b> <b>July 1, 2015 – June 30, 2016</b>
Base salary (CHF)	1,900,000	1,790,308
Cash bonus (CHF)	600,000	304,661
Stock options (CHF)	1,750,000	516,427
<b>Total (CHF)</b>	<b>4,250,000</b>	<b>2,611,396</b>
Stock options (number)	30,500	23,550 <sup>1</sup>

<sup>1</sup> The balance number of 6,950 unused options (30,500–23,550) has been allocated to the newly hired EM member as described in the next paragraph.

### Newly hired EM members

Effective July 1, 2015, Christoph Rentsch was appointed as a new Chief Financial Officer (CFO) of Santhera and joined the EM. As the maximum total compensation approved at the 2015 ASM was not sufficient to compensate the newly joined CFO, his compensation was based on the additional amount as provided for in art. 26 of the Articles. Such additional amount is capped at 50% of each compensation element of the EM members as approved by the 2015 ASM.

The approvals were as follows: CHF 1,900,000 for the fixed compensation in cash; CHF 600,000 for the variable short-term compensation, consisting of a bonus; and a total maximum amount of CHF 1,750,000 for the variable long-term compensation, i.e. for a maximum of 30,500 options to be issued.

Based on the above 50% allowance, the maxima for Mr. Rentsch were CHF 950,000 for the fixed compensation in cash, CHF 300,000 for the variable cash bonus and 22,200 options<sup>1, 2</sup>.

	<b>Approved</b> <b>July 1, 2015 – June 30, 2016</b>	<b>Paid/payable</b> <b>July 1, 2015 – June 30, 2016</b>
Base salary (CHF)	950,000	414,733
Cash bonus (CHF)	300,000	70,397
Stock options (CHF)	875,000	827,831
<b>Total (CHF)</b>	<b>2,125,000</b>	<b>1,312,961</b>
Stock options (number)	22,200 (15,250 <sup>1</sup> + 6,950 <sup>2</sup> )	22,000

<sup>1</sup> Based on the additional amount as provided for in article 26 of the Articles (30,500 divided by 2).

<sup>2</sup> Reflects the difference between the total number of options approved for allocation to the EM members (30,500) and those effectively granted to the EM members without the CFO (23,550).



## **Outlook for EM compensation**

According to the new voting procedure (for details see section "Approval of Compensation by the ASM"), it is intended to submit to the 2016 ASM:

1. The maximum total amount of the fixed compensation for the Executive Management for the period from January 1 to December 31, 2016, of CHF 2,450,000.
2. The maximum total amount of the fixed compensation for the period from January 1 to December 31, 2017, of CHF 2,600,000.

## **Executive Contracts**

The employment contracts with the EM members have been amended for compliance with the OaEC and the Company's Articles of Incorporation and provide for a notice period of one year. Any noncompete clauses for the period after termination of an employment agreement shall not exceed one year with the maximum compensation for such period of the last total annual compensation of an EM member in question. In case of a change in control and related thereto (i) a substantial change in the terms of employment, or (ii) a dismissal without cause, the contract of certain EM members can provide a maximum of a 12 month's salary payment while no notice period has to be observed.

## **Loans and Credits**

In accordance with the Articles, loans to members of the Board and EM may only be on market terms and may only be made by the Company or by any of its directly or indirectly controlled companies, whereas the total sum of total outstanding loans to a particular member, including the amount to be granted, shall not exceed twice the most recent annual compensation to such member. In 2015, no loans or credits were made to the members of the Board, EM or to their related parties.

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

In connection with option exercises by several former members of the Board and EM, Santhera had to contribute to the proceeds from options, as these are subject to social security payments in accordance with applicable laws. With regard to the former Board members, Santhera made a total of CHF 5,590 (2014: CHF 167,755) for such payments in 2015.

**Disclosure of compensation of former Board members for the years 2015 and 2014 (audited)**

<b>In CHF</b>	<b>Total payment</b>
<b>2015</b>	
Klaus Schollmeier	5,590
<b>Total</b>	<b>5,590</b>
<b>2014</b>	
Klaus Schollmeier	121,151
Timothy Rink	41,777
Peter Wolf	4,827
<b>Total</b>	<b>167,755</b>

With regard to the former EM members, Santhera made a total of CHF 24,556 (CHF 44,760) for such payments in 2015 (2014).

**Disclosure of compensation of former EM members for the years 2015 and 2014 (audited)**

<b>In CHF</b>	<b>Total payment</b>
<b>2015</b>	
Barbara Heller	24,556
<b>Total</b>	<b>24,556</b>
<b>2014</b>	
Barbara Heller	23,017
Helmut Kessmann	21,743
<b>Total</b>	<b>44,760</b>

## Shareholdings of Members of the Board and Executive Management

Disclosure of shareholdings in the Company of Board members for the years 2015 and 2014 (audited)

	Number of shares	Number of stock options (vested)	Number of stock options (unvested)
<b>2015</b>			
Martin Gertsch	38,109	0	3,000
Jürg Ambühl	30,000	0	4,000
<b>Total</b>	<b>68,109</b>	<b>0</b>	<b>7,000</b>
<b>2014</b>			
Martin Gertsch	21,609	0	16,500
Jürg Ambühl	17,000	0	13,000
<b>Total</b>	<b>38,609</b>	<b>0</b>	<b>29,500</b>

Disclosure of shareholdings in the Company of Executive Management members for the years 2015 and 2014 (audited)

	Number of shares	Number of stock options (vested)	Number of stock options (unvested)
<b>2015</b>			
Thomas Meier	72,902	0	12,250
Nicholas Coppard	1	0	9,000
Günther Metz	0	11,000	5,000
Christoph Rentsch	0	0	15,000
Giovanni Stropoli	400	0	15,000
Oliver Strub	0	10,000	5,000
<b>Total</b>	<b>73,303</b>	<b>21,000</b>	<b>61,250</b>
<b>2014</b>			
Thomas Meier	38,508	48,644	59,500
<b>Total</b>	<b>38,508</b>	<b>48,644</b>	<b>59,500</b>

## Report of the Statutory Auditor on the Compensation Report

Basel, April 11, 2016

We have audited the accompanying compensation report of Santhera Pharmaceuticals Holding AG for the year ended 31 December 2015. The audit was limited to the information according to articles 14–16 of the Ordinance against Excessive Compensation in Stock Exchange Listed Companies (Ordinance) contained in the tables labeled “audited” on pages 66 to 76 of the compensation report.

### Responsibility of the Board of Directors

The Board of Directors is responsible for the preparation and overall fair presentation of the compensation report in accordance with Swiss law and the Ordinance. The Board of Directors is also responsible for designing the compensation system and defining individual compensation packages.

### Auditor's responsibility

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

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

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

### Opinion

In our opinion, the compensation report for the year ended 31 December 2015 of Santhera Pharmaceuticals Holding AG complies with Swiss law and articles 14–16 of the Ordinance.

