



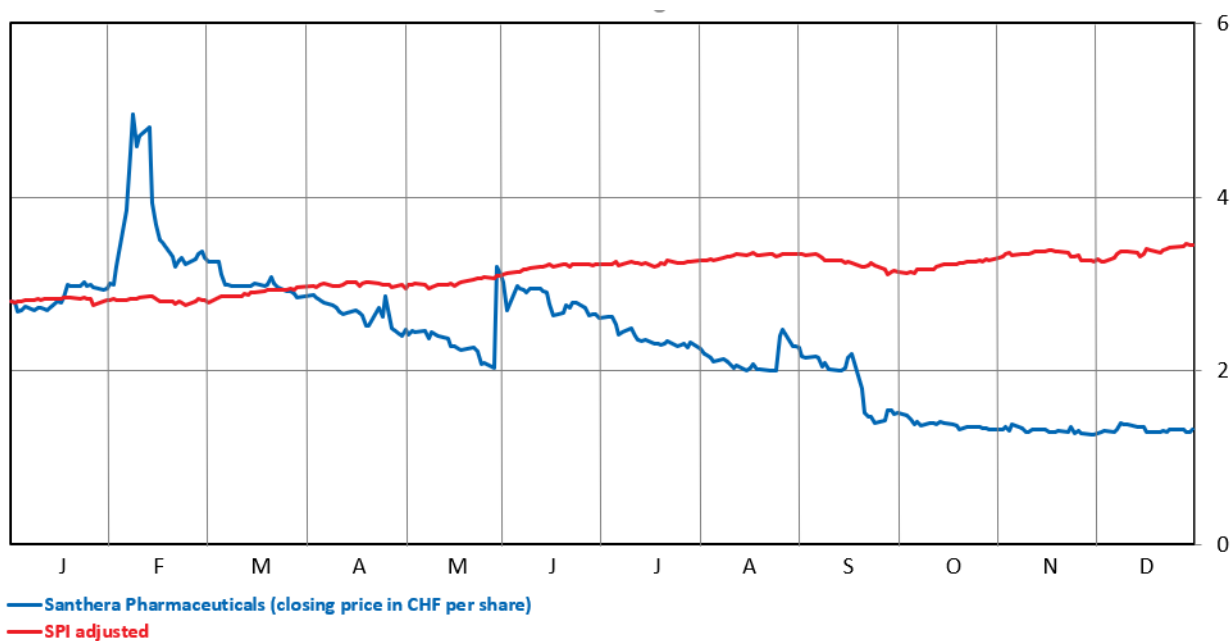
**Annual Report 2021**

## Financial Key Figures

IFRS consolidated, in CHF thousands	2021	2020
Revenue from contracts with customers	-1,595	15,008
Operating expenses	-51,872	-58,347
Operating result	-56,888	-53,076
Net result	-55,526	-67,659
Basic and diluted net result per share (in CHF)	-1.62	-5.08
Cash and cash equivalents at December 31 *	21,208	12,411
Net change in cash and cash equivalents	8,797	-18,947

\* Cash and cash equivalents

## Share Price Development in 2021



High	CHF 4.95 (February 10, 2021)
Low	CHF 1.26 (November 29/30, 2021)
Share price performance in 2021	-52.5%
Share price at year-end	CHF 1.33
Market capitalization at year-end	CHF 72 million
Average trading volume	234,362 shares/day

(based on closing share prices)

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## Letter to Our Shareholders

Dear Shareholders,

Our overarching goal for 2021 was to advance our lead therapy candidate vamorolone for Duchenne muscular dystrophy (**DMD**) towards registration and approval—and we are very pleased to have delivered on key milestones as promised.

### **Lead pipeline candidate vamorolone on track for expected first market entry in early 2023**

Vamorolone is under joint development by ReveraGen and Santhera for Duchenne muscular dystrophy (**DMD**) patients who require anti-inflammatory and muscle preserving treatment comparable, the current standards of care but with an improved safety and tolerability profile to overcome side effects that often lead to premature treatment discontinuation in real world practice.

This approval stage compound has been designed to engage with the glucocorticoid receptor (GR) to retain the beneficial anti-inflammatory action of glucocorticoid steroids, the standard of care in DMD, but has been specifically engineered to reduce the downstream activation of genes responsible for some of the most important side effects that lead to prematurely discontinuation or require significant medical resources to manage the side effects that also place an increased burden on children and their families.

The positive pivotal Phase 2b VISION-DMD study demonstrated statistically significant superiority of vamorolone compared with placebo across multiple efficacy endpoints with 2 doses across a 3-fold dose range but importantly, showed no growth stunting, had no detrimental impact on biomarkers of bone health, fewer and clinically less severe behavioral issues and showed a dose dependent effect on weight gain, Cushing features and adrenal suppression.

Furthermore, recent analyses comparing the long-term efficacy and safety of vamorolone to deflazacort and prednisone, the current standard of care, indicate that vamorolone has comparable efficacy but has a unique bone sparing profile that resulted in no stunting of growth as well as fewer and less severe spinal fractures. This data will shortly be presented at several medical and scientific congresses.

Following a successful pre-NDA meeting with the FDA, Santhera initiated a rolling NDA submission in the U.S. in March 2022 which we expect to complete by the end of June 2022. This truly represents a tremendous milestone for Santhera and an important step for the Duchenne community. We look forward to continuing to work closely with the FDA in the coming months. Commercial launch would start in the U.S., subject to approval which we expect in Q1-2023 at the earliest, followed by Europe where a marketing authorization application (**MAA**) submission is planned for Q3-2022.

Upon approval, we plan to launch vamorolone in the U.S. and selected European countries with our own organization. We are operating in the rare disease area in which expert guidelines have already established the use of glucocorticoid steroids as a first line standard of care, including recommendations for screening of side effects where vamorolone has unique competitive advantages. In addition, parent of

children with DMD as well as young men with this condition typically form advocacy groups that are well informed concerning the latest advancements in the development of emerging therapies. Because patients are usually treated at a limited number of expert reference centers, physicians can be located and targeted efficiently by a small and highly skilled in-house team.

### **Establishing market readiness and transitioning Santhera to the commercial stage**

Following the restructuring in 2020, Santhera used 2021 to embark on the path forward with a focus on preparations for the transition to a commercial stage company. At leadership level, we have made strategic appointments to support the next phase of Santhera's development, including hiring Stephanie Brown as President for North America and Member of the Executive Management team to oversee our U.S. operations as we prepare for potential commercialization. Most recently, Dr. Shabir Hasham has been promoted to Chief Medical Officer and Member of the Executive Management, a key appointment that will strongly support the advancement of our clinical projects by providing medical and regulatory project leadership and oversight.

We expect our workforce to expand in connection with the preparations for a potential launch of vamorolone in DMD in the U.S. and later in the largest European countries and to support our planned development of vamorolone in other indications and clinical development of lonodelestat.

### **Regulatory clarity and commercial viability of vamorolone paving the way for additional financing**

In 2021, we secured up to CHF 42 million (net) in funding, comprised of a CHF 20 million equity financing, a CHF 15 million placement of private convertible bonds and upsizing of an existing financing arrangement of up to CHF 10 million. This supported planned operations through to completion of the rolling NDA filing, scheduled for the end of June. In early 2022, we also repaid our convertible bonds which resulted in a significant reduction in the Company's debt, thereby strengthening the balance sheet. On June 2, we announced the partial deferral of an upcoming milestone payment to partner ReveraGen and an upsizing of an existing financing arrangement with Highbridge Capital. The agreements reduce near-term liquidity needs by USD 20 million and is expected to provide additional funds of up to USD 40 million, extending cash reach into Q1-2023 or up to the approval of vamorolone in the U.S., anticipated in Q1-2023 subject to priority review being granted.

Financing continues to remain a priority. Several of our financing options have been hampered by the strong market downturn and the crisis owing to the war in Europe. The XBI Biotech index, representing the biotechnology segment of the S&P Total Market Index, has lost nearly two thirds in value<sup>1</sup> since its peak and the aggregate enterprise value of the world's biotech sector is down 72% over the same time span<sup>2</sup>. This has led to hesitation on the part of potential investors to invest, however, feedback from our close interactions with the financial community indicates that our long-term value creation starts to be recognized.

<sup>1</sup> Decline of 61% between its peak on February 8, 2021 and May 13, 2022

<sup>2</sup> Enterprise value defined as market capitalization plus total debt minus cash and cash equivalents. Source: CapitalIQ and Torreya Analysis, May 16, 2022

With the capital increase approvals by the last Extraordinary General Meeting in December 2021, Santhera's shareholders paved the way for additional equity-based fund raising. We take this as a powerful signal of support and endorsement of our strategy but also as an obligation to preserve shareholder interests. As a pharmaceutical company with a late-stage clinical candidate nearing market readiness, we have various options for financing besides equity-based, including public offerings and debt capital procurement, including royalty deals for future revenue streams, hybrid equity/debt deals, and external partnerships for both vamorolone and lonodelestat which can be tailored to specific milestones.

Based on our financial forecasts, and after the recent new funding, we estimate that the Company will need to secure approximately CHF 40-50 million (including settling the USD 30 million milestone payment due upon FDA approval) to reach breakeven with vamorolone in DMD anticipated during H2-2024).

#### **Focused pipeline approach to maximize the potential of our development candidates**

Although vamorolone is our main strategic focus, we also saw progress in the other assets in our pipeline. In 2021, we continued the development of lonodelestat, our second clinical development candidate targeting pulmonary indications. In March 2021, we announced promising clinical trial data from our Phase 1b trial of lonodelestat in cystic fibrosis (**CF**). Next stage Phase 2a trials in CF and an acute pulmonary indication are to start in H2-2022.

For Raxone® (idebenone), our commercial product licensed to Chiesi Group outside of North America and France, we successfully completed the Phase 4 trials LEROS and PAROS in the rare ophthalmic indication Leber's hereditary optic neuropathy (**LHON**) with positive results. This not only supports further reimbursement negotiations in Europe but also increases product visibility which could lead to partnering interests for North America.

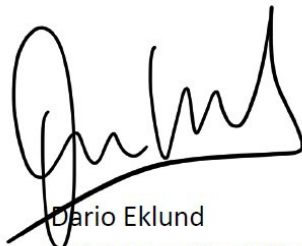
Post-period end, we have signed strategic agreements in the rare disease space further exploiting the potential of our pipeline products. In January 2022, we entered into an exclusive license agreement with Sperogenix Therapeutics, a China-based company specializing in orphan diseases, for the Greater China area. Under this agreement, Sperogenix has in-licensed vamorolone for rare disease indications for a total consideration of up to USD 124 million and plans to initiate a regulatory filing for vamorolone for DMD in China upon US FDA approval which could lead to market entry in China as early as in 2024. In February 2022, we signed a gene therapy agreement with SEAL Therapeutics which will further develop a gene therapy approach intended for the treatment of congenital muscular dystrophy in exchange for payments based on future proceeds of SEAL Therapeutics.

In 2021, Santhera has delivered on its promise to advance the development of its pipeline with the aim of bringing life-changing products to the rare disease space. Looking forward, we are preparing for the next phase of Santhera's development as we get the Company ready for the potential market entry of vamorolone, initially in the U.S. Our special thanks go to our employees for their dedication, unparalleled patience and endurance, weathering through difficult times without losing sight of our vision of helping patients with rare diseases by providing novel therapies to alleviate their suffering. We would also like to thank you, our shareholders, for your continued support, and we look forward to an exciting phase for Santhera which—looking back in a year's time—we can hopefully refer to as a breakthrough year.

Sincerely,



Elmar Schnee  
Chairman



Dario Eklund  
Chief Executive Officer

## REVIEW OF 2021

### Last Year's Events—Building the Basis for Future Growth

Throughout 2021 and into 2022, Santhera made progress on all fronts. Santhera realigned its organization, initiated the NDA submission with vamorolone in DMD to the U.S. FDA, further advanced its core pipeline projects, started expanding its U.S. operations in view of a near-term launch, concluded agreements potentially giving rise to non-dilutive cash inflows, and implemented various measures to secure funding and strengthen its capital structure.

#### Corporate restructuring was completed and the organization aligned to future priorities

In March 2021, Santhera completed a restructuring process to reduce costs and prioritize vamorolone's clinical progress following the termination of the Puldysa® program in late 2020. The business was streamlined to primarily focus on bringing vamorolone to patients by leveraging the Company's know-how in the DMD space, regulatory expertise, strong relationships with key clinical experts and the patient community as well as its proven track record of successfully commercializing a rare disease product. Following the positive results of the VISION-DMD study, the prerequisite for regulatory submissions and subsequent product launches, Santhera started expanding its workforce again. Key appointments are being made at headquarters in Switzerland but the priority is on attracting talent for the U.S. subsidiary, based in the Boston metropolitan area, to enable the start of pre-commercialization activities.

#### Securing financing to advance the pipeline and fund operations

One of the priorities for Santhera during 2021 remained securing financing to provide sufficient liquidity at least up to the regulatory filing for vamorolone in DMD, a key milestone which the Company expects to achieve in June 2022 with the completion of the rolling NDA submission. The Company continued cost saving measures initiated already in 2020, restructured the balance sheet and, in parallel, evaluated various share-based and non-dilutive financing alternatives in order to further extend its cash reach.

In May 2021, with the objective to reduce the debt overhang, Santhera partially redeemed its 2017/22 Bonds through an exchange offer and the issuance of new senior unsecured convertible bonds due 2024 (the 2021/24 Bonds, ISIN CH0563348744). Upon settlement of this bond restructuring effective May 4, 2021, the aggregate principal amount of the 2017/22 Bonds was reduced from originally CHF 60,000,000 to CHF 15,155,000 and new 2021/24 Bonds in the aggregate principal amount of CHF 30,270,375 were issued. In February 2022, the remaining 2017/22 Bonds were fully repaid and delisted from SIX Swiss Exchange. Up to January 31, 2022, 2021/24 Bonds in the aggregate principal amount of CHF 10,708,875 were converted, leaving a remaining amount of CHF 19,561,500 in circulation, and maturing in August 2024 unless converted beforehand. In addition, a private 2021/24 convertible bond, as announced on September 20, 2021, in the amount of CHF 12,730,500 remains outstanding. In summary, total and short-term convertible debt was significantly reduced from an original amount of CHF 60 million maturing in February 2022 to approximately CHF 32 million maturing in August 2024.



## REVIEW OF 2021

In September, Santhera announced a strengthening of its capital structure via an equity financing of CHF 20 million, a placement of private convertible bonds of CHF 15 million and upsizing of an existing financing arrangement of up to CHF 10 million. The new funding secures operations to mid-2022 and allowed for the repayment of the convertible bond which matured in February 2022.

At the Extraordinary General Meeting (held on March 18, 2021), the Annual General Meeting (held on June 22, 2021) and another Extraordinary General Meeting (held on December 15, 2021), Santhera's shareholders approved various increases of the Company's share capital. With their consent to all proposed capital increases, Santhera's shareholders gave the Company a flexible financing instrument and enabled the Board of Directors to issue new shares for financing purposes and to enter into equity or equity-based financings or re-financings, all at a moment favorable to Santhera.

As of December 31, 2021, the Company had a cash balance of CHF 21.2 million including CHF 13.9 million which was restricted for use in repaying 2017/22 convertible bonds. During 2022, Santhera will require additional funding to enable continued pipeline development and preparations for the commercialization of vamorolone.

### **Positive pivotal data for vamorolone in VISION-DMD study**

The key clinical achievement of the past year was the announcement in June 2021 of positive and statistically significant 24-week results from the VISION-DMD study, a pivotal Phase 2b study comparing two doses of vamorolone (2 or 6 mg/kg/day) to placebo and to prednisone (0.75 mg/kg/day, internal control arm) in the treatment of Duchenne muscular dystrophy (**DMD**). The trial, run by ReveraGen BioPharma in collaboration with Santhera, covered a total treatment period of 48 weeks. During the second 24 weeks of the study (Period 2), patients on placebo and prednisone were switched to vamorolone. The study completed in November 2021 and 48-week data demonstrated durable and sustained efficacy of vamorolone and no loss of efficacy when switching from prednisone to vamorolone at 6mg/kg/day. Furthermore, it confirmed no stunting of growth or detrimental impact on biomarkers of bone metabolism with a consistent safety profile as that observed during the first 24-weeks of treatment with vamorolone.