Ernst & Young Ltd

/s/ Jolanda Dolente  
Licensed audit expert  
(Auditor in charge)

/s/ Nicole Riggenschach  
Licensed audit expert

# Corporate Governance Report

## Content

General Information .....	79
Group Structure and Shareholders (DCG 1) .....	79
Capital Structure (DCG 2) .....	81
Board of Directors (DCG 3) .....	83
Executive Management (DCG 4 and 3.6) .....	86
Compensation, Shareholdings and Loans (DCG 5) .....	89
Shareholders' Participation (DCG 6) .....	89
Changes of Control and Defense Measures (DCG 7) .....	90
Auditors (DCG 8) .....	90
Information Policy (DCG 9) .....	91

## General Information

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

The information published below conforms to the Directive Corporate Governance (**DCG**) of the SIX Swiss Exchange (**SIX**). In order to avoid redundancies, references are inserted to other parts of the financial report. Santhera's website [www.santhera.com](http://www.santhera.com) provides 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	CHE-105.388.338
Listing	SIX Swiss Exchange
Symbol	SANN
Security ID	2714864
ISIN	CH0027148649
Market capitalization	CHF 562 million (December 30, 2015)
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 3.2 " <i>Investments in shareholdings</i> " to the statutory financial statements of the Company.

Santhera operates through its wholly owned subsidiaries (DCG 1.1.3):

Company	Domicile	Activities
Santhera Pharmaceuticals (Schweiz) AG	Liestal, CH	Headquarters; development of pharmaceutical drugs, administrative functions
Santhera Pharmaceuticals (Liechtenstein) AG	Ruggell, LI	Logistics/distribution
Santhera (Germany) GmbH	Munich, DE	Medical information
Santhera (Netherlands) B.V.	Nieuwegein, NL	Medical information
Santhera (UK) Ltd	London, GB	Medical information
Santhera (Italy) S.r.l.	Milano, IT	Medical information
Santhera Pharmaceuticals (Canada), Inc.	Montréal, CA	Development of pharmaceutical drugs
Santhera Pharmaceuticals (USA), Inc.	Charlestown, Massachusetts, US	Advocacy / patient liaison
Santhera Pharmaceuticals (Deutschland) GmbH	Lörrach, DE	Regulatory and development in the EU
Oy Santhera Pharmaceuticals (Finland) Ltd	Helsinki, FI	Administrative

None of these subsidiaries is listed on a stock exchange (DCG 1.1.2). The development 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 4.2 *"Significant Shareholders"* to the statutory financial statements of the Company.

#### Cross-shareholdings (DCG 1.3)

There are no cross-shareholdings.

## Capital Structure (DCG 2)

### Ordinary, conditional and authorized capital (DCG 2.1/2.2)

The Company has one class of registered shares with a nominal value of CHF 1 each (Shares). As of December 31, 2015, it had the following ordinary, authorized and conditional share capital:

Type of capital	Capital as per commercial register		Effectively outstanding capital		Expiry	Section in Articles
	Amount in CHF	As % of ordinary capital	Amount in CHF	As % of ordinary capital		
<b>Ordinary capital</b>	5,564,492	100.0	6,262,798	100.0		3
<b>Authorized capital<sup>1</sup></b>	910,000	16.4	910,000	14.5	May 10, 2017	3a
<b>Conditional capital for warrants/option rights granted in connection with debt instruments<sup>2</sup></b>	950,000	17.1	650,000	10.4	For conversion rights: 10 years from issue date. For options: 7 years from issue date.	3c
<b>Conditional capital for ESOP/BSOP/EIP<sup>3</sup></b>	800,000	14.4	401,694	6.4		3b

1 On December 2, 2015, Santhera completed a placement of 590,000 shares via an accelerated bookbuilding process and raised gross proceeds of CHF 54.8 million. The shares were sold at a price of CHF 93.0 per share, a discount of 4.5% to the volume-weighted average price of December 1, 2015.

2 On August 7, 2015, Santhera completed the sale of 300,000 registered shares of common stock yielding an aggregate income of CHF 27.7 million. The shares were sold by the independent broker Kepler Chevreux within four days (August 3 to 6) at an average price of CHF 92.38 per share.

3 In 2015, former and current employees and Board members exercised 398,306 options converting them into the same amount of shares.

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

For details with regard to the Company's ESOP, BSOPs and EIP, see note 17 "*Stock Option Plans*" to the consolidated financial statements.

### Changes in share capital (DCG 2.3)

For changes in capital that occurred in 2013 and 2014, see the Company's Annual Report 2014, which can be downloaded from [www.santhera.com/reports](http://www.santhera.com/reports). For changes that took place in 2015, see note 12 "*Share Capital*" to the consolidated financial statements of the Company.



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

As of December 31, 2015, 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 Annual Shareholders' Meeting (**ASM**) resolves in favor of a dividend payment.

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

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

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

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

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

### *Convertible loans*

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

### *Options, warrants*

See the statutory financial statements of the Company and note 17 "*Stock Option Plans*" to the consolidated financial statements.

## Board of Directors (DCG 3)

### Board and committee memberships (DCG 3.1/3.2/3.3 and 3.4)

	Year of birth	Nationality	First elected	Elected until	Board
Jürg Ambühl	1949	CH	2009	2016	Member
Martin Gertsch	1965	CH	2006	2016	Chairman

#### *Jürg Ambühl*

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

#### *Martin Gertsch*

Martin Gertsch is an experienced chief financial officer in the life science industry. Until January 2014, he served as chief financial officer of Acino Holding. Before, he was vice-president head of finance EMEA at Synthes and held chief financial and chief operating officer positions at 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. Mr. Gertsch is a Swiss certified fiduciary and Swiss certified public accountant. He has also completed several executive-level development programs at IMD (International Institute for Management Development) in Lausanne, Switzerland. Mr. Gertsch is a Board member of Evolva Holding and Board member of the University Center of Dentistry, Basel (UZB).

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

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

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

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

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

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

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

See table in section on DCG 4.3.

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

According to the Company's Articles, the Board consists of no more than eight members. The term of office of a Board member must not exceed one year, whereby a year means the period between two ASMs. 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 of 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 2016 ASM. The Board members are elected on an individual basis. The Chairman is elected by the shareholders.

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

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

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

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

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

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

#### *Core tasks of the Board*

The Board is entrusted with the ultimate direction of the Company and supervision of the Executive Management. The Board's nontransferable and inalienable duties include the duty to (i) ultimately manage the Company and issue the necessary directives, (ii) determine the organizational structure of the Company, (iii) organize the accounting system, financial control (including the Company's internal control system, risk management as well as financial planning), and (iv) appoint, recall and ultimately supervise the persons entrusted with the management and representation of the Company. The nontransferable and inalienable duties also comprise responsibility for preparation of the Annual Report and the ASM, carrying out shareholders' resolutions, and notification to the judge in case of overindebtedness of the Company. The full Board approves the Company's budget and major contracts if they are not within budget. It also reviews filing strate-

gies before regulatory authorities such as the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA). It reviews and approves merger and acquisitions projects including licensing transactions of a material size and the Company's commercialization strategy.