These positive results have paved the way for a rolling new drug application (**NDA**) submission to the U.S. FDA, ongoing at present, and highlighted opportunities for potential differentiation of vamorolone compared with the standard of care in DMD. The chapter "Vamorolone Highlights" expands on the promising product profile and outlines future steps.

### **Rolling NDA submission started for vamorolone in DMD**

In November 2021, Santhera announced that the U.S. FDA considered the proposed efficacy and safety data package sufficient to support the filing of an NDA. Rolling submission commenced at the end of March 2022. Acceptance of the NDA will be subject to the FDA's review of the complete filing.

## REVIEW OF 2021

Santhera and ReveraGen expect to complete the NDA filing in June 2022. Based on FDA review timelines, notification from the FDA on the acceptance of the filing for review is expected by the end of August 2022. In its assessment, the FDA will also determine eligibility of vamorolone for priority review which Santhera and ReveraGen will request as part of the rolling NDA submission. If granted, this would shorten the review time and set an anticipated approval date for as early as Q1-2023.

In Europe, Santhera plans to submit a marketing authorization application (**MAA**) for vamorolone for the treatment of DMD to the European Medicines Agency (**EMA**) in Q3-2022. Assuming a review time of about one year, this could pave the way for approval and launch in H2-2023. Santhera expects the first European launch country to be Germany.

### **Building up U.S. operations to prepare for commercialization**

Subject to FDA approval, Santhera plans to launch vamorolone in the U.S., the first country, shortly thereafter with its own organization. Under the leadership of Stephanie Brown, who joined Santhera in December 2021 as President North America and Member of the Executive Management Team, a launch readiness program is being advanced which includes organizational readiness, hiring and building the team and intensifying the pre-commercialization activities.

### **FDA orphan grant funding for clinical trial with vamorolone in Becker muscular dystrophy**

Beyond DMD, in November 2021, ReveraGen received a USD 1.2 million grant from the FDA to support the initiation of a vamorolone clinical trial in Becker muscular dystrophy (**BMD**), a progressive muscle wasting disease similar to DMD. The funding comes under the FDA's "Clinical Studies of Orphan Products Addressing Unmet Needs of Rare Diseases (RO1)" and adds to existing grants from the National Institutes of Health, NIAMS, and the Foundation to Eradicate Duchenne. Whilst development pipeline has greatly expanded for DMD in recent years, there remain very few clinical trials in BMD. Like for DMD, current standard of care involves the use of corticosteroids, which are often not tolerated by patients due to their side effects.

### **Lonodelestat showed positive results in early phase cystic fibrosis trial**

Lonodelestat, a potent and selective peptide inhibitor of human neutrophil elastase (**hNE**), has the potential to treat CF and other lung diseases associated with increased neutrophil elastase activity. Clinical investigation of lonodelestat continues in cystic fibrosis (**CF**). In March 2021, Santhera announced positive results of a Phase 1b study with the drug candidate. The Phase 1b multiple ascending dose (**MAD**) trial of orally inhaled multiple doses of lonodelestat in patients with CF identified doses with good tolerability and no serious patient-reported adverse events occurred in the trial. On this basis, Santhera is currently assessing the clinical development program to advance lonodelestat in CF, as well as other inflammatory pulmonary conditions. Plans for a 12-week Phase 2a clinical trial of lonodelestat in CF together with a second Phase 2a study in an acute pulmonary indication are underway, with initiation expected in the second half of 2022. The chapter "Lonodelestat Highlights" explains the Company's development plans in more detail.

## REVIEW OF 2021

### **Exclusive license agreement signed with Sperogenix for vamorolone in Greater China region**

Post period end, in January 2022, Santhera announced that it has entered into an exclusive license agreement with Sperogenix Therapeutics for vamorolone in the Greater China region. This is alongside the pursuit of potential partnerships and collaborations for vamorolone in territories outside North America and Europe, where Santhera plans to commercialize vamorolone with its own organization. The deal is worth a total consideration of up to USD 124 million, including a double-digit upfront cash compensation and DMD-related US-regulatory milestone payments amounting to a combined USD 20 million, as well as further double-digit royalties on net sales. An upfront cash payment was received upon closing of the transaction in January 2022. Under the terms of the agreement, Santhera granted Sperogenix Therapeutics exclusive development and commercialization rights to vamorolone in DMD and all other rare disease indications for Greater China (including mainland China, Hong Kong, Macau, and Taiwan). Santhera will remain responsible for manufacturing and supply while Sperogenix will focus on regulatory and development work and future commercialization. Sperogenix plans to initiate a regulatory filing for vamorolone for DMD in China upon US FDA approval which could lead to market entry in China as early as in 2024.

### **Gene therapy agreement signed with SEAL Therapeutics**

In February 2022, Santhera entered into a new agreement with SEAL Therapeutics, a spin-off company from the Biozentrum of the University Basel, which will further develop a gene therapy approach for the treatment of LAMA2-deficient congenital muscular dystrophy. As a result, the Company has discontinued all previous related gene therapy license and research agreements with the University of Basel as well as Rutgers, The State University of New Jersey. Santhera will be eligible for payments based on future proceeds of SEAL Therapeutics, which will provide a potential source of non-dilutive income. This transaction follows Santhera's announcement at half-year results in October 2021, where the Company confirmed that it will focus on vamorolone in DMD and Ionodelestat in CF, halt the further development of omigapil and pursue partnering to exploit the potential of its gene therapy approach.

### **Evaluation of additional indications and partnering for platform-like molecules**

Santhera continues the pursuit of partnering opportunities for vamorolone in additional indications outside DMD and in geographies outside the U.S. and Europe which could result in significant future non-dilutive income streams. Preclinical data with vamorolone have already been obtained in in vitro and in vivo models for asthma, multiple sclerosis, inflammatory bowel disease, rheumatoid arthritis, critical illness muscle disease, and brain tumor.

## REVIEW OF 2021

Data available from the VISION-DMD study has characterized the dissociative mechanism of action of vamorolone, as having comparable efficacy to glucocorticoid steroids with the potential to be bone and growth sparing, whilst having fewer and less severe behavioral problems. Santhera will focus its development plan on rare pediatric conditions where such a product profile is expected to represent clear clinical benefit over current standards of care. Santhera intends to engage with the FDA, who in the pre-NDA meeting minutes recognized the potential public benefit of vamorolone in pediatric conditions, to define a path forward.

In parallel, the Company is open to collaborations with partners to assess and exploit the potential of lonodelestat in other pulmonary diseases beyond CF.

### **Post-authorization measures (PAMs) with Raxone successful and nearing completion**

Beyond its core candidates of vamorolone and lonodelestat, Santhera announced positive topline results from its long-term Phase 4 LEROS study of Raxone (idebenone) for the treatment of Leber's hereditary optic neuropathy (LHON) in June 2021. The primary endpoint, the proportion of eyes with clinically relevant benefit after 12 months treatment with Raxone, was met with high statistical significance ( $p=0.002$ ). The study was designed with guidance and approval from the European Medicines Agency (EMA) and was part of a post-authorization commitment (PAM). This clinically robust evidence of long-term effectiveness confirms and extends previous findings, is expected to facilitate market access, allowing patients to benefit where currently no effective treatments alternatives are available. Santhera holds EU marketing authorization for Raxone. The last part of the PAM is expected to be completed in July 2022. In 2019, Santhera out-licensed rights for the product outside North America and France to Chiesi Group. Until the settlement of reimbursement matters, Santhera is providing Raxone for LHON to patients in France for free. Under the licensing agreement, the Company is entitled to contingent variable near- to mid-term milestone payments from Chiesi Group of up to EUR 49 million subject to the achievement of certain commercial milestones for Raxone.

### **Santhera's next steps**

2021 has laid the groundwork for a newly invigorated and focused Santhera, which has already reaped rewards with the completion of important clinical and regulatory milestones. 2022 is another important year, as we gear up for anticipated commercial activities in the U.S. and beyond.

## FINANCIAL HIGHLIGHTS

### Financial Performance & Financing Outlook

**In 2021, Santhera reported revenue of CHF -1.6 million and a net loss of CHF 55.5 million. Liquid funds (cash and cash equivalents) at year-end amounted to CHF 21.2 million.**

#### 2021 full-year net revenues

In 2021, Santhera reported net revenue of CHF -1.6 million (2020: CHF 15.0 million). Revenue from out-licensing transactions and net sales to licensing partners remained fairly stable year-on-year. The negative net sales in the EU in 2021 are attributable to a CHF 10.8 million adjustment to net sales recorded in 2021 due to uncertainties and status of negotiations around pricing reimbursement in France. Based on the agreement with the authorities in France, Santhera has supplied Raxone free of charge from August 2021 following its removal from the list of reimbursed drugs. Reimbursement discussions are ongoing. Santhera continues to supply the product in France following the outlicensing and transfer to Chiesi Group in 2019.

#### Cost of goods sold

Cost of goods sold amounted to CHF 3.8 million (2020: CHF 10.4 million). The reduction reflects the inclusion of an inventory impairment of CHF 6.0 million in 2020 related to the discontinuation of Puldysa. Ongoing cost of goods represents continuing supply of Raxone.

#### Operating expenses

Operating expenses of CHF 51.9 million (2020: CHF 58.4 million) were 11% lower due to reduced expenses for development, marketing and sales, and general administrative purposes following the termination of the Puldysa program in 2020 and the subsequent restructuring.

Development expenses were CHF 29.7 million and CHF 34.2 million for the year ended December 31, 2021, and 2020, respectively. The decrease in expenses was primarily due to lower contract research organization expenses and other third-party clinical trial expenses following the termination of the Puldysa Phase 3 SIDEROS study, offset by increased expenses to support the development of vamorolone to completion of the VISION-DMD study, in addition to a reduction in staff costs following organizational restructuring.

Marketing and sales expenses were CHF 9.3 million and CHF 11.5 million for the year ended December 31, 2021 and 2020, respectively. The decrease was primarily a result of the ceasing of Puldysa activities following the termination of the program announced in October 2020. Ongoing expenses relate to pre-commercialization activities for vamorolone and meeting ongoing obligations in relation to Raxone outlicensed to Chiesi Group.

General and administrative expenses remained largely unchanged with CHF 12.7 million and CHF 12.4 million for the year ended December 31, 2021 and 2020, respectively.

## FINANCIAL HIGHLIGHTS

### Financial income and expenses

The net financial income of CHF 2.1 million (2020: expense of CHF 14.4 million) reflects effects of the exchange of the 17/22 convertible bond which were partially offset by the costs associated for financing.

### Net result

The net result for the year ended December 31, 2021, was a loss of CHF 55.5 million, or CHF -1.62 per share, compared to a net loss of CHF 67.7 million or CHF -5.08 per share for the year ended December 31, 2020. comment

### Cash flow and cash balance

As of December 31, 2021, the Company had cash and cash equivalents of CHF 21.2 million compared to CHF 12.4 million as of December 31, 2020.

Net cash used in operating activities was CHF 37.4 million for the twelve months ended December 31, 2021, compared to CHF 43.5 million for the twelve months ended December 31, 2020.

### Shareholders' equity

Total consolidated equity as of December 31, 2021, amounted to CHF 1.3 million compared to a net equity deficit of CHF 6.4 million as of December 31, 2020.

### Recent financing activities and outlook

In order to provide Santhera with additional fundraising flexibility, the Company has issued and plans to issue additional treasury shares. During March, 2022, post period end, Santhera issued 18,600,000 additional treasury shares with a nominal value of CHF 1 each consisting 3,100,000 shares from authorized capital and 15,500,000 shares as an ordinary capital increase. As a result, Santhera's issued share capital currently amounts to CHF 73,725,702. This number includes 4,328 shares that have been issued from conditional capital which have not yet been updated in the commercial register. Santhera expects to hold 21,768,585 shares as treasury shares until market conditions permit for a favorable financing transaction. In addition, with the exception of the aforementioned 4,328 shares, Santhera updated its articles of association to reflect past share issuances out of the conditional capital for employee participation and out of the conditional capital for financings.

Concurrently with the ordinary capital increase and as decided by the EGM on December 15, 2021, Santhera's authorized capital has increased from CHF 24,203,905 to CHF 34,203,905 and its conditional capital for financing has increased from CHF 21,374,664 to CHF 31,374,664.

## FINANCIAL HIGHLIGHTS

On June 2, 2022, the Company entered into an amendment to the timing of an upcoming milestone payment to partner ReveraGen, thereby reducing near-term financial obligations of the Company by CHF 20 million. The Company also upsized its existing financing arrangement with certain funds managed by Highbridge Capital Management, LLC ("Highbridge") which will provide up to CHF 40 million of additional financing. Santhera expects the combination of these events to extend its liquidity runway into 2023 or up to approval of vamorolone in the U.S. which, subject to priority review being granted, is expected in Q1-2023. The first tranche of CHF 20 million was drawn on June 3, 2022.

### **Funding outlook**


Santhera has a significant amount of treasury shares from past EGM authorization which are available for future placement which may include existing shareholders' subscription rights, depending on market conditions. This, in combination with cash balances as of December 31, 2021, of CHF 21.2 million and recently increased facilities, provides flexibility to secure sufficient funding beyond FDA approval of vamorolone in DMD. In order to reach profitability with vamorolone in DMD, which is currently expected, at the earliest, during H2-2024, Santhera estimates that the Company will need to secure an additional CHF 40-50 million to fund its operations, including U.S. approval milestone payments and its debt service. Following today's announcements, this is around 50% less than the previously communicated funding need of about CHF 100 million.

In parallel, Santhera is evaluating a number of different options to secure additional financing for the Company which besides equity-based funding also includes a rights offering, debt financing, royalty financing, standby equity distribution agreement as well as the monetization of assets.

## RARE DISEASE FOCUS

### Our Pipeline

Passionate about providing treatment options for rare diseases, Santhera focuses its efforts on promising therapeutic options for rare **neuromuscular** and **pulmonary** diseases with high unmet medical need.

Molecule	Indication	IND	Ph 1	PoC	Pivotal	Filing	Market	Milestones and remarks
<b>Vamorolone</b> • dissociative steroid • oral suspension	Duchenne muscular dystrophy	VISION-DMD						Q2-21: Positive pivotal data Q4-21: Successful study completion Q1-22: US NDA rolling submission
	Becker muscular dystrophy							Q4-21: IND authorization obtained Q2-22: Start Phase 2a FDA grant to partner 
	Steroid alternative in multiple pediatric rare indications							New IND applications in planning
<b>Lonodelestat</b> • hNE inhibitor • via nebulizer	Cystic fibrosis							Q1-21: Successful Phase 1 MAD H2-22: Start of Phase 2a (non-user of CFTR therapy)
	Multiple respiratory conditions with high hNE activity							New IND applications in planning

IND: investigational new drug; PoC: proof of concept; NDA: new drug application; FDA: Food and Drug Administration; hNE: human neutrophil elastase; MAD: multiple ascending dose; CFTR: cystic fibrosis transmembrane conductance regulator

Vamorolone worldwide license from ReveraGen in Sep 2020; Lonodelestat worldwide license from Spexis (formerly Polyphor) in Feb 2018.

**Vamorolone**, our lead pipeline candidate, is in development for the treatment for Duchenne muscular dystrophy (**DMD**). At the end of March 2022, Santhera started the rolling submission of a new drug application (**NDA**) with the U.S. Food and Drug Administration and expects to complete the filing in June 2022. In the EU, a corresponding marketing authorization application (**MAA**) is planned to be submitted in Q3-2022.

**Lonodelestat**, in early clinical stage, is an innovative new investigational drug for which Phase 2a studies in the prime indication cystic fibrosis (**CF**) and in an acute pulmonary indication are in preparation to commence in the second half of 2022.

Both vamorolone and lonodelestat represent **platform type pipeline molecules**, each with potential for out-licensing or development in a range of additional indications beyond DMD and CF respectively in collaboration with partners. Vamorolone obtained an IND authorization for the treatment of Becker muscular dystrophy (**BMD**), a progressive muscle wasting disease similar to Duchenne muscular dystrophy but usually milder, and a Phase 2a study is in preparation by the partner company ReveraGen Biopharma. In addition, the product is being evaluated as a steroid alternative for multiple pediatric rare diseases with IND applications in the planning phase. For lonodelestat, based on its mode of action as an inhibitor of human neutrophil elastase (**hNE**), multiple respiratory conditions which are characterized by high hNE activity are under evaluation.