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

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

The adoption of resolutions and elections by the Board require a majority of the votes cast. To validly pass a resolution, more than half of the members of the Board must be present at the meeting. In case of an impasse, the Chairman has a casting vote. In the period under review, all resolutions by the Board were taken unanimously. Meetings may also 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 an ongoing basis. It also assesses the Company's internal control system and is responsible for the Company's risk management, accounting principles and policies as well as tax structures. The Board communicates with the Company's external auditors concerning the results of their interim audits, audits of the annual and reviews of the interim financial statements and assesses important or critical accounting topics with the Executive Management and the external auditors.

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

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

#### *Meetings in 2015*

In 2015, the Board held three meetings in person which on average lasted more than eight hours. In addition, the Board held five teleconferences which on average lasted one hour, not counting the monthly update calls and additional calls as required.

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

As a rule, the CEO, the CFO 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. Other members of Executive Management are invited to attend discussions of their areas of responsibility (commercial operations, development and business development). Other members of senior management are present when HR, financial, and supply chain topics are discussed. In addition, other employees are invited for certain agenda items covering their area of expertise, for example, to discuss results and progress of clinical studies and submissions to regulatory authorities. 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 had a risk management report prepared. Among the key risks identified were the launch of Raxone in the European Union for the treatment of Leber's hereditary optic neuropathy (LHON), the regulatory risk in the EU and the US with respect to Duchenne muscular dystrophy (DMD), and the retention of key personnel.

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

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

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

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

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

The CEO, together with Executive Management, is responsible for implementation of the decisions taken by the Board and its Committees. With the support of the management team – consisting of the members of Executive Management, the Vice-President (**VP**) Head Human Resources, the VP Finance & Accounting and the VP Technical Development & Operations – he prepares the business strategy and business plan for decision by the Board. In accordance with the Group Directive "Competencies & Responsibilities," the CEO approves material contracts, decides on the Company's intellectual property rights and the handling of lawsuits. He also allocates financial, personnel and other resources within Santhera and supervises the members of the management team. The management team has regular meetings that usually cover the following topics: product revenues, development programs and clinical studies, regulatory strategies, resource allocation, business development, competitive situation, risk management and internal control system, corporate affairs including important contracts, supply chain and information on subsidiaries, financing situation and strategies, internal and external financial reporting, financial controlling, public and investor relations, human resources, taxes, legal and compliance.

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

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

\* as of February 1, 2015

\*\* as of July 1, 2015

*Thomas Meier*

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

*Nicholas Coppard*

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

*Günther Metz*

Günther Metz spent more than 20 years in the life science industry and has been working for Santhera since its inception in 2004. Mr. Metz began his career in drug discovery at the French company Fournier Pharma, and thereafter joined the German start-up Graffinity, which in 2004 merged with MyoContract to form Santhera. Mr. Metz held various research management positions in cross-functional teams and while working at Santhera gained broad experience across the preclinical and clinical pharmaceutical value chain in diverse indications. In 2008, he transitioned to a new area of responsibilities in business development and licensing, taking up the role of Vice-President (VP) Busi-

ness Development at Santhera. Mr. Metz received his PhD in biophysics from the University Freiburg, Germany, in 1992 and subsequently held a postdoctoral research position at Yale University, New Haven, Connecticut, US, supported by a fellowship from the Alexander von Humboldt Foundation.

#### *Christoph Rentsch*

With a background in finance, and long-standing experience in the pharmaceutical industry, Christoph Rentsch brings a profound knowledge of the international public and private funding markets to Santhera. Mr Rentsch started his career in investment banking at Credit Suisse. Subsequently, he worked in various senior management functions for the Alusuisse-Lonza Group both in Switzerland and in the USA. As Head of Group Funding and Capital Markets at Roche, he was responsible for all finance transactions on group level for more than 8 years. In 2003 he became partner of Caperis Ltd, an investment advisory and management firm, before joining privately held Polyphor as CFO, where he supported the company in key stages of its development. Mr Rentsch joined Santhera in 2015. He holds a degree in Economics and Business Administration from the University of Applied Sciences, Basel.

#### *Giovanni Stropoli*

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

#### *Oliver Strub*

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

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

No member of Executive Management 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 post.

**Permitted mandates in other companies (DCG 3.3 and 4.3)**

<b>Body</b>	<b>Maximum of mandates on board of listed companies</b>	<b>Maximum of mandates on board of privately held companies</b>
Board members	4	8
Members of Executive Management	2	4

**Management contracts (DCG 4.4)**

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

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

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

**Shareholders' Participation (DCG 6)****Voting rights and representation restrictions (DCG 6.1)**

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

**Statutory quora (DCG 6.2)**

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

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

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

**Agenda rules (DCG 6.4)**

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



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

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

**Changes of Control and Defense Measures (DCG 7)****Duty to make an offer (DCG 7.1)**

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

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

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

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

Other than that, as of December 31, 2015, 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 Jolanda Dolente. She assumed her responsibility in 2015.

**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	2015	2014
Audit services		180	135
Audit-related services		12	0

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

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

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

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

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

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

Investors and other parties interested in subscribing to the Company's news service may do so by registering themselves on [www.santhera.com/subscription](http://www.santhera.com/subscription). For contact details, see reverse side of the 2015 Annual Report.

#### **Corporate events 2016**

2016 Annual Shareholders' Meeting

Wednesday, May 11, 2016, in Basel Switzerland

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

#### **Contact**

Thomas Meier, PhD, Chief Executive Officer

Phone +41 61 906 8950

[thomas.meier@santhera.com](mailto:thomas.meier@santhera.com)

## Forward-Looking Statements

This Annual Report expressly or implicitly contains certain forward-looking statements concerning Santhera Pharmaceuticals Holding AG and its business. Such statements involve certain known and unknown risks, uncertainties and other factors, which could cause the actual results, financial condition, performance or achievements of Santhera Pharmaceuticals Holding AG to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. There can be no guarantee that any of the development projects described will succeed or that any new products or indications will be brought to market. Similarly, there can be no guarantee that Santhera Pharmaceuticals Holding AG or any future product or indication will achieve any particular level of revenue. In particular, management's expectations could be affected by, among other things, uncertainties involved in the development of new pharmaceutical products, including unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the Company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing and other political pressures. Santhera Pharmaceuticals Holding AG is providing the information in this Annual Report as of the date of the publication, and does not undertake any obligation to update any forward-looking statements contained herein as a result of new information, future events or otherwise.



**Santhera Pharmaceuticals Holding AG**

Hammerstrasse 49

4410 Liestal

Switzerland

Phone +41 61 906 8950

Fax +41 61 906 8951

[www.santhera.com](http://www.santhera.com)



# 2016

Interim Condensed Report  
January to June 2016

# **Report on the Six Months Ending June 30, 2016, and Interim Condensed Consolidated Financial Statements**

## **Contents**

Santhera Announces Financial Results for the First Half-Year 2016 and Reports Solid Sales Growth .....	2
Interim Condensed Consolidated Financial Statements .....	6
Report on the Review of Interim Condensed Consolidated Financial Statement .....	16
Trademarks .....	17
Forward-Looking Statements .....	17

## Santhera Announces Financial Results for the First Half-Year 2016 and Reports Solid Sales Growth

Santhera Pharmaceuticals reports solid sales growth for the first half-year 2016. By end of the reporting period sales of Raxone® for Leber's hereditary optic neuropathy (LHON) had reached CHF 7.2 million, recorded primarily in Germany and France with an increasing sales contribution from additional mid-sized markets. Santhera has filed a Marketing Authorization Application (MAA) in Europe for Raxone for the treatment of Duchenne muscular dystrophy (DMD) in patients not taking glucocorticoids. The MAA was submitted as Type II variation of the existing marketing authorization for LHON and is currently under review by the Committee for Medicinal Products for Human Use (CHMP). Santhera will start a randomized, double-blind, placebo-controlled phase III (SIDEROS) trial shortly to assess the efficacy of Raxone in DMD patients receiving concomitant glucocorticoids. If successful, data from this trial will be used to support a label extension to include all DMD patients irrespective of their glucocorticoid use status. Santhera will also approach the US Food and Drug Administration (FDA) with the intent to re-engage in further discussions on the accelerated approval pathway for the glucocorticoid non-using patients, in whom clinically relevant benefit with Raxone has already been demonstrated.

### *Key Financials in the First Half-Year 2016*

- **Increasing sales for Raxone drove topline growth**

In the first six months of 2016, Raxone generated net sales of CHF 7.2 million (1H 2015: CHF 1.5 million; 2H 2015: CHF 2.8 million), mainly driven by increased Raxone sales to LHON patients in Germany and France.

- **Intensified commercial and clinical activities increased operating expenses**

Operating expenses in the first half-year were CHF 22.6 million (1H 2015: CHF 7.5 million). Preparation of regulatory filings for DMD in Europe and the US and the implementation of late stage clinical trials led to higher development expenses of CHF 8.1 million (1H 2015: CHF 2.9 million). Marketing and sales expenses rose to CHF 8.9 million (1H 2015: CHF 1.5 million) and general and administrative expenses (G&A) to CHF 5.5 million (1H 2015: CHF 3.1 million). These increases reflect the expansion of Santhera's operations, especially the commercial activities, the ongoing roll-out of Raxone for LHON across Europe and market entry preparations for Raxone for DMD. In summary, the operating loss amounted to CHF 17.2 million (1H 2015: CHF -6.2 million) leading to a net result of CHF -18.0 million (1H 2015: CHF -6.4 million).

- **Sound financial basis to advance commercial and development strategies as planned**

As of June 30, 2016, Santhera had cash and cash equivalents of CHF 63.6 million (December 31, 2015: CHF 76.9 million). Net change in cash and cash equivalents in the first half-year of 2016 was CHF -13.3 million.

## **Company Highlights**

- **Solid uptake of Raxone for LHON in Europe**

By end of the reporting period Raxone sales were recorded primarily in Germany and France with an increasing sales contribution from additional mid-sized markets. Santhera expects reimbursement decisions by a number of European Authorities in the second half of 2016 and early 2017.

- **Relevance of pulmonary benefits for patients with DMD reconfirmed at first “Duchenne Pulmonary Outcomes Workshop”**

In April 2016, Santhera participated in the “Duchenne Pulmonary Outcomes Workshop”, organized by Parent Project Muscular Dystrophy (PPMD), the leading US advocacy organization working to end Duchenne. The workshop convened experts in the research and clinical care of DMD patients who examined current and future assessments of pulmonary function. Santhera presented data from its phase III DELOS trial, which demonstrated clinically relevant efficacy of Raxone (idebenone) in preserving respiratory function, a key objective for DMD therapy. Previously, a patient and caregiver survey conducted by PPMD clearly demonstrated that the DMD community highly values treatment options for pulmonary complications.

- **Marketing Authorization Application (MAA) filed in Europe for Raxone for DMD**

In May 2016, Santhera submitted a MAA to the European Medicines Agency (EMA) for Raxone for the treatment of DMD in patients with respiratory function decline and not taking concomitant glucocorticoids. The new indication was submitted as Type II variation of the Company's existing marketing authorization for Raxone which was granted last year. Shortly thereafter, on June 21, the EMA validated Santhera's application thereby confirming that the submission is complete and the review process by the Committee for Medicinal Products for Human Use (CHMP) has begun.

- **Update on US filing strategy for DMD**

In July 2016, Santhera reported that the FDA commented on the proposed subpart H approval pathway and requested that a second phase III trial be completed providing additional data to support NDA filing for Raxone in all DMD patients, irrespective of their glucocorticoid use status. The FDA confirmed that a positive outcome of the planned SIDEROS trial has the potential to provide the supplementary efficacy data to support NDA filing in all DMD patients whether they use glucocorticoid or not. Santhera will work closely with the DMD patient community and clinical experts with the intent to engage the FDA in further discussions on an accelerated pathway to approval in the glucocorticoid non-using patients, in whom clinically relevant benefit has already been demonstrated.

- **Publication on bronchopulmonary benefits of Raxone in DMD in *Neuromuscular Disorders***

In June, additional data from the pivotal phase III trial (DELLOS) were published in *Neuromuscular Disorders*, the official journal of the World Muscle Society (McDonald et al., *Neuromuscular Disorders* 2016, 26: 473–480). These data show that DMD patients treated with Raxone have a reduced risk of bronchopulmonary complications including fewer hospitalizations caused by such complications and a reduced need for systemic antibiotic treatment compared to patients receiving placebo.



- **Received US fast-track designation for omigapil – CALLISTO study on track**

In May, Santhera received Fast Track Designation from the FDA for omigapil for the treatment of congenital muscular dystrophy (CMD). Previously, omigapil was granted Orphan Drug Designation for CMD in both the EU and the US. Santhera, in collaboration with the US National Institutes of Health (NIH), is currently conducting a clinical phase I study (CALLISTO) with omigapil in CMD patients. CALLISTO assesses the pharmacokinetics, safety, and tolerability of omigapil in ambulatory and non-ambulatory children affected by CMD. On August 30, Santhera announced that the Office of Orphan Products Development (OOPD) at the FDA has granted Santhera an award of USD 246'000 in support of its ongoing CALLISTO trial.