## NEUROMUSCULAR

### Vamorolone Highlights

**During 2021, Santhera and its licensor ReveraGen successfully completed studies with vamorolone for early stage patients with Duchenne muscular dystrophy (DMD) requiring an anti-inflammatory, muscle preserving treatment with a potentially differentiated safety and tolerability profile. These achievements culminated in the start of a rolling submission of a new drug application (NDA) to the U.S. FDA in March 2022. Subject to FDA approval, Santhera plans to launch vamorolone in the U.S., the first country, shortly thereafter with its own organization.**

DMD is one of the most common and devastating types of muscular degeneration affecting 30,000 - 35,000 patients in U.S. and EU combined. It is an inherited condition and primarily affects boys, commonly diagnosed at an age between three and five years on average. DMD is characterized by a loss of the protein dystrophin, which links the muscle cytoskeleton and extracellular matrix to maintain muscle integrity. The absence of dystrophin results in progressive muscle damage leading to weakness, loss of muscle tissue and early loss of function. Patients are commonly unable to walk by their teenage years. Progressive respiratory and cardiac muscle weakness leads to a need for mechanical ventilation and support treatments to prolong the life of the patient beyond the second decade of life. The prime therapeutic goal in ambulant boys with DMD is the preservation of motor function and delaying the time to wheelchair dependence.

Corticosteroids are effective anti-inflammatory agents and current standard of care in DMD. They are prescribed to preserve muscle strength and slow the decline in muscle function caused by DMD in all patients regardless of their underlying genetic mutation. However, their long-term use is hindered by their well-known side effects (e.g. weight gain, cushingoid features, behavioral problems, stunted growth and increased rate of fractures) that often result in down-titration to sub therapeutic doses to manage tolerability issues and eventually premature discontinuation of treatment.

#### **Novel mode of action of vamorolone drives differentiated clinical profile**

Vamorolone is characterized as a dissociative steroidal anti-inflammatory drug candidate with a novel mechanism of action and pharmacological profile. The compound binds to the same receptor as glucocorticoids but its reengineered molecular structure allows for a modified interaction with the receptor that 'dissociates' efficacy from typical steroid safety concerns. In addition, the molecular engineering also prevents vamorolone from being a substrate for 11 $\beta$ -Hydroxysteroiddehydrogenase, an enzyme that is also associated with detrimental effects on bone and muscle with glucocorticoid steroids. Collectively, this novel molecule retains steroid like anti-inflammatory efficacy but uniquely may be growth- and bone-sparing with a dose dependent profile for other common side effects typically associated with chronic glucocorticoids use. In addition, preclinical studies have also shown that vamorolone is a mineralocorticoid antagonist, unlike other glucocorticoids, which may translate into additional benefits in a disease where cardiomyopathy develops and is the current focus of further investigation.

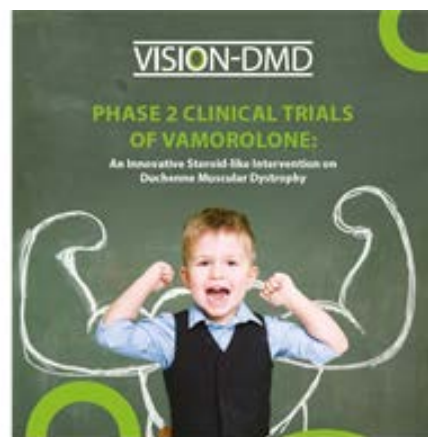
Vamorolone was well tolerated in clinical studies, and now the addition of these potential safety advantages may allow treating physicians to initiate and maintain treatment on vamorolone for longer than current standard of care.

## NEUROMUSCULAR

### Positive results with vamorolone in the pivotal VISION-DMD study provided basis for ongoing NDA filing

VISION-DMD was a Phase 2b study comprising a (1) pivotal double-blind 24-week period to demonstrate efficacy and safety of vamorolone (2 and 6 mg/kg/day) versus placebo and prednisone (0.75 mg/kg/day, internal control arm), followed by a (2) 24-week period to evaluate the maintenance of efficacy and collect additional longer-term safety and tolerability data. 121 ambulant boys aged 4 to <7 years with Duchenne muscular dystrophy (DMD) were included in the study. The trial met its primary endpoint of superiority in change of time to stand from supine position (**TTSTAND**) velocity with vamorolone 6 mg/kg/day versus placebo ( $p=0.002$ ) at 24 weeks (period 1).

Vamorolone 6 mg/kg/day also met its secondary efficacy endpoints – including six-minute walk test (**6MWT**), time to run/walk 10 meters (**TTRW**) – and no statistically significant differences were observed between vamorolone and prednisone. During the second 24 weeks of this 48-week study (period 2), all participants received vamorolone. Participants from the placebo and prednisone arms were randomized to either the 2 or 6 mg/kg/day dose of vamorolone and the vamorolone arms continued on their existing dose. Efficacy observed at 24 weeks for vamorolone 6 mg/kg/day was maintained across multiple endpoints over 48 weeks. In study participants starting on prednisone 0.75 mg/kg/day and switching to vamorolone 6 mg/kg/day after 24 weeks, efficacy was maintained across all functional endpoints.



### Clinical study data show a favorable safety and tolerability profile of vamorolone

In addition to efficacy, the VISION-DMD study aimed to characterize the favorable tolerability profile of vamorolone with the potential to offer an alternative to current standard of care.

Treatment with vamorolone 6 mg/kg/day was well tolerated with an incidence of clinically relevant adverse events similar to placebo. Whilst the safety profile of vamorolone shares some risks with those described with glucocorticoids, such as adrenal suppression, cushingoid features or weight gain in a dose dependent manner, it shows clinically important differences indicating an improved safety profile:

- An absence of deleterious effects on bone metabolism with the potential to reduce the incidence and severity of vertebral fractures
- Normal growth reducing the risk of short growth stature
- A reduced frequency and severity of behaviour-related events

In clinical studies, vamorolone was generally well tolerated. The most commonly reported adverse events versus placebo from the VISION-DMD study were cushingoid features, vomiting and vitamin D deficiency. Adverse events were generally of mild to moderate severity.

## NEUROMUSCULAR

### **NDA filing to the U.S. FDA initiated—MAA submission to the European EMA to start in Q3-2022**

Santhera has commenced the NDA filing of vamorolone for the treatment of DMD as a rolling submission following a successful pre-NDA meeting with the FDA held in November 2021. In its conclusions from that meeting, the FDA stated the proposed clinical efficacy and safety data package to be sufficient to support an NDA filing of vamorolone for the treatment of DMD. Acceptance of the NDA will be subject to FDA's review of the complete filing.

Santhera and ReveraGen expect to complete the NDA filing in Q2-2022. Based on FDA review timelines, notification from the FDA on the acceptance of the filing for review is expected by the end of August 2022. In its assessment, the FDA will also determine eligibility of vamorolone for priority review which Santhera and ReveraGen will request as part of the rolling NDA submission. If granted, this would shorten review time and set an anticipated approval date for as early as Q1-2023. Subject to FDA approval, Santhera plans to launch vamorolone in the U.S., the first country, shortly thereafter with its own organization.

In Europe, Santhera plans to submit a marketing authorization application (**MAA**) for vamorolone for the treatment of DMD to the European Medicines Agency (**EMA**) in Q3-2022. Assuming a review time of about one year, this could pave the way for approval and launch in H2-2023. Santhera expects the first European launch country to be Germany.

Vamorolone has been granted Orphan Drug status in the U.S. and in Europe for DMD, and has received Fast Track and Rare Pediatric Disease (**RPD**) designations from the US FDA and Promising Innovative Medicine (**PIM**) status from the UK MHRA for DMD. Based on the RPD designation, Santhera and ReveraGen are eligible to apply for priority review which, if granted, would provide access to a priority review voucher that can be sold. As part of the agreement with ReveraGen and Idorsia, Santhera would retain 10% of the proceeds, or an estimated USD 10 million, of the sale of such. Vamorolone is an investigational medicine and is currently not approved for use by any health authority.

### **Vamorolone study in Becker muscular dystrophy to start – additional indications under evaluation**

Partner company ReveraGen received an IND authorization for vamorolone in Becker muscular dystrophy (**BMD**) and a USD 1.2 million grant from the FDA under their "Clinical Studies of Orphan Products Addressing Unmet Needs of Rare Diseases (R01)" grants program to support a Phase 2a clinical trial of vamorolone BMD which is planned to start by the end of June 2022. The double-blind trial will test efficacy and safety of daily vamorolone on motor outcomes and established biomarker outcomes, with participants randomized 2:1 vamorolone or placebo.

BMD is caused by partial loss of function of the dystrophin protein in muscle tissues and some non-muscle cells, with progressive dysfunction of skeletal muscles and/or heart muscle (cardiomyopathy). In contrast to DMD, where a complete loss of dystrophin is present, the severity of BMD ranges from nearly as severe as DMD to asymptomatic.

Santhera is currently evaluating vamorolone's potential in treating certain other inflammatory and non-inflammatory diseases with high unmet medical need beyond DMD and BMD.

## NEUROMUSCULAR

### Phase 2 study started to evaluate vamorolone in broader age groups of DMD patients

An open-label, multiple dose Phase 2 study (clinicaltrials.gov identifier: NCT05185622) is evaluating the safety, tolerability, pharmacokinetics, pharmacodynamics, and exploratory clinical efficacy of vamorolone over a treatment period of 12 weeks in steroid-naïve boys ages 2 to <4 years, and glucocorticoid-treated and currently untreated boys ages 7 to <18 years with DMD. The study, which aims to enroll 44 participants and is part of the Pediatric Investigation Plan (PIP) to support the authorization of a medicine for children, started in March 2022 and completion is expected by year-end. *Defeat Duchenne Canada*, a patient advocacy group providing leadership in research, advocacy and support in the fight to defeat DMD, is supporting the study.

### Achievements

- Mar 29, 2022: Start of rolling submission of NDA with the FDA based on the successful VISION-DMD study and additional clinical data from Phase 2 open label trials spanning a treatment period of 2.5 years.
- Jan 3, 2022: Exclusive license agreement for vamorolone in rare diseases in Greater China with Sperogenix Therapeutics for a total consideration of up to USD 124 million
- Nov 23, 2021: Positive topline results with vamorolone after completion of the VISION-DMD study. Vamorolone given throughout the study showed sustained efficacy across multiple endpoints over 48 weeks, no loss of efficacy switching from prednisone to vamorolone and the favorable safety and tolerability profile was confirmed.
- Nov 17, 2021: Successful FDA pre-NDA meeting for vamorolone in DMD in which the FDA considered both the proposed clinical efficacy and safety data package sufficient for an NDA filing.
- Sep 27, 2021: FDA orphan grant funding to initiate an exploratory Phase 2 clinical trial with vamorolone in adults and children with BMD.
- Jun 1, 2021 – Santhera and ReveraGen announced positive and statistically highly significant topline 24-week results with vamorolone compared to placebo in the pivotal VISION-DMD study.

### Near-term milestones

- Completion of the rolling NDA submission to the FDA in Q2-2022.
- Start of Phase 2 trial with vamorolone for the treatment of Becker muscular dystrophy (BMD) by the end of June 2022.
- Submission of a marketing authorization application (MAA) for vamorolone for the treatment of DMD to the European Medicines Agency (EMA) in Q3-2022.

## SANTHERA AND THE PATIENT DMD COMMUNITY

### Patients Come First, also in Unprecedented Times

Santhera's dedication to the Duchenne muscular dystrophy patient community runs deep, and the Company's commitment to Duchenne patients and their families and caregivers continued to be a priority throughout 2021. As Santhera continues to evolve in 2022 with the achievement of important pipeline milestones, its commitment to serve and support the global Duchenne community has never been greater.

With the advent of the global COVID-19 pandemic, Santhera and its partners had to quickly adapt clinical development plans. With Santhera's support, its partner ReveraGen Biopharma was able to continue and complete the critical Phase 2b VISION-DMD study for the lead clinical candidate vamorolone. Importantly, the vamorolone expanded access program (**EAP**) for trial participants with Duchenne who completed the VISION-DMD trial has also continued uninterrupted throughout the pandemic. Currently, about 150 patients participate in the vamorolone EAP, some of them for up to three years.

Throughout 2020 and 2021, Santhera concentrated on innovative ways to support the Duchenne advocacy, research, and clinical ecosystem as it was forced to quickly transform activities to a virtual format. In parallel, the Company began working with a Duchenne advocacy expert with deep ties to the patient community. This collaboration has further extended an unparalleled level of knowledge for Santhera about the everyday challenges and hopes of patients and families affected by the disorder and the Company is bringing this heightened level of focus and urgency to its development and launch plans for vamorolone.

Many children diagnosed with Duchenne are now living longer and healthier lives due to improvements and a level of standardization in clinical care, the availability of some therapeutic products for Duchenne, and a deeper understanding of the genetic causes and manifestations of the disorder. This improved outlook for Duchenne patients and their families has come about largely because of the razor-sharp focus and relentless work of the global Duchenne advocacy community, and Santhera is grateful and humbled to support the work of these advocates and organizations.

Santhera's President, North America, Stephanie Brown said: "We have a passionate team at Santhera dedicated to developing novel medicines for the treatment of rare diseases. We continue to be inspired by the Duchenne community, for their persistence, resilience and commitment in the advancement of education, research and support for people living with Duchenne muscular dystrophy."

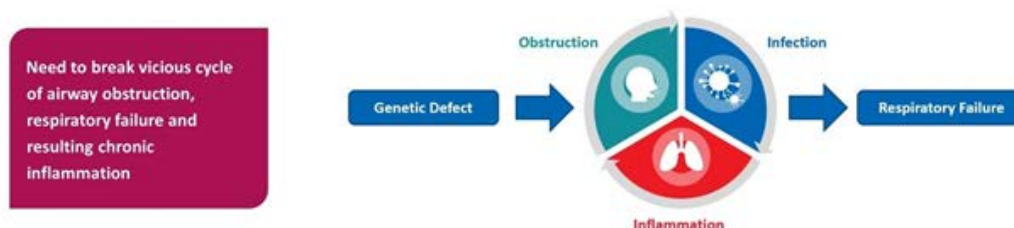
In 2022, Santhera is focused on programs that will support patients and families and help lighten some of the burdens associated with a Duchenne diagnosis. We believe that the future for Duchenne patients has never been brighter, with more of the diagnosed graduating from high school and college, entering the workforce, and living more independently than ever before. The development of products and programs to help these patients achieve their goals and dreams is at the forefront of everything we do at Santhera.

## PULMONARY

### Lonodelestat Highlights

**Lonodelestat, a selective inhibitor of an enzyme called human neutrophil elastase (hNE), is in development to treat cystic fibrosis (CF) and other neutrophil-driven pulmonary diseases. It is expected to provide a benefit for patients by addressing the acute or chronic inflammation which destroys pulmonary tissue over time. Following the completion of the Phase 1 program, Santhera now plans to start Phase 2a studies in CF and an acute pulmonary indication. Excessive neutrophil activity in a range of pulmonary inflammatory diseases provides a rationale for pipeline expansion and potential opportunities for lonodelestat beyond CF.**

Cystic fibrosis (CF) is a rare, life-threatening, progressive genetic disease affecting primarily the lung but also the digestive system. The symptoms in the lung are characterized by build-up of mucus obstructing the airways leading to persistent infection and chronic inflammation, thereby limiting the ability to breathe over time. CF is typically diagnosed in young children mostly within the first year of age.



More than 80,000 patients in the US and Europe combined have been diagnosed with CF. While treatments have been approved to ameliorate airway obstruction and treat infections, currently no drug has been approved to directly target inflammation in this disease. Whereas CFTR-modulating therapies have changed CF-patient's perspective, there still remains a need for treatments that effectively break the vicious cycle of obstruction, infection and inflammation. This applies for both non-CFTR-modulator-eligible patients, accounting for 10-20% of the total CF population, as for many patients treated with CFTR modulators.

#### **Lonodelestat targets elastase, a protease responsible for pulmonary damage**

Activated neutrophils (a type of white blood cell) are believed to liberate high levels of hNE in the lung, which in turn causes damage to structural, cellular and soluble components of the microenvironment in the lung. These high levels of hNE play a central role in the deterioration of lung function associated with CF and correlate with the severity of CF as determined by measures of lung function. Inhibition of hNE is expected to stop or slow damage to lung tissue, may help preserve lung function and may help improve the overall quality of life for individuals with CF.