- **SIDEROS trial with Raxone in DMD-patients using glucocorticoids to start imminently**

The first patient is expected to be enrolled shortly in Santhera's randomized, double-blind, placebo-controlled phase III SIDEROS study. The trial is designed to confirm the efficacy of Raxone in patients currently taking glucocorticoids who are experiencing respiratory function decline, a patient population previously not enrolled in the positive phase III DELOS trial. If successful, this study will provide data to support the use of Raxone in all DMD patients experiencing respiratory decline irrespective of their glucocorticoid use status. Raxone for DMD was granted Orphan Drug Designation in the EU and the US and Fast Track Designation in the US.

### ***Outlook and Guidance***

The Marketing Authorization Application for Raxone in DMD is currently under review by the CHMP and Santhera expects a response from the regulatory authority in the first quarter 2017.

In July 2016, Santhera was advised by the FDA that the successful completion of the SIDEROS trial together with data from the previously successful phase III DELOS trial will provide the necessary data to support NDA filing for Raxone in all DMD patients irrespective of the glucocorticoid use status. In the interest of patients and due to the fact that the benefit of Raxone has already been demonstrated in the glucocorticoid non-using patients, Santhera will approach the FDA with the intent to re-engage in further discussions on an accelerated pathway to approval specifically for this patient population.

Santhera currently expects net sales of Raxone in 2016 to reach CHF 16 to 18 million.

# Interim Condensed Consolidated Financial Statements

## Contents

Interim Consolidated Balance Sheet .....	6
Interim Consolidated Income Statement (Reviewed) .....	7
Interim Consolidated Statement of Comprehensive Income (Reviewed) .....	8
Interim Consolidated Statement of Cash Flows (Reviewed) .....	9
Interim Consolidated Statement of Changes in Equity (Reviewed) .....	10
Notes to the Interim Condensed Consolidated Financial Statements (Reviewed) .....	11
1 General Information .....	11
2 Summary of Significant Accounting Policies .....	11
3 Seasonality .....	12
4 Exchange Rates of Principal Currencies .....	12
5 Inventories .....	12
6 Cash and Cash Equivalents .....	12
7 Share Capital .....	12
8 Segment and Geographic Information .....	13
9 Operating Expenses by Nature .....	14
10 Income taxes .....	14
11 Stock Option Plans .....	14
12 Related Party Transactions .....	15
13 Subsequent Events .....	15
Report on the Review of Interim Condensed Consolidated Financial Statements .....	16

## Interim Consolidated Balance Sheet

	in CHF thousands	Notes	June 30, 2016 (reviewed)	Dec. 31, 2015 (audited)
<b>Assets</b>				
Tangible assets		9	493	398
Intangible assets		9	28,025	29,559
Financial assets long-term			266	190
Deferred tax asset			2,231	3,061
<b>Noncurrent assets</b>			<b>31,015</b>	<b>33,208</b>
Prepaid expenses and accrued income			899	1,513
Inventories		6	5,798	3,441
Trade and other receivables			3,604	2,131
Cash and cash equivalents		7	63,564	76,859
<b>Current assets</b>			<b>73,865</b>	<b>83,944</b>
<b>Total assets</b>			<b>104,880</b>	<b>117,152</b>
<b>Equity and liabilities</b>				
Share capital		8	6,275	6,263
Capital reserves and share premium			379,339	377,031
Retained earnings			-291,105	-273,133
Employee benefit reserve			-4,355	-2,958
Treasury shares			-177	-177
Other components of equity			-787	-779
<b>Total equity</b>			<b>89,190</b>	<b>106,247</b>
Pension liabilities			5,601	3,957
<b>Total noncurrent liabilities</b>			<b>5,601</b>	<b>3,957</b>
Trade and other payables			3,833	3,666
Accrued expenses			6,256	3,282
<b>Total current liabilities</b>			<b>10,089</b>	<b>6,948</b>
<b>Total liabilities</b>			<b>15,690</b>	<b>10,905</b>
<b>Total equity and liabilities</b>			<b>104,880</b>	<b>117,152</b>

## Interim Consolidated Income Statement (Reviewed)

for the half-year ended June 30, in CHF thousands	Notes	2016	2015 <sup>1</sup>
Net sales	9	7,210	1,455
Cost of goods sold		-1,911	-159
<i>Of which amortization intangible asset</i>		-1,519	0
Other operating income		61	23
Development	10	-8,101	-2,863
Marketing and sales	10	-8,949	-1,535
General and administrative	10	-5,479	-3,133
Other operating expenses	10	-38	-4
<b>Operating expenses</b>	<b>10</b>	<b>-22,567</b>	<b>-7,535</b>
<b>Operating result</b>		<b>-17,207</b>	<b>-6,216</b>
Financial income		509	104
Financial expenses		-424	-266
<b>Result before taxes</b>		<b>-17,122</b>	<b>-6,378</b>
Income taxes	11	-849	-2
<b>Net result</b>		<b>-17,971</b>	<b>-6,380</b>
<b>Basic and diluted loss per share (in CHF)</b>		<b>-2.87</b>	<b>-1.28</b>

<sup>1</sup> Some amounts have been restated in comparison with the interim report 2015. For further details related to the nature of the corrections please refer to the annual report 2015 (refer there to note 2 "Correction of errors"). As a result of the re-statement, net result for the half-year ended June 30, 2015, decreased by TCHF 169 and basic and diluted loss per share increased by CHF 0.04 compared to the amounts disclosed in the interim report 2015.

## Interim Consolidated Statement of Comprehensive Income (Reviewed)

for the half-year ended June 30, in CHF thousands	2016	2015 <sup>1</sup>
<b>Net result</b>	<b>-17,971</b>	<b>-6,380</b>
<i>Items never to be reclassified subsequently to net income in subsequent periods:</i>		
Actuarial gains/(losses) on defined benefit plans	-1,397	94
<i>Items to be reclassified subsequently to net income in subsequent periods:</i>		
Currency translation differences	-9	-18
<b>Other comprehensive result</b>	<b>-1,406</b>	<b>76</b>
<b>Total comprehensive result</b>	<b>-19,377</b>	<b>-6,304</b>

<sup>1</sup> Some amounts have been restated in comparison with the interim report 2015. For further details related to the nature of the corrections please refer to the annual report 2015 (refer there to note 2 "Correction of errors"). As a result of the re-statement, other comprehensive result for the half-year ended June 30, 2015, increased by TCHF 487 compared to the amounts disclosed in the interim report 2015.

## Interim Consolidated Statement of Cash Flows (Reviewed)

for the half-year ended June 30, in CHF thousands	Notes	2016	2015 <sup>1</sup>
Result before taxes		-17,122	-6,378
Depreciation of tangible assets		73	33
Amortization of intangible assets		1,546	7
Expenses for share options		1,984	773
Change in pension liabilities		247	110
Taxes paid		-19	-2
Change in net working capital		48	-1,873
Total financial result		-85	162
Interest received		0	1
Interest paid		-10	0
<b>Cash flow from operating activities</b>		<b>-13,338</b>	<b>-7,167</b>
Investments in tangible assets		-176	-73
Disposal of intangible assets		6	0
Investments in intangible assets		-11	-59
Investments in other financial assets		-78	0
<b>Cash flow from investing activities</b>		<b>-259</b>	<b>-132</b>
Proceeds from option exercise		336	519
<b>Cash flow from financing activities</b>		<b>336</b>	<b>519</b>
Effects of exchange rate changes on cash and cash equivalents		-34	-179
<b>Net increase/(decrease) in cash and cash equivalents</b>		<b>-13,295</b>	<b>-6,959</b>
Cash and cash equivalents at January 1		76,859	17,435
<b>Cash and cash equivalents at June 30</b>		<b>63,564</b>	<b>10,476</b>

<sup>1</sup> Some amounts have been restated in comparison with the interim report 2015. For further details related to the nature of the corrections please refer to the annual report 2015 (refer there to note 2 "Correction of errors").

## Interim Consolidated Statement of Changes in Equity (Reviewed)

	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, 2015</b>			<b>4,974</b>	<b>293,650</b>	<b>-279,083</b>	<b>-1,287</b>	<b>-177</b>	<b>-762</b>	<b>17,315</b>
Net result			0	0	-6,380	0	0	0	-6,380
Other comprehensive income			0	0	0	94	0	-18	-76
<b>Total comprehensive result for the period</b>			<b>0</b>	<b>0</b>	<b>-6,380</b>	<b>94</b>	<b>0</b>	<b>-18</b>	<b>-6,304</b>
Share-based payment transactions <sup>1</sup>	10		0	773	0	0	0	0	773
Capital increase option exercise			75	589	0	0	0	0	664
<b>Balance at June 30, 2015</b>			<b>5,049</b>	<b>295,012</b>	<b>-285,463</b>	<b>-1,193</b>	<b>-177</b>	<b>-780</b>	<b>12,448</b>
<b>Balance at January 1, 2016</b>			<b>6,263</b>	<b>377,031</b>	<b>-273,134</b>	<b>-2,958</b>	<b>-177</b>	<b>-778</b>	<b>106,247</b>
Net result			0	0	-17,971	0	0	0	-17,971
Other comprehensive income			0	0	0	-1,397	0	-9	-1,406
<b>Total comprehensive result for the period</b>			<b>0</b>	<b>0</b>	<b>-17,971</b>	<b>-1,397</b>	<b>0</b>	<b>-9</b>	<b>-19,377</b>
Share-based payment transactions	10		0	1,984	0	0	0	0	1,984
Capital increase option exercise			12	324	0	0	0	0	324
<b>Balance at June 30, 2016</b>			<b>6,275</b>	<b>379,339</b>	<b>-291,105</b>	<b>-4,355</b>	<b>-177</b>	<b>-787</b>	<b>89,190</b>

<sup>1</sup> Some amounts have been restated in comparison with the interim report 2015. For further details related to the nature of the corrections please refer to the annual report 2015 (refer there to note 2 "Correction of errors"). As a result of the re-statement share based payment transactions increased by CHF 169 in the six month period ended June 30, 2016.

## Notes to the Interim Condensed Consolidated Financial Statements (Reviewed)

### 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 neuromuscular and mitochondrial diseases, an area which includes many orphan and niche indications with no current therapy.

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

The consolidated interim financial statements were approved for publication by the Board of Directors (**Board**) on September 5, 2016.

### 2 Summary of Significant Accounting Policies

The accounting policies used in the preparation of the interim financial statements are consistent with those used in the preparation of the Group's annual financial statements for the year ended December 31, 2015, except for the adoption of new standards and interpretations as of January 1, 2016, as noted below.

#### *Basis of preparation*

These unaudited consolidated interim financial statements were prepared in accordance with IAS 34 Interim Financial Reporting and should be read in conjunction with the annual financial statements for the year ended December 31, 2015.

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

#### *Changes in accounting policies*

The accounting policies adopted in the preparation of the interim condensed consolidated financial statements are consistent with those followed in the preparation of the Group's annual consolidated financial statements for the year ended December 31, 2015.

In 2016 the Group has implemented various minor amendments to existing standards and interpretations, which have no impact on the Group's overall results and financial position or on disclosures in this interim report.



### 3 Seasonality

The operating result is not subject to significant seasonal variations during the financial year.

### 4 Exchange Rates of Principal Currencies

	Income statement in CHF average rates		Balance sheet in CHF as of period end	
	Six months ended June 30, 2016	Six months ended June 30, 2015	June 30, 2016	Dec. 31, 2015
1 Euro (EUR)	1.0960	1.0583	1.0884	1.0826
1 US dollar (USD)	0.9822	0.9475	0.9793	0.9927
1 British pound (GBP)	1.4080	n/a	1.3189	1.4694
1 Canadian dollar (CAD)	0.7380	0.7680	0.7558	0.7157

### 5 Inventories

This position consists mainly of active pharmaceutical ingredient and semi-finished products which are kept by Santhera as stock for market supply, development and inventory risk management purposes (security stock) for Raxone/Catena.

### 6 Cash and Cash Equivalents

	in CHF thousands	June 30, 2016	Dec. 31, 2015
Cash at banks and on hand			
in CHF		59,134	69,570
in EUR		2,726	6,270
in GBP		1,526	772
in USD		51	191
in CAD		55	56
other currencies		72	0
<b>Total at period end</b>		<b>63,564</b>	<b>76,859</b>

### 7 Share Capital

#### *Ordinary share capital*

During the reporting period ending June 30, 2016, 11,800 Shares were issued out of conditional share capital upon the exercise of stock options. As a result, as of June 30, 2016, the issued nominal share capital amounted to CHF 6,274,598, divided into 6,274,598 Shares at a nominal value of CHF 1 each.

In the same period for 2015, 74,721 Shares were issued from conditional capital upon the exercise of stock options.

### ***Authorized share capital***

On the occasion of the Annual Shareholders' Meeting (**ASM**) on May 11, 2016, Santhera's shareholders approved the increase and extension of the authorized share capital of the Company. The Board is authorized to increase the share capital at any time until May 10, 2018 through the issuance of up to 1,500,000 Shares with a nominal value of CHF 1 each.