Lonodelestat, licensed from Spexis (formerly Polyphor), is a highly potent, reversible and selective hNE inhibitor. The compound effectively inhibits free and membrane-bound hNE in very low (pico-molar) concentrations after inhaled and intranasal administration in various in vivo models of lung diseases. Lonodelestat is designed to provide a benefit for the patients in their long-term outcome by addressing the chronic inflammation which otherwise destroys pulmonary tissue over time. In the Phase 1 clinical trials, lonodelestat was administered by inhalation via an optimized eFlow® nebulizer developed by PARI Pharma GmbH.

## PULMONARY

### Successful Phase 1 program paves way for Phase 2 clinic development

Following two completed single dose studies, showing high drug concentrations in sputum and within the lung, complete inhibition of hNE after inhalation as well as good tolerability, Santhera successfully completed a multiple ascending dose (**MAD**) study with lonodelestat. In the MAD trial, 32 patients were randomized in four cohorts of eight patients each and received lonodelestat starting with 80 mg once a day (**QD**), 80 mg twice a day (**BID**), and 160 mg QD, each administered for 15 days, followed by the fourth cohort with 40 mg QD administered for 28 days. In all four cohorts and over all treatment durations, lonodelestat demonstrated a good tolerability and no serious or severe (grade 3 or higher) adverse events were reported by the patients. Results showed a linear dose-exposure relationship over the dose range from 40 mg to 160 mg, with no accumulation in plasma or sputum. In all cohorts, a transient, near complete inhibition of hNE activity was observed after inhalation. To date, the CF development program achieved key objectives by identifying a safe dose regimen, establishing the effect on the inflammatory biomarker and demonstrating high local targeting through inhalation. Based on the outcome of the Phase 1 trials, Santhera is currently preparing a 12-week Phase 2a clinical trial of lonodelestat in CF which is expected to start in the second half of 2022.

Lonodelestat has EU orphan drug designations (**ODD**) for the treatment of CF as well as for AATD and PCD. Santhera acknowledges the support of the Cystic Fibrosis Foundation (**CFF**) by providing funding for the conduct of the Phase 1a and 1b safety trials with lonodelestat.

### Lonodelestat holds promise beyond CF

Chronic inflammation related to pathologically hNE levels is associated with a number of additional indications which provides opportunities beyond CF for a very potent and selective elastase inhibitor directly delivered to the lung via inhalation such as lonodelestat. Apart from that, Santhera is currently preparing a Phase 2a clinical trial with lonodelestat in an acute pulmonary indication which is planned to start in the second half of 2022.

### Achievements

Mar 1, 2021 – Positive results from its multiple ascending dose Phase 1b study with lonodelestat, a potent inhibitor of human neutrophil elastase (hNE), in patients with cystic fibrosis (CF).

### Near-term targets

- Phase 2a efficacy trials of lonodelestat in CF and an acute pulmonary indication expected to start in the second half of 2022.

THIS IS US

## Our Vision, Our Promise, Our Values

Santhera's employees jointly defined what they stand for—and expressed it in our Company values. Since then, these values have become an integral part of the Company culture, one that serves as a role model in everyday work life and is also integral part of the employee performance assessments.

Our vision is to improve the lives of people with rare diseases, by delivering therapeutic options where none previously existed.



Everything we do at Santhera, we do with **respect**. For the patients that inspire us with their courage, for the scientists at the cutting edge of therapeutic breakthroughs, for all our stakeholders in this important and rewarding enterprise, and for the partnerships with our colleagues.



**Passion** is the cornerstone of Santhera's aspirations to improve patients' lives. Our focus is on individuals with rare diseases – small groups of patients often overlooked by the wider pharmaceutical industry. We feel strongly that all patients deserve the best care, regardless of the prevalence of their condition.



The area of rare diseases presents many challenges, and our mission to improve the lives of patients with rare diseases requires great resolve and dedication. Only by ensuring our ongoing **commitment** will we be able to overcome the challenge of bringing new therapies to market.



A core pillar that gives the other values cohesion and depth. By fostering a strong team spirit at Santhera, and by combining our efforts with trusted external partners – from clinicians to scientists to patient organizations – we can achieve success through **collaboration**.



Where passion gives us drive, **accountability** gives us direction. Our results-driven approach to research, development and commerce with integrity at its heart, ensures we will deliver benefits to all our stakeholders, including effective solutions for the patients affected by rare and devastating diseases.



## THIS IS US

## Meet the Team

Santhera is led by an experienced team<sup>3</sup> with a vast background in the pharmaceuticals and biotech industry, from small and large companies.

### Board of Directors



Elmar Schnee, Chairman



Philipp Gutzwiller



Thomas Meier, Founder



Patrick Vink

### Executive Committee



Dario Eklund, CEO



Andrew Smith, CFO



Stephanie Brown,  
President North America



Shabir Hasham, Chief Medical  
Officer (from May 1, 2022)



Günther Metz, Head  
Business Development



Oliver Strub, General Counsel

### Extended Management Team

Rudolf Hausmann, Head Technical Development & Operations  
Sarah Holmes-Klotz, Head People & Culture (from March 1, 2022)  
Eva Kalias, Head Investor Relations & Communications (from May 1, 2022)  
Neville Kodkani, Head Global Marketing & Partner Management  
Andreas Missy, Chief of Staff  
Sabine Pilot, Head of Development (from May 1, 2022)  
Geert Jan van Daal, Head European Affiliates & EU Market Access

<sup>3</sup> Details on the profiles of the team members can be viewed in the Corporate Governance section in this annual report or by visiting <http://www.santhera.com/about-overview>

# Consolidated Financial Statements

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## Consolidated Balance Sheet

Assets	As of December 31, in CHF thousands	Notes	2021	2020
Tangible assets		5	1,324	1,902
Intangible assets		6, 7	64,596	67,673
Financial assets long-term			468	552
Deferred tax assets		8	88	837
<b>Noncurrent assets</b>			<b>66,476</b>	<b>70,964</b>
Prepaid expenses			1,069	344
Inventories		9	428	481
Trade and other receivables		10	1,936	4,487
Cash and cash equivalents		11	21,208	12,411
<b>Current assets</b>			<b>24,641</b>	<b>17,723</b>
<b>Total assets</b>			<b>91,117</b>	<b>88,687</b>
<b>Equity and liabilities</b>				
Share capital		12	54,608	19,430
Capital reserves and share premium			509,513	480,005
Retained earnings			-556,425	-500,899
Employee benefit reserve			-437	-2,320
Treasury shares		12	-5,020	-1,580
Translation differences			-911	-990
<b>Total equity</b>			<b>1,328</b>	<b>-6,354</b>
Convertible bonds		13	25,796	57,875
Noncurrent derivative financial instruments		13	3,683	0
Noncurrent warrant liability		13	4,723	0
Noncurrent lease liabilities		14	1,203	1,927
Noncurrent accrued expenses		16	16,808	0
Pension liabilities		23	4,794	6,170
<b>Total noncurrent liabilities</b>			<b>57,007</b>	<b>65,972</b>
Trade and other payables		15	4,585	5,715
Accrued expenses		16	9,710	8,645
Income tax payable			266	60
Current contract liabilities			0	1,126
Current lease liabilities		14	609	769
Current exchangeable notes		13	1,488	10,595
Convertible bonds		13	13,880	0
Current warrant liability		13	1,650	0
Current derivative financial instruments		13	402	125
Current provisions		17	192	2,034
<b>Total current liabilities</b>			<b>32,782</b>	<b>29,069</b>
<b>Total liabilities</b>			<b>89,789</b>	<b>95,041</b>
<b>Total equity and liabilities</b>			<b>91,117</b>	<b>88,687</b>

## Consolidated Income Statement

For the year ended December 31, in CHF thousands	Notes	2021	2020
Net sales	20	-4,963	11,252
Revenue from out-licensing transactions	20,21	1,126	1,597
Net sales to licensing partner	20,21	2,242	2,159
<b>Revenue from contracts with customers</b>		<b>-1,595</b>	<b>15,008</b>
Cost of goods sold		-3,767	-10,431
<i>Of which amortization intangible assets</i>		-3,040	-3,039
Other operating income		346	694
Development	22	-29,715	-34,228
Marketing and sales	22	-9,332	-11,474
General and administrative	22	-12,725	-12,440
Other operating expenses	22	-100	-205
<b>Operating expenses</b>	<b>22</b>	<b>-51,872</b>	<b>-58,347</b>
<b>Operating result</b>		<b>-56,888</b>	<b>-53,076</b>
Financial income	24	22,901	1,055
Financial expenses	24	-20,730	-15,435
<b>Result before taxes</b>		<b>-54,717</b>	<b>-67,456</b>
Income taxes	25	-809	-203
<b>Net result</b>		<b>-55,526</b>	<b>-67,659</b>
Basic and diluted net result per share (in CHF)	26	-1.62	-5.08

## Consolidated Statement of Comprehensive Income

For the year ended December 31, in CHF thousands	Notes	2021	2020
<b>Net result</b>		<b>-55,526</b>	<b>-67,659</b>
<i>Items never to be reclassified to net income in subsequent periods:</i>			
Actuarial gains/losses on defined benefit plans	23	1,883	840
<i>Items to be reclassified to net income in subsequent periods:</i>			
Currency translation differences		79	-133
<b>Other comprehensive result</b>		<b>1,962</b>	<b>707</b>
<b>Total comprehensive result</b>		<b>-53,564</b>	<b>-66,952</b>

## Consolidated Cash Flow Statement

For the year ended December 31, in CHF thousands	Notes	2021	2020
Result before taxes		<b>-54,717</b>	<b>-67,456</b>
Depreciation and impairment of tangible assets	5	634	3,960
Amortization and impairment of intangible assets	6,7	3,090	3,177
Expenses for equity rights plans	19 23	2,761	3,029
Change in fair value of derivatives	24	-8,656	-617
Realized gain on exchange of convertible bonds	24	-13,439	0
Change in pension liabilities	23	507	-2,106
Reversal of current provisions	17	-589	2,034
Change in noncurrent accruals	16	16,808	0
Taxes paid		-70	10
Change in net working capital		1,767	3,245
Total financial result	24	16,485	14,380
Interest received		1	3
Interest paid		-1,941	-3,169
<b>Cash flow from/(used in) operating activities</b>		<b>-37,359</b>	<b>-43,510</b>
Investments in tangible assets	5	-2	-29
Investments in intangible assets	6	-13	-5
Change in investments in other long-term financial assets		84	97
Change in restricted cash		0	1,500
<b>Cash flow from/(used in) investing activities</b>		<b>69</b>	<b>1,563</b>
Proceeds from capital increase		20,272	0
Proceeds from sale of treasury shares		81	901
Purchase of treasury shares		-56	-922
Proceeds from convertible notes (Highbridge and IRIS)	13	22,000	24,559
Proceeds from bond	13	13,792	0
Repayment of exchangeable note	13	-3,500	0
Payment of principal portion of lease liabilities	14	-739	-1,071
Transaction costs for financial instruments	24	-3,439	-70
Cost of issuance share capital		-2,389	-247
<b>Cash flow from/(used in) financing activities</b>		<b>46,022</b>	<b>23,150</b>
Effects of exchange rate changes on cash and cash equivalents		65	-150
<b>Net increase/(decrease) in cash and cash equivalents</b>		<b>8,797</b>	<b>-18,947</b>
Cash and cash equivalents at January 1		12,411	31,358
<b>Cash and cash equivalents at December 31</b>	11	<b>21,208</b>	<b>12,411</b>

## Consolidated Statement of Changes in Equity

In CHF thousands	Notes	Share capital	Capital reserves and share premium	Retained earnings	Employee benefit reserve	Treasury shares	Translation differences	Total
<b>Balance at January 1, 2020</b>								
		<b>11,165</b>	<b>448,084</b>	<b>-433,240</b>	<b>-3,160</b>	<b>-745</b>	<b>-857</b>	<b>21,247</b>
Net result		0	0	-67,659	0	0	0	<b>-67,659</b>
Other comprehensive result	22	0	0	0	840	0	-133	<b>707</b>
<b>Total comprehensive result for the period</b>		<b>0</b>	<b>0</b>	<b>-67,659</b>	<b>840</b>	<b>0</b>	<b>-133</b>	<b>-67,659</b>
Transactions for equity rights plans	19, 22	0	3,029	0	0	0	0	<b>3,029</b>
Capital increase for financing transactions	13	4,569	0	0	0	-4,569	0	<b>0</b>
Delivery of shares upon conversion of IRIS loans	13	0	11,909	0	0	2,079	0	<b>13,988</b>
Delivery of shares upon conversion of Highbridge loans	13	3,696	15,661	0	0	880	0	<b>20,237</b>
Capital increase Idorsia	6, 13	0	1,998	0	0	367	0	<b>2,365</b>
Cost of issuance share capital		0	-247	0	0	0	0	<b>-247</b>
Change in treasury shares		0	-429	0	0	408	0	<b>-21</b>
<b>Balance at December 31, 2020</b>		<b>19,430</b>	<b>480,005</b>	<b>-500,899</b>	<b>-2,320</b>	<b>-1,580</b>	<b>-990</b>	<b>-6,354</b>
<b>Balance at January 1, 2021</b>								
		<b>19,430</b>	<b>480,005</b>	<b>-500,899</b>	<b>-2,320</b>	<b>-1,580</b>	<b>-990</b>	<b>-6,354</b>
Net result		0	0	-55,526	0	0	0	<b>-55,526</b>
Other comprehensive result	22	0	0	0	1,883	0	79	<b>1,962</b>
<b>Total comprehensive result for the period</b>		<b>0</b>	<b>0</b>	<b>-55,526</b>	<b>1,883</b>	<b>0</b>	<b>79</b>	<b>-54,241</b>
Transactions for equity rights plans	19, 22	0	2,465	0	0		0	<b>2,465</b>
Capital increase for financing transactions	13	33,512	1,133	0	0	-20,841	0	<b>13,804</b>
Delivery of shares upon conversion of Idorsia loans	13	0	2,905	0	0	3,595	0	<b>6,500</b>
Delivery of shares upon conversion of Highbridge loans	13	1,666	17,289	0	0	8,400	0	<b>27,355</b>
Delivery of shares upon conversion of bonds	6, 13	0	8,356	0	0	4,501	0	<b>12,857</b>
Cost of issuance share capital		0	-2,389	0	0	0		<b>-2,389</b>
Delivery of shares for financing facility		0	0	0	0	233	0	<b>233</b>
Change in treasury shares		0	-251	0	0	672	0	<b>421</b>
<b>Balance at December 31, 2021</b>		<b>54,608</b>	<b>509,513</b>	<b>-556,425</b>	<b>-437</b>	<b>-5,020</b>	<b>-911</b>	<b>1,328</b>



# Notes to the Consolidated Financial Statements

## 1 General Information

Santhera Pharmaceuticals Holding AG (the **Company**, together with its subsidiaries **Santhera** or **Group**) is a Swiss specialty pharmaceutical company focused on the development and commercialization of products for the treatment of neuromuscular and pulmonary diseases, areas which include many orphan and niche indications with high unmet medical need.

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 Hohenrainstrasse 24 in 4133 Pratteln, Switzerland.

The consolidated financial statements were approved for publication by the Board of Directors (**Board**) on June 9, 2022. They are subject to approval by the Annual General Meeting of Shareholders (**AGM**) on June 30, 2022.

## 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 preparation of the financial statements requires management to make estimates and assumptions, which have an effect on the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the balance sheet date and on the reported amounts of revenues and expenses during the reporting period. These estimates are based on historical experience and management's knowledge of current events and actions the Company may undertake in the future, however, actual results ultimately may differ from those estimates.