### ***Conditional share capital***

As of June 30, 2016, the Company had conditional share capital, pursuant to which the share capital may be increased by

- (i) a maximum amount of CHF 550,000 through the issuance of up to 550,000 Shares with the exercise of option rights. This part of the conditional share capital was increased from formerly CHF 401,694, as per December 31, 2015, to CHF 550,000 as approved at the ASM on May 11, 2016. During the first half of 2016, 11,800 options were exercised, reducing the available conditional capital to CHF 538,200 as per June 30, 2016. In the same period 2015, 74,721 options were exercised, reducing the available conditional capital to CHF 725,279 as per June 30, 2015 (see note 12 "Stock Option Plans").
- (ii) a maximum amount of CHF 650,000 by issuing up to 650,000 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.

## **8 Segment and Geographic Information**

### ***Segment information***

Santhera operates in one business segment, namely development and commercialization of products for the treatment of neuromuscular and mitochondrial diseases. The Board and the Executive Management, being the chief operating decision makers, 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 for the treatment of LHON. Geographic revenue information is based on location of the customer.

### ***Geographic information***

<b>Net sales</b>			
	six months ended June 30, in CHF thousands	<b>2016</b>	<b>2015</b>
Europe		7,179	1,455
Rest of the world		31	0
<b>Total</b>		<b>7,210</b>	<b>1,455</b>

**Noncurrent assets (excluding financial instruments and deferred tax assets)**

	in CHF thousands	June 30, 2016	Dec. 31, 2015
Switzerland		28,429	29,876
European Union		89	80
North America		0	1
<b>Total</b>		<b>28,518</b>	<b>29,957</b>

**9 Operating Expenses by Nature**

	six months ended June 30, in CHF thousands	2016	2015 <sup>1</sup>
External development expenses		-5,993	-2,290
Patent and license expenses		-122	-98
Marketing expenses		-3,925	-320
Employee expenses		-9,904	-4,573
<i>of which non-cash-relevant expenses for share-based payments</i>		-1,984	-773
General and administrative expenses		-2,188	-1,160
Depreciation, amortization and impairment		-101	-40
Reversal of impairment on inventories		0	1,111
Lease expenses		-296	-161
Other operating expenses		-38	-4
<b>Total operating expenses</b>		<b>-22,567</b>	<b>-7,535</b>

<sup>1</sup> Some amounts have been restated in comparison with the interim report 2015. For further details please refer to the annual report 2015 (refer there to note 2 "Correction of errors").

Increased expenses for the reporting period in 2016 result from additional staff hired for marketing activities in LHON as well as development operations for LHON and DMD.

**10 Income Taxes**

	six months ended June 30, in CHF thousands	2016	2015
Income taxes		-19	-2
Deferred taxes		-830	0
<b>Total</b>		<b>-849</b>	<b>-2</b>

Movements on deferred taxes relate to temporary differences on inventory.

## 11 Stock Option Plans

Santhera has established Employee Stock Option Plans (ESOP), the ESOP 2004, the ESOP 2008, the ESOP 2010, the ESOP 2015, the 2006 Executive Incentive Plan (EIP) and Board Stock Option Plans (BSOP), the BSOP 2011 and BSOP 2015 to align the long-term interests of the Board, the Executive Management and employees. Options granted under the stock option plans are equity-settled. New grants are currently only possible under the ESOP 2015 and BSOP 2015.

In the reporting period ended June 30, 2016, a total of 142,392 options with exercise prices between CHF 69.30 and CHF 89.45 were granted. In the half-year period ending June 30, 2015, a total of 94,260 options with exercise prices between CHF 84.10 and CHF 105.50 were granted.

The fair value of stock options is determined at each grant date by using the Hull-White option pricing model. For the calculation of the fair value of stock options granted during the reporting period in 2016, the same range of valuation parameters as disclosed in the financial statements as of December 31, 2015, was applied, except for the CHF risk-free interest rate (between 0.00% and -0.30%) and the expected volatility (39%). The non-cash-relevant expenses for all unvested stock options in the reporting period 2016 amounts to TCHF 1,984 compared to TCHF 773 in the same period in 2015.

### *Options outstanding*

	six months ended June 30, number of options	2016	2015
<b>At January 1</b>		<b>223,834</b>	<b>477,580</b>
Granted <sup>1</sup>		142,392	94,260
Forfeited		-5,071	-2,700
Expired		-4,963	0
Exercised		-11,800	-74,721
<b>At June 30<sup>2</sup></b>		<b>344,392</b>	<b>494,419</b>

<sup>1</sup> The weighted average fair value of the stock options granted during the reporting period in 2016 was CHF 24.18 (CHF 43.09 in the comparative reporting period 2015).

<sup>2</sup> Based on the closing price of CHF 76.90 of the Santhera Shares on June 30, 2016, a total of 72,308 stock options were in the money, whereof 50,646 were vested (on June 30, 2015, the closing Share price was CHF 90.00; a total of 440,166 options were in the money, whereof 381,431 were vested).

## 12 Related Party Transactions

During the reporting period 2016, a total of 6,562 options were granted to members of the Board and 30,550 options were granted to members of the Executive Management. In the same period in 2015, a total of 7,000 options were granted to members of the Board and 53,500 options to members of the Executive Management.

## 13 Subsequent Events

None.

## Report on the Review of Interim Condensed Consolidated Financial Statements

Basel, September 5, 2016

### Introduction

We have reviewed the interim condensed consolidated financial statements (Interim Consolidated Balance Sheet, Interim Consolidated Income Statement, Interim Consolidated Statement of Comprehensive Income, Interim Consolidated Statement of Cash Flows, Interim Consolidated Statement of Changes in Equity and Notes) of Santhera Pharmaceuticals Holding AG for the six-month period ended 30 June 2016 (pages 6 to 15). The Board of Directors is responsible for the preparation and presentation of these interim condensed consolidated financial statements in accordance with International Financial Reporting Standard IAS 34 "Interim Financial Reporting". Our responsibility is to express a conclusion on these interim condensed consolidated financial statements based on our review.

### Scope of Review

We conducted our review in accordance with International Standard on Review Engagements 2410 "Review of Interim Financial Information Performed by the Independent Auditor of the Entity". A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

### Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim condensed consolidated financial statements are not prepared, in all material respects, in accordance with International Financial Reporting Standard IAS 34 "Interim Financial Reporting".

Ernst & Young AG

/s/ Jolanda Dolente  
Licensed audit expert  
(Auditor in charge)

/s/ Nicole Riegenbach  
Licensed audit expert

## **Trademarks**

Raxone® is a trademark of Santhera Pharmaceuticals.