### Material uncertainties and ability to continue operations

Cash and cash equivalents amounted to CHF 21.2 million as of December 31, 2021, of which CHF 13.9 million was used for the repayment of the 2017/22 convertible bond on maturity in February 2022. However, because the funds as of December 31, 2021 and as of the date of these financial statements are insufficient to allow the Company to reach the value inflection points after the completion of vamorolone regulatory filing, material uncertainties remain as to the Company's ability to continue as a going concern until December 31, 2022. Executing the Company's strategy significantly depends on the following

- The acceptance by the U.S. FDA of the NDA submission for vamorolone expected in Q3-2022
- Further funding to ensure the continuation of its operations through December 31, 2022
- No material adverse advents as it relates the reimbursement status of Raxone in France (see note 18 Commitments and Contingent Liabilities)
- Ability to settle current debt obligations

The US NDA submission for vamorolone in ambulant patients with DMD, is in progress and expected to be completed during Q2-2022, with the acceptance of the submission by the FDA expected in Q3-2022. In the event of acceptance, the Management and Board of Directors plan to raise additional funds through a capital increase in the second half of 2022 in order to finance further development to support a European submission and pre-commercialization activities. Should further funding not be available, pending approval of the submission, the Company may review further organizational restructuring measures and reduction in business activities as well as consider the monetization of assets (e.g., out-licensing rights of lonodelestat or outlicensing rights in certain geographic markets of vamorolone ).

On June 2, 2022, the Company increased its financing facility with Highbridge Capital to provide up to CHF 40 million to increase the cash runway to the next key inflection point, namely the approval of vamorolone in DMD in the U.S. which is expected in Q1-2023 subject to priority review, and to allow for additional time to raise additional finance after the vamorolone results. The respective agreement with Highbridge Capital provides for a tranche of CHF 20 million, which is unconditional and which Santhera has requested immediately upon signing. These CHF 20 million have been received on June 3, 2022, of which CHF 8.5 million was used to refinance outstanding exchangeable notes. The remaining balance (CHF 20 million) is divided into two tranches, each amounting to CHF 10 million, and each drawdown is subject to Highbridge Capital's consent.

In addition, on June 2, 2022, the Company announced an amendment to the agreement with ReveraGen, resulting in a reduction of the milestone payment due upon FDA approval (expected in Q1-23) by USD 20 million in exchange for an increase of the sales milestone by USD 20 million (due when vamorolone annual revenue reaches USD 100 million).

Shareholders should note that whilst the Management and Board of Directors consistently continue to apply best efforts to evaluate and execute available options, there is no guarantee that the development studies will be successful, regulatory approvals obtained, that there are no material adverse events as it relates to the reimbursement status of Raxone in France and any transaction can be realized or that such transaction would generate sufficient funds to finance operations through December 31, 2022. These material uncertainties may cast significant doubts about ability of the Company and the Group to continue as a going concern. If going concern cannot be supported, consolidated financial statements would have to be prepared using liquidation values.

However, the Management and the Board of Directors of Santhera are of the view that it is more likely than not that the Group will continue to secure additional funds needed in order to operate its business as planned with the objective to meet all of its obligations until December 31, 2022. Hence, the consolidated financial statements have been prepared on a going concern basis.

## **Consolidation**

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

The consolidated financial statements of Santhera include the accounts of Santhera Pharmaceuticals Holding AG, Pratteln, Switzerland, and its wholly owned subsidiaries Santhera Pharmaceuticals (Schweiz) AG, Pratteln, Switzerland; Santhera Pharmaceuticals (USA), Inc., Burlington, 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 (in liquidation, expected to be completed during 2022); Santhera (Germany) GmbH, München, Germany; Santhera (Netherlands) B.V., Nieuwegein, The Netherlands; Santhera (UK) Limited, London, United Kingdom; and Santhera Pharmaceuticals (Spain), S.L.U, Irun, Spain.

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.

### **Changes in accounting policies**

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

The Group has not early adopted any other standard, interpretation or amendment that has been issued but is not yet effective.

The following new, revised or amended standards became effective January 1, 2021, but did not have an impact on these Consolidated Financial Statements.

- Amendments to IFRS 9, IAS 39 and IFRS 7: Interest Rate Benchmark Reform – Phase 2 (effective January 1, 2021)

Other new, revised or amended standards have been published but are not yet effective and have not been early adopted by the Group. None of the changes in IFRS are expected to have a significant impact on the consolidated financial statements.

### **Segment reporting**

Santhera has one operating segment, namely the development and commercialization of products for the treatment of neuromuscular and pulmonary 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 a consolidated level according to operating expenses by function. Santhera generates revenue from sales of Raxone for the treatment of LHON, out-licensing transactions and sales to licensing partners. 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 the statements of comprehensive income/equity.

**Intangible assets**

Patents, licenses, sub-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 or 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 life-time of their patent or orphan drug protection (up 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
Right-of-use assets (lease liabilities)	2 to 6 years
Leasehold improvements	2 to 10 years

**Impairment of assets**

Assets include intangible assets not yet available for use, intangible assets with finite useful lives and tangible assets (including right-of-use 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. The Impairment testing is performed at the same time every year or whenever there is an indication that the asset may be impaired. Once an intangible asset starts to be used, amortization starts. Testing for indicators of impairment for intangible assets with definite useful lives and for tangible assets is done at the end of each reporting period.

**Trade and other receivables**

Receivables which generally have 30 to 60 days payment terms are stated at their nominal value less an allowance for any uncollectible amount based on expected credit losses.

**Inventories**

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

**Financial assets**

Purchases or sales of financial assets that require delivery of assets within a time frame established by regulation or convention in the market place (regular way trades) are recognized on the transaction date. Generally, Santhera classifies its financial assets in the following categories:

*Financial assets subsequently measured at amortized cost*

These are financial assets held to collect contractual cash flows representing principal and interest only. With the exception of trade receivables, they are initially measured at fair value plus transaction costs. Trade receivables are measured at the transaction price established in accordance with IFRS 15. Subsequent to initial recognition these financial assets are measured at amortized cost using the effective interest rate and are subject to impairment using the expected credit loss model.

*Financial assets at fair value through profit or loss*

Santhera classifies all other financial assets at fair value through profit or loss. Principally, these are instruments held for trading. 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 or loss. 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.

*Interest income*

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

**Leases**

The Group assesses at contract inception whether a contract is, or contains, a lease. That is, if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

The Group applies a single recognition and measurement approach for all leases, except for short-term leases and leases of low-value assets. The Group recognizes lease liabilities to make lease payments and right-of-use assets representing the right to use the underlying assets.

*Right-of-use assets*

The Group recognizes right-of-use assets at the commencement date of the lease. Right-of-use assets are measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any remeasurements of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognized, initial direct costs incurred, and lease payments made at or before the commencement date. Unless the Group is reasonably certain to obtain ownership of the leased asset at the end of the lease term, the recognized right-of-use assets are depreciated on a straight-line basis over the shorter of its estimated useful life and the lease term. Right-of-use assets are subject to impairment.

*Lease liabilities*

At the commencement date of the lease, the Group recognizes lease liabilities measured at the present value of lease payments to be made over the lease term. The lease payments include fixed payments less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees. The lease payments also include the exercise price of a purchase option reasonably certain to be exercised by the Group and payments of penalties for terminating a lease, if the lease term reflects the Group exercising the option to terminate. The variable lease payments that do not depend on an index or a rate are recognized as expense in the period during which the event or condition that triggers the payment occurs.

In calculating the present value of lease payments, the Group uses the incremental borrowing rate at the lease commencement date if the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is increased to reflect the accumulation of interest and reduced by the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a

change in the lease term, a change in the in-substance fixed lease payments or a change in the assessment to purchase the underlying asset.

#### *Short-term leases and leases of low-value assets*

The Group applies the short-term lease recognition exemption to its short-term leases. It also applies the lease of low-value assets recognition exemption to leases that are considered of low value (i.e., below CHF 5,000). Lease payments on short-term leases and leases of low-value assets are recognized as expense over the lease term.

### **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.

### **Treasury shares**

Treasury shares are purchased at cost and recognized as deduction from equity. Income or loss from subsequent sale is presented in equity.

### **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 the changes occur.

Derivatives may be embedded in other contractual arrangements. Santhera accounts for an embedded derivative separately from the host contract when:

- the host contract is not an asset in the scope of IFRS 9
- the host contract is not itself carried at fair value through profit or loss
- the terms of the embedded derivative would meet the definition of a derivative if they were contained in a separate contract
- the economic characteristics and risks of the embedded derivative are not closely related to the economic characteristics and risks of the host

Separated embedded derivatives are measured at fair value, with all changes in fair value recognized in profit or loss.

#### *Other liabilities measured at amortized costs*

This category principally covers debt instruments and trade and other payables. They are initially recognized at fair value less transaction costs 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, Santhera reassesses unrecognized deferred tax assets and the carrying amount of deferred tax assets. Santhera 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), the number of potential shares from stock option plans and the convertible bonds or notes.

## 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 life-long 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 various equity settled 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. The fair value of instruments granted is determined at the grant date and recognized as personnel expense over the period Santhera receives services for each award. Where 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 an outflow of resources 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 from contracts with customers is recognized at an amount that reflects the consideration to which Santhera expects to be entitled in exchange for transferring goods or services to a customer.

Net sales from the sale of products are recognized at the point in time when the customer obtains control of those products which is generally upon delivery at the customer. Revenue is net of value-added tax, rebates, discounts, returns and after eliminating intercompany sales.

Where revenue arrangements include variable consideration, such amounts are not included in the estimated transaction price unless it is highly probable that a significant reversal of the cumulative revenues recognized will not occur in future periods once the uncertainty related to the variable consideration is resolved. Payment terms usually range between 30 and 60 days for the sale of goods. Customer returns and variable consideration are not material.

#### *Revenue from out-licensing, incl. revenue from royalties*

Out-licensing agreements are concluded, where the counterparty has to pay license fees which are usually in the form of upfront and milestone payments as well as royalty payments. Santhera determines its performance obligations under such arrangements and in case of multiple deliverables allocates the transaction price to each distinct performance obligation on a relative stand-alone selling price basis. Typically, these arrangements include



obligations such as maintenance of patents, research and development support and services, memberships in joint steering committees and other involvement in the arrangement, in which case the upfront and milestone payments may represent advance payments for future services and/or the right to access the underlying intellectual property of the Group. Revenue from such agreements is recognized upon transfer of control of the license or services rendered.

Sales-based or usage-based royalties received in exchange for licenses of intellectual property are recognized as revenue at the later of when: (1) the subsequent sale or usage occurs; or (2) the performance obligation to which some or all of the sales-based or usage-based royalty has been allocated is satisfied (in whole or in part) where the license is the only or predominant item to which the royalty relates.

*Revenue associated with upfront payments or performance milestones*

Such revenue is recognized in accordance with respective agreements.

**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 indicators at each balance sheet date. Assets not available for use are tested annually for impairment.

### **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:

- Assessment of the Group's ability to continue as a going concern.
- Revenue recognition and related accruals in relation to sales made in France, due to ongoing France reimbursement process. See notes 15 and 18 "French Social Security" for a description of developments and significant judgements applied.
- Measurement and impairment testing of intangible assets not yet available for use, see note 7 "Impairment Test for Intangible Assets".
- Valuation of derivative financial instruments in connection with financial liabilities, see note 13 "Financial Liabilities".
- Actuarial valuations in the context of defined benefit pension plans where various assumptions on e.g., discount rates, salary increase rates and mortality rates, etc. bear significant uncertainties due to the long-term nature of the plans, see note 24 "Employee Expenses and Benefits".

#### 4 Exchange Rates of Principal Currencies

	Income statement in CHF average rates		Balance sheet in CHF year-end rates	
	2021	2020	2021	2020
1 Euro ( <b>EUR</b> )	1.0823	1.0702	1.0339	1.0822
1 US dollar ( <b>USD</b> )	0.9144	0.9390	0.9127	0.8812
1 British pound ( <b>GBP</b> )	1.2559	1.2045	1.2330	1.2036
1 Canadian dollar ( <b>CAD</b> )	0.7275	0.7003	0.7176	0.6911

## 5 Tangible Assets

In CHF thousands	Right-of-use assets vehicles	Right-of-use assets offices	Equip- ment	IT hard- ware	Leasehold improve- ments	2021
<b>Cost</b>						
At January 1	46	4,252	886	1,036	1,628	7,848
Additions <sup>1</sup>	0	0	0	2	0	2
Disposals	-46	0	0	-82	-91	219
Exchange differences	0	0	-6	-12	0	-18
<b>At December 31</b>	<b>0</b>	<b>4,252</b>	<b>880</b>	<b>944</b>	<b>1,537</b>	<b>7,613</b>
<b>Accumulated depreciation and impairment losses</b>						
At January 1	46	3,046	698	951	1,205	5,946
Additions	0	377	39	110	108	634
Disposals	-46	0	0	-132	-91	-269
Exchange differences	0	-4	-6	-12	0	-22
<b>At December 31</b>	<b>0</b>	<b>3,419</b>	<b>731</b>	<b>917</b>	<b>1,222</b>	<b>6,289</b>
<b>Net book value <sup>2</sup></b>	<b>0</b>	<b>833</b>	<b>149</b>	<b>27</b>	<b>315</b>	<b>1,324</b>

In CHF thousands	Right-of-use assets vehicles	Right-of-use assets offices	Equip- ment	IT hard- ware	Leasehold improve- ments	2020
<b>Cost</b>						
At January 1	737	4,112	902	1,109	1,614	8,474
Additions <sup>1</sup>	26	173	15	14	15	243
Disposals	-776	0	-26	-81	0	-883
Remeasurements	69	0	0	0	0	69
Exchange differences	-10	-33	-5	-6	-1	-55
<b>At December 31</b>	<b>46</b>	<b>4,252</b>	<b>886</b>	<b>1,036</b>	<b>1,628</b>	<b>7,848</b>
<b>Accumulated depreciation and impairment losses</b>						
At January 1	269	787	412	871	531	2,870
Additions	248	741	92	137	207	1,425
Impairment <sup>2</sup>	300	1,530	222	29	468	2,549
Disposals	-768	0	-26	-81	0	-875
Exchange differences	-3	-12	-2	-5	-1	-23
<b>At December 31</b>	<b>46</b>	<b>3,046</b>	<b>698</b>	<b>951</b>	<b>1,205</b>	<b>5,946</b>
<b>Net book value <sup>2</sup></b>	<b>0</b>	<b>1,206</b>	<b>188</b>	<b>85</b>	<b>423</b>	<b>1,902</b>

<sup>1</sup> Including non-cash items (e.g., right of use assets)

<sup>2</sup> Net book value of right-of-use assets amounts to TCHF 833 and the value of owned tangible assets amounts to TCHF 491 in 2021. In 2020 the net book value of right-of-use assets amounts to TCHF 1,206 and the value of owned tangible assets amounts to TCHF 696. See note 14 "Financial Liabilities" for further information on leases.

## 6 Intangible Assets

	In CHF thousands	vamorolone (in process R&D)	lonodeles- tat (in pro- cess R&D)	Idebenone	IT software/ patents	2021
<b>Cost</b>						
At January 1		47,145	6,210	30,387	800	84,542
Additions		0	0	0	13	13
<b>At December 31</b>		<b>47,145</b>	<b>6,210</b>	<b>30,387</b>	<b>813</b>	<b>84,555</b>
<b>Accumulated amortization</b>						
At January 1		0	0	16,206	663	16,869
Additions		0	0	3,040	50	3,090
<b>At December 31</b>		<b>0</b>	<b>0</b>	<b>19,246</b>	<b>713</b>	<b>19,959</b>
<b>Net book value</b>		<b>47,145</b>	<b>6,210</b>	<b>11,141</b>	<b>100</b>	<b>64,596</b>

	In CHF thousands	vamorolone (in process R&D)	lonodeles- tat (in pro- cess R&D)	Idebenone	IT software/ patents	2020
<b>Cost</b>						
At January 1		34,780	6,210	30,387	796	72,173
Additions <sup>1</sup>		12,365	0	0	5	12,370
Exchange differences		0	0	0	-1	-1
<b>At December 31</b>		<b>47,145</b>	<b>6,210</b>	<b>30,387</b>	<b>800</b>	<b>84,542</b>
<b>Accumulated amortization</b>						
At January 1		0	0	13,168	526	13,694
Additions		0	0	3,038	120	3,158
Impairment		0	0	0	18	18
Exchange differences		0	0	0	-1	-1
<b>At December 31</b>		<b>0</b>	<b>0</b>	<b>16,206</b>	<b>663</b>	<b>16,869</b>
<b>Net book value</b>		<b>47,145</b>	<b>6,210</b>	<b>14,181</b>	<b>137</b>	<b>67,673</b>

<sup>1</sup> The additions include the non-cash items of the exercise of the option to obtain worldwide rights to vamorolone in Duchenne muscular dystrophy and all other indications from September 2020 in the amount of CHF 12.4 million (refer to note 7 "Impairment Test for Intangible Assets")

During 2021, intangible assets in use were assessed for impairment (refer to note 7 "Impairment Test for Intangible Assets").