## **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.

**Santhera Pharmaceuticals Holding AG**

Hammerstrasse 49

4410 Liestal

Switzerland

Phone +41 61 906 89 50

Fax +41 61 906 89 51

[www.santhera.com](http://www.santhera.com)

**Contacts**

Thomas Meier, PhD

Chief Executive Officer

Phone +41 61 906 89 50

[thomas.meier@santhera.com](mailto:thomas.meier@santhera.com)

Christoph Rentsch

Chief Financial Officer

Phone +41 61 906 89 65

[christoph.rentsch@santhera.com](mailto:christoph.rentsch@santhera.com)

Daniel Piller

Head Communications

Phone +41 61 906 89 26

[daniel.piller@santhera.com](mailto:daniel.piller@santhera.com)

## **Santhera Reports Preliminary Key Financial Figures for 2016 and Provides Corporate Update**

**Liestal, Switzerland, January 26, 2017 – Santhera Pharmaceuticals (SIX: SANN) announces preliminary, unaudited key financial figures for 2016. The Company reports net revenues of CHF 19.0 million (+340% year-on-year) from sales of its lead product Raxone® for the treatment of Leber's hereditary optic neuropathy (LHON). Santhera submitted Marketing Authorization Applications (MAA) for Raxone for the treatment of Duchenne muscular dystrophy (DMD) in the EU and Switzerland and made significant progress in all product development programs. Cash and cash equivalents by year-end amounted to CHF 49.8 million.**

### **Commercial and Financial Highlights**

- In 2016, the Company reported net revenues from product sales of CHF 19.0 million which is more than four-fold the net sales of the prior year (2015: CHF 4.3 million). Net sales for the second half of 2016 of CHF 11.8 million represent an increase of 64% compared to the first half of 2016 (CHF 7.2 million).
- Raxone was sold into 15 EU countries, with the majority of sales reached in France and Germany. Based on the number of packs sold, it is estimated that by year-end 2016 more than 280 LHON patients were receiving Raxone (year-end 2015: approx. 120).
- By end of 2016 full reimbursement for Raxone in LHON was achieved for Germany, Sweden, Norway, and Luxembourg. In several other countries, including France, Raxone availability is currently governed by special reimbursement schemes. The Company expects to reach full reimbursement in additional EU countries in 2017.
- By end of 2016 Santhera held CHF 49.8 million in cash and cash equivalents (end of 2015: CHF 76.9 million).
- For 2016, the Company expects a net result of CHF –33 to –38 million.
- The Company's outstanding shares amounted to 6'279'857 as of December 31, 2016.
- For 2017, Santhera expects net sales of Raxone for the currently approved indication to reach CHF 21 to 23 million.

### **Pipeline and Regulatory Highlights achieved in 2016**

- Santhera submitted a MAA to the European Medicine Agency for Raxone for the treatment of DMD in patients with respiratory function decline and not taking concomitant glucocorticoids. Santhera expects an opinion from the Committee for Medicinal Products for Human Use (CHMP) on this second indication late in Q1 / early in Q2 2017.



## Santhera Reports Preliminary Key Financial Figures for 2016

January 26, 2017 / Page 2 of 3

- Santhera also submitted the corresponding MAA to the Swiss Agency for Therapeutic Products (Swissmedic).
- Santhera started a new randomized, double-blind, placebo-controlled Phase III trial (SIDEROS) designed to assess the efficacy of Raxone in delaying the loss of respiratory function in DMD patients receiving concomitant glucocorticoid therapy. The trial will be conducted in approximately 60 centers in Europe and in the US and has started to enroll patients. Treatment duration is 18 months and results of the SIDEROS trial are expected in H2 2019.
- The UK's Medicines and Healthcare Products Regulatory Agency (MHRA) designated Raxone as Promising Innovative Medicine (PIM) and as suitable candidate for entry into Step II of the Early Access to Medicines Scheme (EAMS).
- Santhera receives Fast Track Designation and a grant from the FDA's Office of Orphan Products Development for omigapil in congenital muscular dystrophy (CMD). The Phase I trial (CALLISTO) progresses as planned and the last patient's first visit is foreseen for Q2 2017 and results are currently planned to be available in H2 2017.
- The fully recruited Phase I/II trial (IPPoMS) with Raxone in primary progressive multiple sclerosis (PPMS) is conducted in collaboration with the US National Institute of Neurological Disorders and Stroke (NINDS). Completion of this trial is currently foreseen by late in 2017 with results to be announced end 2017 / early 2018.

"We are very excited about Santhera's strong progress last year, as witnessed by accelerating sales and regulatory submissions for DMD," commented **Thomas Meier**, PhD, CEO of Santhera. "While pushing ahead with the commercialization of Raxone in LHON, our main focus in 2017 will be on the preparation for market entry of Raxone as a therapy of DMD and the advancement of the SIDEROS trial."

---

### Conference call:

An investor conference call with Thomas Meier, PhD, CEO of Santhera, will be held on January 26, 2017, at 13:00 hrs CET to discuss the results. Dial-in participants are invited to call on the following numbers about 10 minutes before the conference call is due to start.

+41 (0)58 310 50 00 (Europe)

+44 (0)203 059 58 62 (UK)

+1 (1)631 570 5613 (USA)

### Upcoming corporate events:

- Release of the audited financial results for 2016 on March 7, 2017
- Annual Shareholders' Meeting on April 4, 2017

## Santhera Reports Preliminary Key Financial Figures for 2016

January 26, 2017 / Page 3 of 3

### About Santhera

Santhera Pharmaceuticals (SIX: SANN) is a Swiss specialty pharmaceutical company focused on the development and commercialization of innovative pharmaceutical products for the treatment of orphan mitochondrial and neuromuscular diseases. Santhera's lead product Raxone is authorized in the European Union, Norway, Iceland and Liechtenstein for the treatment of Leber's hereditary optic neuropathy (LHON). For Duchenne muscular dystrophy (DMD), the second indication for Raxone, Santhera has filed a Marketing Authorization Application (MAA) in the European Union and Switzerland. In collaboration with the US National Institute of Neurological Disorders and Stroke (NINDS) Santhera is developing Raxone in a third indication, primary progressive multiple sclerosis (PPMS), and omigapil for congenital muscular dystrophy (CMD), all areas of high unmet medical need. For further information, please visit the Company's website [www.santhera.com](http://www.santhera.com).

*Raxone® is a trademark of Santhera Pharmaceuticals.*

### For further information, contact:

Thomas Meier, PhD, Chief Executive Officer  
Phone +41 61 906 89 64  
[thomas.meier@santhera.com](mailto:thomas.meier@santhera.com)

Christoph Rentsch, Chief Financial Officer  
Phone +41 61 906 89 65  
[christoph.rentsch@santhera.com](mailto:christoph.rentsch@santhera.com)

### US investor contact

Hans Vitzthum, LifeSci Advisors, LLC  
Phone +1 212 915 2568  
[hans@lifesciadvisors.com](mailto:hans@lifesciadvisors.com)

### US Public Relations contact

Deanne Eagle, Planet Communications  
Phone +1 917 837 5866  
[deanne@planetcommunications.nyc](mailto:deanne@planetcommunications.nyc)

### Disclaimer / Forward-looking statements

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

###