## 7 Impairment Test for Intangible Assets

### Idebenone

"Idebenone" represents the intangible asset of Santhera which has become available for use in September 2015 and has an estimated useful life of 10 years. On August 2, 2019, Santhera closed a licensing transaction with Chiesi Farmaceutici S.P.A., Parma, Italy (Chiesi). After such licensing transaction, in fiscal years 2019 and 2020, the carrying amount of the intangible asset continued to be supported by ongoing and expected revenues from Raxone (idebenone) received from Chiesi and the market in France with respect of the approved treatment for LHON. In 2021, the uncertainties and status of negotiations around pricing and reimbursement in France (refer to Note 19, section "French Social Security" for further information) constituted a triggering event for an impairment assessment. As part of this impairment assessment, Santhera concluded that the carrying amount of the intangible asset continued to be supported by the expected future economic benefits derived from the asset.

### Vamorolone and Ionodelestat

"Vamorolone" and "Ionodelestat (POL6014)" are intangible assets which were added in 2018. The carrying amount for vamorolone was further increased in 2020 due to the option exercise and assignment of vamorolone license with ReveraGen and Idorsia respectively. They are not yet available for use. Therefore, they are subject to an impairment test at least once annually or in case of triggers for impairment.

Management used a risk-adjusted Net Present Value (**rNPV**) model which contains several assumptions in order to verify the recoverable amount. This is a customary way for the valuation of pharmaceutical intangibles. The rNPV model considers mainly the period over the net cash flows of the development and use patent period of the products; hence the models contain data for the periods from 2022 through 2032 for vamorolone and 2037 for ionodelestat. No terminal value was calculated since it is probable that after the exclusivity period the sales could decrease. For the purpose of estimating these cash flows as per December 31, 2021, Santhera made general estimates for:

	2021	2020
WACC	10.0%	12.0%
Tax rate	15.0%	18.0%

Considering the markets and respective risk-profile for both assets, Santhera used the same WACC and tax rate assumptions for the impairment testing of vamorolone and ionodelestat. Other input elements for the calculation of the rNPV are based on the individual agreements with Polyphor, Idorsia or ReveraGen together with management estimates, such as the expected revenues based on estimated market size and patient numbers, expected market penetration rates, product pricing and project- or product-related costs taking into account externally available data where relevant. Management estimates probability of reaching the market lies between 25% (2020: 25%) for ionodelestat and 90% (2020: 45%) for vamorolone, reflecting the uncertainty as to whether a final and successful market registrations can be achieved, and considering standard industry success factor measures.

The impairment test of the recoverable amount of the intangible assets performed, as of December 31, 2021 and 2020, did not result in the requirement to recognize an impairment. Santhera performed a sensitivity analysis considering reasonable changes in the assumptions used, such as changes in number of patients on drug, sales price and probability of reaching the market. The sensitivity analysis for 2021 did not reveal any indicators of impairment as at the reporting date or further disclosure.

## 8 Deferred Tax Assets

### Net deferred tax assets recorded

	In CHF thousands	2021	2020
Temporary differences on inventory		88	837
<b>Deferred tax assets recognized</b>		<b>88</b>	<b>837</b>
Temporary differences on intangible assets, net		1,318	1,677
Temporary differences on convertible bonds		57	290
Tax loss carryforwards		-1,375	-1,967
<b>Deferred tax liabilities recognized</b>		<b>0</b>	<b>0</b>
Tax loss carryforwards		252,071	194,878
Of which recorded		-10,223	-14,626
<b>Of which unrecorded</b>		<b>241,848</b>	<b>180,252</b>
Expiring in			
1 year		2,514	1,090
2 years		41,999	2,964
3 years		41,237	41,999
4 years		27,734	41,237
5 years		1,455	27,734
More than 5 years		98,772	37,086
Without expiration		28,137	28,142
<b>Total unrecorded tax loss carryforwards</b>		<b>241,848</b>	<b>180,252</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 recognized on temporary differences related to pension obligations from IAS 19 (TCHF 4,794 at December 31, 2021, and TCHF 6,170 at December 31, 2020, respectively).

## 9 Inventories

	In CHF thousands	2021	2020
Semi-finished goods		0	85
Finished goods		428	396
<b>Total at December 31</b>		<b>428</b>	<b>481</b>

Inventory for Raxone provided as free goods to France is drawn from inventory previously fully impaired.

## 10 Trade and Other Receivables

	In CHF thousands	2021	2020
Trade receivables (gross)		1,121	2,389
Other receivables		974	2,164
Allowance for expected credit losses		-23	-66
Specific allowance for credit losses		-136	0
<b>Total at December 31</b>		<b>1,936</b>	<b>4,487</b>

Trade receivables in 2021 result from product sales, see note 20 "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.

Shown below is the information of the expected credit losses on the Group's trade receivables using a provision matrix:

	Current	0-30 days	31-60 days	61-90 days	91-180 days	181-360 days	>360 days	As of Dec. 31, 2021
Expected credit loss rate (in %)	0.3%	0.9%	2.1%	4.2%	7.7%	11.5%	13.0 to 25%	
Estimated total gross carrying amount at default (in TCHF)	376	528	8	51	103	48	7	<b>1,121</b>
Expected credit loss (in TCHF)	1	5	0	2	8	6	1	<b>23</b>

	Current	0-30 days	31-60 days	61-90 days	91-180 days	181-360 days	>360 days	As of Dec. 31, 2020
Expected credit loss rate (in %)	0.3%	0.9%	2.1%	4.2%	7.7%	11.5%	13.0 to 25%	
Estimated total gross carrying amount at default (in TCHF)	1,653	230	76	64	105	73	168	<b>2,389</b>
Expected credit loss (in TCHF)	5	2	2	3	8	9	37	<b>66</b>

Changes in the allowance for expected credit losses (ECL) of are as follows:

	In CHF thousands	2021	2020
<b>Expected credit losses at January 1</b>		<b>-66</b>	<b>-146</b>
Reversal of allowance for ECL		0	146
Increase in allowance ECL		-93	-66
<b>Outstanding at December 31</b>		<b>-159</b>	<b>-66</b>

## 11 Cash and Cash Equivalents

	In CHF thousands	2021	2020
Cash at banks and on hand			
In CHF		20,301	11,183
In EUR		288	913
In GBP		61	74
In USD		468	130
In CAD		24	48
Other currencies		66	63
<b>Total at December 31</b>		<b>21,208</b>	<b>12,411</b>
<hr/>			
Of which: Short-term deposits			
In CHF		341	0

## 12 Share Capital

### Ordinary share capital

During 2021, the total amount of 16,980,658 Shares was issued out of the authorized share capital and 7,912,954 from conditional capital and an ordinary increase of 10,284,502 shares for settlement of Idorsia Exchangeable Note and Equity placement in September 2021 as well as financing arrangements in connection with Highbridge Capital Management, LLC, USA (Highbridge) (see note 13 "Financial Liabilities"). As a result, as of December 31, 2021, the share capital amounted to CHF 54,607,810 (2020: CHF 19,429,696), divided into 54,607,810 (2020: 19,429,696) Shares at a nominal value of CHF 1 each.

### Treasury shares

In the second half of 2016, Santhera entered into an agreement for market making with a well-known bank. Independently, the bank buys and sells Shares on the market on behalf of the Company, this agreement was terminated during the year. On December 31, 2021, Santhera had nil treasury Shares held in relation to market making (2020: 57,991 treasury Shares).

Santhera created treasury Shares from its authorized capital in order to use them for financing arrangements of the Group (exchangeable notes). On December 31, 2021, Santhera held 5,019,879 treasury Shares for financing arrangements (2020: 1,580,063).

### Authorized share capital

With the approvals of the shareholders at the EGM held on March 18, 2021, the AGM on June 22, 2021, and a second EGM on December 15, 2021, during the reporting period, the authorized capital was increased by 16,980,659 shares in six capital increases. As at December 31, 2021, the available authorized capital amounted to CHF 27,303,905, allowing for 27,303,905 shares to be newly issued until December 14, 2023.



### Conditional share capital

With the approvals of the shareholders at the EGM held on March 18, 2021, the AGM on June 22, 2021, and a second EGM on December 15, 2021, during the reporting period, the conditional capital was increased by 7,912,954 shares in three capital increases.

As of December 31, 2021, the Company had a conditional share capital, pursuant to which the share capital may be increased by

- a maximum amount of CHF 5,425,677 (2020: CHF 687,052) through the issuance of up to 5,425,677 (2020: 687,052) Shares, under the exclusion of shareholders' pre-emptive rights, for equity rights being exercised under the Company's equity rights plans, see note 20 "Equity Rights Plans", and
- a maximum amount of CHF 21,878,228 (2020: CHF 1,104,658) by issuing up to 21,878,228 (2020: 1,104,658) 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 Financial Liabilities

Santhera measures certain financial instruments at fair value. Fair values are categorized into the following hierarchy based on the inputs used to measure them:

- Level 1: Quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2: Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly (as prices) or indirectly (derived from prices).
- Level 3: Unobservable inputs for the asset or liability. These inputs reflect the best estimates of Santhera based on criteria that market participants would use to determine prices for assets or liabilities at the reporting date.

### 13.1 Financial liabilities - Equity linked instruments

Santhera has established different equity-linked financing programs in order to receive additional liquidity in support of the Company's ongoing regulatory and development programs.

#### Highbridge

During 2021, Santhera issued exchangeable notes in the amount of CHF 22.0 million to Highbridge. Each note is convertible at the discretion of its holder into a number of shares. All exchangeable notes have been converted into shares of Santhera stock with the exception of tranche 9, of which CHF 2.0 million is outstanding as of December 31, 2021. Out of this amount CHF 0.5 million is presented as Current derivative financial instruments.

During 2021, the Company has amended different equity-linked financing agreements in order to receive additional liquidity in support of the Company's ongoing development pipeline. Commitment fees for the amendments to Highbridge facilities, warrants, equal to 15% of the total aggregate amount of the remaining existing facility and new money tranches, were issued and are exercisable into Santhera Shares at the discretion of Highbridge. A total of 984,769 warrants with a fair value of CHF 1.58 per warrant, were issued in May and 1.0 million warrants with a fair value of 1.05 per warrant were issued in September and represent transaction costs. The warrants are classified as financial liabilities at initial recognition and subsequently.

On July 13, 2020, Santhera issued exchangeable notes in the amount of CHF 7.5 million to Highbridge. Each note is convertible at the discretion of its holder into a number of shares. Between November 1, 2020, and December 31, 2020, a second tranche of CHF 5 million and a third tranche of CHF 2 million have been issued. The first and the second tranches have been fully converted into shares of Santhera, a balance of CHF 0.75 million from the third tranche is outstanding as of December 31, 2020. Out of this amount CHF 0.125 million is presented as current derivative financial instruments. During the 2020 the total gross proceeds were CHF 14.5 million, proceeds net of transaction costs were CHF 13.7 million.

The exchangeable notes are hybrid contracts containing a host that is a financial liability and different embedded derivatives. Since the economic characteristics and risks of the host and the embedded derivatives are not closely related, the embedded derivatives are separated from the host. The compound embedded derivative includes different features like interest rate choices, a compound interest rate calculation based on the interest rate choice, discounts based on share prices, a floor for share prices and different exchange rights. There is an interdependence between the mentioned features, which is why they are recognized as one compound embedded derivative with their fair value.

The embedded financial derivatives, are valued by an independent consultant at period end at fair value, applying a simulation-based valuation approach. They are classifying as Level 3 financial instruments in the fair value hierarchy. Some input parameters may not be observable in the market and may be derived from market prices or rates or estimated based on assumptions. One of the significant unobservable inputs is the volatility, which is derived from Santhera's historical share price. The period of volatility data used is measured according to the remaining life of the exchangeable note. The observed volatility as of December 31, 2021, amounts to 73.3% and 64.7% as of December 31, 2021 and 2020, respectively. There are also assumptions made based on the expected remaining lifetime and in connection with the expected exercise date which is March 11, 2023. By construction, the compound financial instrument issued to Highbridge will be exercised early, before maturity. For valuation purposes, it was therefore assumed that the expected exercise date is between the investing date and the maturity date.

As of December 31, 2021, the carrying amount of the host for notes issued but not yet converted amounted to TCHF 1,488 and is included in the balance sheet under current exchangeable notes and the separated embedded derivative is included with a fair value of TCHF 0.4 in current derivative financial instruments.

As of December 31, 2020, the carrying amount of the host for notes issued but not yet converted amounted to TCHF 642 and is included in the balance sheet under current exchangeable notes and the separated embedded derivative is included with a fair value of TCHF 125 in current derivative financial instruments.

As of December 31, 2021, the fair value of the 984,769 warrants total TCHF 542 and the 1,000,000 warrants total TCHF 660. For notes that have been converted into shares, the May warrants are included in the balance sheet under long term liabilities, for the notes not issued the warrants are included in prepaid assets, while the warrants related to the note outstanding as of December 31, 2021 is included in the carrying value of the note.

### **Warrants from Equity Raise**

As part of the equity raise, Santhera issued one warrant for every two shares, for a total of 6,335,039 warrants. As of December 31, 2021, the fair value of the warrants total TCHF 4,181 and are included in the balance sheet under long term liabilities.

## Sensitivity analysis:

Embedded derivative	December 31, 2021		December 31, 2020	
	Increase/decrease in volatility assumption	Effect on result before taxes in CHF thousands	Increase/decrease in volatility assumption	Effect on result before taxes in CHF thousands
Change in volatility	+5%	-5	+5%	0
	-5%	4	-5%	0
<hr/>				
Warrants	Increase/decrease in volatility assumption	Effect on result before taxes in CHF thousands	Increase/decrease in volatility assumption	Effect on result before taxes in CHF thousands
Change in volatility	+5%	-40	+5%	0
	-5%	50	-5%	0

**Idorsia**

On September 1, 2020, as part consideration for the assignment of the license for vamorolone, Santhera issued non-interest-bearing exchangeable notes in the amount of CHF 10 million to Idorsia, with a maturity date of September 1, 2021. These notes entitle Santhera for different redemption options by settling the nominal amount fully in cash or by delivering a combination of cash and Santhera shares with differing discounts on the share price depending on the portion of Santhera shares delivered.

On September 1, 2021 Santhera repaid the Idorsia exchangeable notes in full by transferring cash of CHF 3.5 million and 3,594,759 shares of Santhera stock in the amount of CHF 6.5 million.

The exchangeable notes issued to Idorsia represent compound financial instruments, including a host contract which classifies as a financial liability and different embedded derivatives that have been valued as one compound derivative. The value of the embedded derivatives was solely based on entity specific information and was insignificant.

**Changes in liabilities arising from equity-linked instruments**

In CHF thousands	Convertible notes High- bridge	Current de- rivative Highbridge	Derivative Warrant	Convertible notes Idorsia	Convertible notes IRIS	Convertible derivative notes IRIS
<b>December 31, 2019</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
Proceeds from convertible notes (Highbridge and IRIS)	13,726	0	0	0	10,833	0
<b>Cash flows in 2020</b>	<b>13,726</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>10,833</b>	<b>0</b>
Non-cash changes						
Recognition of financial in- struments	0	3,416	0	9,930	0	2,348
Derecognition of derivative financial instruments on warrants exercise	0	0	0	0	360	-360
Nominal value of converti- ble notes converted into shares	-13,844	-3,583	0	0	-12,000	0
Effective interest- method/transaction cost/fair value adjustments	760	613	0	23	807	0
Derecognition of derivative financial instruments on conversion of notes	0	-321	0	0	0	-1,988
<b>December 31, 2020</b>	<b>642</b>	<b>125</b>	<b>0</b>	<b>9,953</b>	<b>0</b>	<b>0</b>
Proceeds from convertible notes	22,000	0	0	0	0	0
Repayment of convertible notes	0	0	0	-3,500	0	0
<b>Cash flows in 2021</b>	<b>22,000</b>	<b>0</b>	<b>0</b>	<b>-3,500</b>	<b>0</b>	<b>0</b>
Non-cash changes						
Initial Recognition from de- rivative financial instru- ments	-8,462	6,786	2,606	0	0	0
Warrants issued on equity raise			6,651			
Nominal value of converti- ble notes converted into shares	-20,750	0	0	-6,500	0	0
Effective interest/amor- tized cost calculation/fair value adjustments	8,058	0	-3,874	47	0	0
Derecognition of derivative financial instruments on conversion of notes	0	-6,509	0	0	0	0
<b>December 31, 2021</b>	<b>1,488</b>	<b>402</b>	<b>5,383*</b>	<b>0</b>	<b>0</b>	<b>0</b>

\* Of this amount, TCHF 4,723 is long-term and TCHF 660 is short-term

### **13.2 Financial liabilities - Convertible bonds**

In February 2017, Santhera issued senior unsecured 2017/22 convertible bonds in the nominal amount of CHF 60 million. The bonds, listed on the SIX, are interest bearing (5%) with a maximum term of 5 years and are convertible into registered Shares of Santhera with a nominal value of CHF 1 each. The initial conversion price was fixed at CHF 86.4006 and was reset in accordance with the terms of the bond in February 2018 to CHF 64.80. In addition, Santhera may call the convertible bonds at any time on or after the second anniversary of the issue date at par, plus accrued interest, if any, if the volume weighted average price (VWAP) of the Shares is at least 160% of the conversion price. On March 25, 2021 Santhera announced an exchange offer for the 2017/22 convertible bonds due in 2022. The holders of the 2017/22 bonds who accepted the exchange offer received, for each of their 2017/22 bonds, one new bond issued in 2021 with a maturity in 2024 (2021/24 convertible bonds) and 26 shares on exchange. The 2021/24 convertible bonds were offered as consideration for the 2017/21 convertible bonds. Santhera did therefore not receive any cash proceeds for the issue of 2021/24 bonds. The nominal amount of the new convertible bond is CHF 30.3 million. The bonds, listed on the SIX, are interest bearing (7.5%) with a maximum term of 39 months and are convertible into registered Shares of Santhera with a nominal value of CHF 1 each. The initial conversion price is fixed at CHF 3.0029. In addition, Santhera may call the convertible bonds at any time on or after the second anniversary of the issue date at par, plus accrued interest, if any, if the VWAP of the Shares is at least 150% of the conversion price. The convertible bonds are measured at amortized costs applying the effective interest method. As of December 31, 2021, 2021/24 Bonds with an aggregate nominal value of CHF 10.7 million had been converted and the remaining outstanding aggregate principal amount of the 2021/24 Bonds was CHF 19.6 million. The fair value of the bond (Level 1) at December 31, 2021, amounts to CHF 14.3 million. At December 31, 2021, the value of the embedded derivative was CHF 1.1 million. The change in the fair value was recognized in the financial result and amounted in 2021 to CHF 3.8 million. The convertible bonds are measured at amortized costs applying the effective interest method. As of December 31, 2021, the remaining aggregate principal amount of the 2017/22 Bonds was CHF 13.9 million. To the extent that the Company does not repurchase or redeem these 2017/22 Bonds, such 2017/22 Bonds continue to be outstanding and will become due for redemption on February 17, 2022. The fair value of the 2017/22 bond (Level 1) at December 31, 2021 amounts to CHF 14.0 million (December 31, 2020: CHF 18 million).

On October 14, 2021, Santhera issued new senior unsecured private convertible bonds to Highbridge with an aggregate principal amount of CHF 15 million (the "21/24 Private Bonds"). The terms of the Private Convertible Bonds are substantially similar to those of the 2021/24 Bonds, except that the conversion price is CHF 1.76 and that the floor price for purposes of interest payments in shares by the Company is CHF 1.25. The net proceeds from the Private Convertible Bonds will be used to redeem the 2017/22 Bonds remaining amount of CHF 14.0 million on maturity in February 2022. The Private Convertible Bonds are currently not listed. The convertible bonds are measured at amortized costs applying the effective interest method.

As consideration for its commitment to subscribe for New Term Loan Notes, Highbridge received 1.5 million new warrants, each of which is exercisable for one Share at an exercise price of CHF 2.00 at any time until September 22, 2026. These new warrants were issued in combination with the 1.0 million warrants related to the new money tranches for a total of 2.5 million warrants issued to Highbridge.

The embedded financial derivatives (conversion right, reset mechanism and early redemption option) are valued by an independent consultant initially and at period end at fair value, applying a simulation-based valuation approach. The valuation of the embedded derivatives is based on input parameters, classified as Level 3. The simulation is mainly based on the historical volatility of Santhera shares. The period of volatility data used is measured according to the remaining life of the convertible bonds. The volatility used as per December 31, 2021, was 34%, 81% and 64%, respectively for the 17/22 Bond, 21/24 Public Bond and the 21/24 Private Bond. (December 31, 2020: 61%) for the 17/22 Bond.

The embedded conversion right and the reset mechanism are directly related and have the same risk exposure. Therefore, these two derivatives are accounted for as a single instrument (i.e. a compound derivative). Due to the reset mechanism, the compound derivative is not settled for a fixed number of equity and hence classifies as a financial liability.

The Convertible bonds are accounted for at amortized costs. The following table shows the amounts of the convertible bonds as of December 31, 2021 and 2020, respectively.

In CHF thousands	Maturity date	Nominal amount		Carrying amount	
		Dec 31, 2021	Dec 31, 2020	Dec 31, 2021	Dec 31, 2020
2017/2022	February 17, 2022	13,945	60,000	13,880	57,875
2021/2024 public	August 17, 2024	19,568	0	15,387	0
2021/2024 private	August 17, 2024	15,002	0	10,409	0
<b>Total</b>		<b>48,515</b>	<b>60,000</b>	<b>39,676</b>	<b>57,875</b>

Sensitivity analysis:

	December 31, 2021		December 31, 2020	
	Increase/decrease in volatility assumption	Effect on result before taxes in CHF thousands	Increase/decrease in volatility assumption	Effect on result before taxes in CHF thousands
<b>Convertible 17/22 Bonds</b>				
Change in volatility	+5%	0	+5%	0
	-5%	0	-5%	0
<b>Convertible Public 21/24 Bonds</b>				
Change in volatility	+5%	-56	NA	NA
	-5%	219	NA	NA
<b>Convertible Private 21/24 Bonds</b>				
Change in volatility	+5%	-132	NA	NA
	-5%	107	NA	NA
<b>Warrants on Private 21/24 Bonds</b>				
Change in volatility	+5%	-60	NA	NA
	-5%	75	NA	NA

**Changes in liabilities arising from convertible bonds**

In CHF thousands	17/22 Bonds	Noncur- rent De- rivative	21/24 Public Bond	Noncur- rent De- rivative	21/24 Pri- vate Bonds	Noncur- rent De- rivative	Current Derivative Warrants
<b>December 31, 2019</b>	<b>56,154</b>	<b>617</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
Change in fair value of de- rivative financial instru- ments	0	-617	0	0	0	0	0
Effective interest/amor- tized cost calculation	1,721	0	0	0	0	0	0
<b>December 31, 2020</b>	<b>57,875</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
Proceeds from current loan	0	0	0	0	15,002	0	0
Redemption on exchange	-44,845	0	0	0	0	0	0
Repurchased	-1,210	0	0	0	0	0	0
Issue on exchange	0	0	30,270	0	0	0	0
Initial recognition of deriv- ative financial instruments	0	0	-7,693	7,693	-4,849	3,274	1,575
Nominal value of converti- ble bonds converted into shares	0	0	-10,709	0	0	0	0
Derecognition of deriva- tive financial instruments on conversion into shares	0	0	0	-2,720	0	0	0
Change in fair value of de- rivative financial instru- ments	0	0	0	-3,847	0	-717	-585
Effective interest/amor- tized cost calculation	2,060	0	799	0	256	0	0
Amortized cost calculation on converted bonds	0	0	2,720	0	0	0	0
<b>December 31, 2021</b>	<b>13,880</b>	<b>0</b>	<b>15,387</b>	<b>1,126</b>	<b>10,409</b>	<b>2,557</b>	<b>990</b>

## 14 Lease Liabilities

	In CHF thousands	2021	2020
<b>Cost</b>			
<b>At January 1</b>		<b>2,696</b>	<b>3,840</b>
Additions		0	199
Disposals		-115	-259
Remeasurements		0	12
Interest expense		63	95
Payments		-802	-1,166
Exchange differences		-30	-25
<b>At December 31</b>		<b>1,812</b>	<b>2,696</b>
Thereof noncurrent		1,203	1,927
Thereof current		609	769

Expenses relating to short-term leases amounting to TCHF 6 were recognized in the consolidated income statement in 2021 (2020: TCHF 16). The total cash outflow for leases amounts to TCHF 808 in 2021 (2020: TCHF 1,182).

## 15 Trade and Other Payables

	In CHF thousands	2021	2020
Trade payables		2,412	3,803
Other payables (nonfinancial)		2,173	1,912
<b>Total at December 31</b>		<b>4,585</b>	<b>5,715</b>

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



## 16 Accrued Expenses

	In CHF thousands	2021	2020
Development programs		4,029	5,153
Liabilities to employees		2,654	671
Accruals for pricing and reimbursement		17,141	475
Accrued marketing and sales expenses		0	376
Accruals for audit, consulting and other		1,539	862
Accruals for interest expenses		1,155	1,108
<b>Total at December 31</b>		<b>26,518</b>	<b>8,645</b>

### Accrued expenses are shown as

<b>Current</b>	<b>9,710</b>	<b>8,645</b>
<b>Noncurrent</b>	<b>16,808</b>	<b>0</b>
<b>Total at December 31</b>	<b>26,518</b>	<b>8,645</b>

Noncurrent accrued expenses relate to an estimate due to uncertainties and status of negotiations around pricing reimbursement for sales made in France in the periods since 2016, refer to Note 19, section "French Social Security" for further information.

## 17 Current Provisions

	In CHF thousands	2021
January 1,		2,034
Utilization of provision		-1,253
Reversal of provision		-589
<b>Total at December 31</b>		<b>192</b>

Current provisions relate to the organization restructuring of the Group announced in 2020 following discontinuation of Puldysa development.

## 18 Commitments and Contingent Liabilities

### Commitments

#### *Commitments for leases (noncancelable)*

	In CHF thousands	2021	2020
Within 1 year		0	10
<b>Total at December 31</b>		<b>0</b>	<b>10</b>

## Commitments to future payments under license agreements

### *Vamorolone license agreements with Idorsia and ReveraGen*

On September 2, 2020, Santhera announced that it had exercised its license option and acquired worldwide exclusive rights, now also including the major markets Japan and South Korea, for all indications. Santhera's obligations to ReveraGen are a payment of up to USD 7 million, payable in monthly instalments of up to USD 500,000, to fund development including the Phase 2b VISION-DMD study and USD 5 million at the time when FDA supports an NDA filing with Phase 2b 6-month data. Santhera is required to pay to Idorsia and ReveraGen regulatory and commercial milestone payments of up to USD 90 million in the DMD indication and five one-time sales milestone payments of up to USD 155 million in aggregate. Regulatory milestone payments by Santhera to Idorsia and ReveraGen for three additional indications amount to up to USD 205 million in aggregate. Upon commercialization of vamorolone, Santhera has committed to pay tiered royalties ranging from a single-digit percentage to low double-digit percentage in total on the annual net sales of vamorolone to Idorsia and ReveraGen. (See also note 30 Events after the Reporting Date).

### *License agreement with Polyphor*

On February 15, 2018, Santhera announced that it had entered into a license agreement with Polyphor Ltd., Allschwil, Switzerland, for POL6014, a clinical stage selective inhibitor of human neutrophil elastase with the potential to treat cystic fibrosis (CF) and other neutrophilic pulmonary diseases. Under the terms of the agreement, Santhera may be required to make cash payments due to future development, regulatory and sales milestones of up to CHF 121 million (i.e., contingent payments). Consistent with existing licensing agreements, such contingent payments have not been capitalized.

### *Collaboration and license agreement with Takeda*

In September 2013, Santhera announced the execution of a termination and license agreement (TLA) with Takeda Pharmaceutical Company Ltd, Osaka, Japan (**Takeda**) about the compound idebenone. After the discontinuation of Santhera's idebenone program which included Puldysa for the treatment of DMD and Friedreich's Ataxia (FA), the TLA currently only applies to indications other than DMD and FA that can be treated with idebenone. Such other indication is LHON, the commercialization rights of which we have out-licensed to Chiesi.

Under the TLA, Santhera has obtained the right to cross-reference Takeda's idebenone data for regulatory purposes, also in LHON. If Santhera makes use of such cross-reference right in LHON, Takeda is eligible to obtain 10% from licensing and/or sales income generated by Santhera in LHON, capped at EUR 3.0 million. In addition, 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. As consideration, Takeda is eligible to receive up to EUR 1.0 million as a percentage from income generated by Santhera to offset this waiver.

When obtaining approval from the EMA to treat LHON patients, Santhera did not have to cross-reference any Takeda data as it could base its submission on data that had been used by Takeda in its MA submission for Mnesis.

### *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. Due to the discontinuation of the idebenone program, this agreement will be terminated shortly.

### *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 dystrophy (**CMD**). The agreement has been terminated in December 2021.

### *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 (**PPMS**). Under the terms of the agreement, Santhera would have to make certain milestone payments to the NIH not exceeding USD 1.4 million in total. Furthermore, the NIH is eligible to a royalty fee of 3% on net sales and 15% of considerations received in case Santhera sub-licenses the program. This Agreement has been terminated.

### *Contracts for clinical development and other*

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

In an earlier transaction, the Company has agreed with a financial advisor on a contingent transaction fee of USD 2 million that becomes payable at the completion of the next raising of finance with gross proceeds above a defined threshold.

### **Accruals and Contingent liabilities**

Santhera believes that the accruals (see note 17 "Accrued Expenses") are adequately based upon currently available information. However, given the inherent difficulties in estimating liabilities relating to clinical development, variable consideration, regulatory, tax, possible litigation and certain other matters due to uncertainty concerning both the amount and timing of future expenditures, additional costs may be incurred materially beyond the amounts accrued.

### **French Social Security – Reimbursement status and reference price of Raxone in France**

#### *General Background*

In France, since obtaining the marketing authorization for Raxone in 2014, Raxone has been reimbursed by the French Social Security under a so-called autorisation temporaire d'utilisation (ATU) and a so-called post-autorisation temporaire d'utilisation (post-ATU) financing scheme (dispositif pérenne). As a result of a subsequent refusal of the French Ministry for Solidarity and Health to register Raxone on the lists of reimbursed products in France for patients and hospitals in December 2019, applicable rules require that Santhera as the holder of the (post-)ATU refund to the French Social Security the difference between the price at which Raxone was sold under the (post-)ATU and a reference price to be set by the Comité économique des produits de santé (CEPS). Technically, the reference price is based, on the one hand, on the price for future sales first negotiated between the CEPS and the pharmaceutical company and, on the other hand, on the discounts, also negotiated by the same parties as part of the future sale price. The reference price is, by nature a theoretical price since it is calculated by deducting the discounts "which may be due for the following year", from the sale price.

*Free of Charge deliveries of Raxone since August 2021*

When Raxone was officially taken off the list of reimbursed products in 2021, Santhera agreed with the French authorities to provide Raxone to existing and newly diagnosed LHON patients in France free of charge (since August 15, 2021) – and as of the date of these financial statements, Santhera continues to make such deliveries. Such free of charge delivery does not amount to a formal settlement with the French authorities but has been primarily initiated to ensure the continued supply of Raxone to LHON patients in France.

*New Submission for Raxone in LHON*

Based on additional data from post approval studies in LHON Santhera submitted an updated dossier to the Commission de la Transparence (CdT) in 2021 to determine the medical value of Raxone. The CdT ruled in January 2022 inter alia that the service médical rendu (SMR) was now “moderate” (and no longer “insufficient”). The amélioration du service médical rendu (ASMR) was determined to be IV (while earlier on no ASMR was given). Also, the CdT’s opinion stated that the drug which might be used to assess the SMR, ASMR and the place of Raxone in the therapeutic strategy in France was Lumevoq, a gene therapy for the treatment of LHON patients under an early access program.

After having received the CdT’s ruling, Santhera started to negotiate a price for Raxone with the CEPS. Such price will not only apply to future sales of Raxone, but also form the basis to calculate a refund for past sales. Santhera currently expects to obtain a final price later in 2022.

At the pricing stage, the price of the comparator(s) listed in the CdT’s opinion should be referred to by the CEPS as a basis for negotiation. The total treatment cost of Raxone over a period of three years (which reflects the key opinion leaders’ consensus on the treatment duration of LHON patients with Raxone) is significantly lower than the amount charged for the only other available treatment for LHON.

Even though the CdT had concluded that the comparator drug was Lumevoq, the CEPS argued that the price of another drug also still under an ATU could not be taken into consideration as a comparator. Santhera believes that the CEPS’ position on this matter is disputable from a strict legal point of view and as of the date of these financial statements is still discussing this matter with the CEPS as part of the negotiations on the sale and reference price for Raxone in France. As part of these most recent discussions with the CEPS, Santhera, because of the difficulties in identifying a single drug as the comparator drug, has suggested to the CEPS the concept of applying a basket approach with possible comparator drugs and using the pricing of such comparator drugs as a reference price.

*Conclusion*

Based on the most recent communications with the CEPS, management and the board deem it most probable that, because of the difficulties in identifying a single drug as the comparator drug, a basket approach (basket of possible comparator drugs) will eventually be used to determine the reference price, which likely will result in a reference price that is below the ATU price for Raxone in France. As such, Santhera has accrued in total CHF 16.8 million as of December 31, 2021, of which CHF 10.7 million have been recorded as a reduction in revenues (resulting in negative net sales in 2021) and of which CHF 6.1 million have been recorded within marketing and sales expenses in 2021. Because such payments, if they would need to be made, are not expected to be made within the next 12 months, the accrual has been classified as noncurrent. Should Santhera be required to make a significant cash payment, the Group’s financial situation, results of operations and prospects may be materially adversely affected.

## 19 Equity Rights Plans

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

### 19.1 Stock Option Plans

#### Employee Stock Option Plans

In 2021, the Company adopted the Employee Long Term Incentive Plan (**ELTIP 2021**) to provide incentives to the Executive Management and other employees equity participation rights (**Equity Participation Rights**) consisting of a combination of stock options and performance share units (**PSUs**). Each vested stock option entitles the participant to purchase one Share. Unless otherwise determined in the Equity Participation Rights Agreement and subject to the exceptions, 33% of the Equity Participation Rights vest on the first anniversary, the next 33% on the second anniversary and the remaining 34% on the third anniversary of the grant date. Participants may exercise the stock options at any time after vesting until they expire on the tenth anniversary of the grant date, or as otherwise determined in the Equity Participation Rights Agreement. Unless otherwise determined in the Equity Participation Rights Agreement, upon the vesting of PSUs, the applicable number of Shares are delivered to participants following the final assessment of the achievement of the performance targets at the third anniversary of the grant date.

The Company adopted the ESOP 2010 and ESOP 2015 (collectively the **ESOP**) to provide incentives to the Executive Management, employees and consultants helping to ensure their commitment to Santhera over the long-term. Option grants were made periodically at the discretion of the Board or as contractually agreed with employees. The ESOP 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. Under the 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. No further grants will be made under the ESOP as we have our 2021 incentive compensation plans.

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

Number of options						2021
	At January 1	Exercised	Granted	Forfeited	Expired	At December 31
ESOP 2010	25,301	0	0	0	0	25,301
ESOP 2015	218,285	0	0	0	0	218,285
ELTIP 2021	0	0	513,725	-8,750	0	504,975
<b>Total</b>	<b>243,586</b>	<b>0</b>	<b>513,725</b>	<b>8,750</b>	<b>0</b>	<b>748,561</b>

Number of options						2020
	At January 1	Exercised	Granted	Forfeited	Expired	At December 31
ESOP 2010	25,301	0	0	0	0	25,301
ESOP 2015	218,741	0	0	-456	0	218,285
<b>Total</b>	<b>244,042</b>	<b>0</b>	<b>0</b>	<b>-456</b>	<b>0</b>	<b>243,586</b>

**Board Stock Option Plans**

In 2021, the Company switched from an option plan to a restricted shares units for the Board, with effect as from June 1, 2021. Under the BRSP 2021, we grant the members of the Board at least 50% of their annual remuneration, as approved by the general meeting of shareholders of the Company, in restricted Shares (the “Restricted Shares”), valued at their fair market value based on the Share price at the grant date and other factors.

The Company adopted the BSOP 2015 (collectively the **BSOP**) to provide incentives to members of the Board. The BSOP contains the same customary provisions as under the ESOP 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 2015 vested and unvested stock options of Board members leaving the Board in good faith do not expire. No further grants can be made under the BSOP.

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

Number of options						2021
	At January 1	Exercised	Granted	Forfeited	Expired	At December 31
BSOP 2015	13,562	0	0	0	0	13,562
<b>Total</b>	<b>13,562</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>13,562</b>

Number of options						2020
	At January 1	Exercised	Granted	Forfeited	Expired	At December 31
BSOP 2015	13,562	0	0	0	0	13,562
<b>Total</b>	<b>13,562</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>13,562</b>

Since July 1, 2016, no more stock options are available for future grants under the ESOP 2015 and/or the BSOP 2015.

**Number of stock options outstanding and exercisable**

Number of options		2021	2020
<b>Outstanding at January 1</b>		<b>257,148</b>	<b>257,604</b>
Granted		504,975	0
Forfeited		0	-456
<b>Outstanding at December 31</b>		<b>762,123</b>	<b>257,148</b>
<b>Exercisable at December 31</b>		<b>762,123</b>	<b>257,148</b>

The value of stock options granted is recognized as personnel expense over the period Santhera receives services.

**Terms of options outstanding at December 31**

Exercise price range for options (in CHF)	Number outstanding	Weighted average remaining contractual life (years)	2021 Number exercisable	Number outstanding	Weighted average remaining contractual life (years)	2020 Number exercisable
From 1.35 to 2.73	504,975	9.72	-			
from 3.89 to 4.53	20,751	1.85	20,751	20,751	2.82	20,751
at 22.25	4,550	2.53	4,550	4,550	3.50	4,550
at 69.30	12,650	4.31	12,650	12,650	5.25	12,650
from 82.10 to 114.50	219,197	3.77	219,197	219,197	4.63	219,653
<b>Total</b>	<b>762,123</b>	<b>7.76</b>	<b>257,148</b>	<b>257,148</b>	<b>4.50</b>	<b>257,604</b>

## 19.2 Share Appreciation Rights Plans / ELTIP

In 2021, the Company adopted the Employee Long-Term Incentive Plan (the “ELTIP 2021”) to provide incentives to the Executive Management and other employees equity participation rights (“Equity Participation Rights”) consisting of a combination of stock options and performance share units (“PSUs”). Each vested PSU entitles the participant to receive between zero and one Share (the latter in case of 100% target achievement) depending on target achievement, which is generally both time-based and performance-based. These target achievements vary and are based on 1) Vamorolone FDA market authorization in the United States; 2) Vamorolone EMA market authorization; 3) Santhera share price higher than CHF 9.0 for five consecutive trading days; 4) a specific number of patients on Vamorolone in the United States and France; 5) first patient visit on new Vamorolone indications and; 6) first patient visit on new lonodelsetat indications. The Board may determine a target achievement rate in excess of 100%. Unless otherwise determined in the Equity Participation Rights Agreement and subject to the exceptions, 33% of the Equity Participation Rights vest on the first anniversary, the next 33% on the second anniversary and the remaining 34% on the third anniversary of the grant date. Unless otherwise determined in the Equity Participation Rights Agreement, upon the vesting of PSUs, the applicable number of Shares are delivered to participants following the final assessment of the achievement of the performance targets at the third anniversary of the grant date.

In June 2021, the Company adopted the RSU (“restricted share units”) 2021 for the members of the Board, with effect as from June 1, 2021. Under the BRSP 2021, members of the Board are granted at least 50% of their annual remuneration, as approved by the general meeting of shareholders of the Company, in restricted Shares (the “Restricted Shares”), valued at their fair market value based on the Share price at the grant date and other factors. Under the BRSP 2021, Restricted Shares are granted by entering into a restricted shares agreement (the “Restricted Shares Agreement”) between the Company and the participant. Annual grants are made as of the day following the Company’s annual general meeting of shareholders (“AGM”). In case of a termination of a participant’s Board mandate, non-vested Restricted Shares vest pro rata based upon the service period of the participant. If the participant has committed a severe breach of his duties or if he voluntarily resigns during the (one-year) term of his mandate, all of his Restricted Shares are forfeited (unless the Board decides otherwise). In case of a termination by reason of disability, unvested Restricted Shares continue to vest after termination of the mandate. In case of termination by reason of death, unvested Restricted Shares vest immediately. Any existing period during which the transferability of the Restricted Shares is limited will continue to run.

Starting with July 1, 2016, Santhera switched from stock option plans to Share Appreciation Rights Plans (**SARP**). It introduced Board Share Appreciation Plans (**BSARP**), the BSARP 2016, the BSARP 2017, for the members of its Board and Employee Share Appreciation Rights Plans (**ESARP**), the ESARP 2016, ESARP 2017 ESARP 2018 and the ESARP 2019, for the Executive Management, employees and consultants. Share appreciation rights (**SAR**) grants are made periodically at the discretion of the Board or as contractually agreed with employees. The SARP contain customary provisions in respect of the adjustment or cancellation of SARs upon termination of employment, retirement, death, disability and certain corporate transactions. All SARPs are administered under the responsibility of the Board. No new grants were made in 2021 under SARS plans.



*SAR / ELTIP outstanding, exercised, forfeited or expired under SAR / ELTIP*

Number of SAR and RSU						2021
	At January 1	Exercised	Granted	Forfeited	Expired	At December 31
ESARP 2016	43,312	0	0	0	0	43,312
BSARP 2017	322,055	0	0	0	0	322,055
ESARP 2017	546,193	0	0	0	0	546,193
ESARP 2019	1,757,746	0	0	-335,600	0	1,422,146
RSU 2021	0	0	356,250	0	0	356,250
PSU 2021	0	0	2,276,725	-80,750	0	2,195,975
<b>Total</b>	<b>2,669,306</b>	<b>0</b>	<b>2,632,975</b>	<b>-416,350</b>	<b>0</b>	<b>4,885,931</b>

Number of SARs						2020
	At January 1	Exercised	Granted	Forfeited	Expired	At December 31
ESARP 2016	43,312	0	0	0	0	43,312
BSARP 2017	156,723	0	165,332	0	0	322,055
ESARP 2017	560,616	0	0	-14,423	0	546,193
ESARP 2018	18,564	0	0	-18,564	0	0
ESARP 2019	978,299	0	1,002,135	-222,688	0	1,757,746
<b>Total</b>	<b>1,757,514</b>	<b>0</b>	<b>1,167,467</b>	<b>-255,675</b>	<b>0</b>	<b>2,669,306</b>

## Fair value calculations for granted instruments

The fair value of a granted instrument is determined at each grant date by using various modeling (in 2021 Monte Carlo and in 2020 the Hull-White pricing model). The calculation of the value was performed by applying the following parameters:

	2021	2020
Market price of stock	CHF 1.26 to 4.95	CHF 2.55 to 12.58
Exercise prices	CHF 1.35 to 2.73	CHF 7.22 to 8.27
Weighted average fair value granted	CHF 0.80 to 1.33	CHF 3.29
Expected volatility <sup>1</sup>	74% to 77%	40% to 41%
CHF risk-free interest rate	-0.30% p.a.	0.0% p.a.
SAR term	3 years	10 years
Expected dividend yield	0%	0%

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

**Number of SAR / ELTIP outstanding and exercisable**

	Number of SAR	2021	2020
<b>Outstanding at January 1</b>		<b>2,669,306</b>	<b>1,757,514</b>
Granted		2,552,225	1,167,467
Exercised		0	0
Forfeited		-335,600	-255,675
Expired		0	0
<b>Outstanding at December 31</b>		<b>4,885,931</b>	<b>2,669,306</b>
<b>Exercisable at December 31</b>		<b>1,589,662</b>	<b>1,048,192</b>

**Terms of PSU/RSU/SAR outstanding at December 31**

Exercise price range (in CHF)	Number outstanding	Weighted average re-maining contractual life (years)	2021 Number exercisable	Number outstanding	Weighted average re-maining contractual life (years)	2020 Number exercisable
From 0.00	2,552,225	2.36	0	0	0	0
from 6.61 to 18.90	1,731,995	7.94	1,072,653	2,067,595	8.87	474,811
from 36.70 to 38.70	345,719	6.06	345,719	345,719	6.98	325,241
from 51.75 to 54.85	228,720	5.07	228,720	228,720	5.99	223,368
from 76.50 to 77.80	27,272	5.18	27,272	27,272	6.10	25,272
<b>Total</b>	<b>4,885,931</b>	<b>4.74</b>	<b>1,674,364</b>	<b>2,669,306</b>	<b>8.35</b>	<b>1,048,192</b>

The value of all instruments is recognized as personnel expense over the period Santhera receives services. In 2021, total personnel expenses of TCHF 2,465 (TCHF 420 related to Development, TCHF 128 related to M&S and TCHF 1,917 to G&A) and in 2020, such grants resulted in personnel expenses of TCHF 3,017 (TCHF 969 related to Development, TCHF 688 related to M&S and TCHF 1,360 to G&A).

## 20 Segment and Geographic Information

### Segment information

Santhera operates in one operating segment, the development and commercialization of specialty niche products for the treatment of neuromuscular and pulmonary diseases. The Board, the Executive Management and senior managers, being the CODM, assess the reporting data and allocate resources as one segment on a consolidated level according to the operating expenses by function. Santhera generates revenue from sales of Raxone for the treatment of LHON, out-licensing transactions and net sales to licensing partner. Geographic revenue information is based on location of the customer.

### Geographic information

#### *Revenue from contracts with customers*

	In CHF thousands	2021	2020
<b>Net sales</b>			
EU		-4,963	11,245
Rest of the world		0	7
Subtotal net sales		-4,963	11,252
<b>Revenue from out-licensing transactions</b>			
EU		1,126	1,597
<b>Net sales to licensing partner</b>			
EU		2,242	2,159
<b>Total</b>		<b>-1,595</b>	<b>15,008</b>

The negative net sales in the EU in 2021 are attributable to a CHF 10.8 million adjustment to net sales recorded in 2021 due to uncertainties and status of negotiations around pricing reimbursement in France. Based on the agreement with the authorities in France, Santhera has supplied Raxone free of charge from August 2021 following its removal from the list of reimbursed drugs. Reimbursement discussions are ongoing, refer to Note 18, section "French Social Security-Reimbursement status and reference price of Raxone in France" for further information.

In 2021, before this adjustment net sales revenue from out-licensing transactions and net sales to licensing partner amounted to CHF 9.1 million with its product Raxone only (2020: CHF 15.0 million). Raxone was sold in 5 European countries, with the majority of sales reached in France (2020: 24 European countries, with the majority of sales reached in France and Germany).

Refer to note 22 Transaction with Chiesi for further information on revenue.

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

	In CHF thousands	2021	2020
Switzerland		65,884	69,444
North America		36	131
<b>Total</b>		<b>65,920</b>	<b>69,575</b>

## 21 Transaction with Chiesi

In 2019, Santhera entered into a licensing transaction with Chiesi Farmaceutici S.p.A., Parma, Italy (Chiesi), whereby Chiesi in-licensed Raxone for the treatment of Leber's hereditary optic neuropathy (LHON). As consideration Santhera

- received a non-refundable upfront payment of EUR 44 million for granting a license to sell Raxone for the treatment of LHON and any other potential ophthalmological indications for all territories worldwide except the US and Canada. The parties also agreed that Santhera will continue to commercialize Raxone for LHON in France until ongoing pricing and reimbursement negotiations have been finalized; and
- is entitled to contingent variable near- to mid-term milestone payments upon reaching certain milestones of up to EUR 49 million.

Santhera assessed whether the goods or services promised in the contract are distinct or represent a series of distinct goods or services and are to be accounted for as separate performance obligations. Santhera identified performance obligations which were fulfilled either with the closing of the transaction in August 2019 (point in time) or over a period of time.

- a) Performance obligations recognized at a point in time: Santhera grants a license to Chiesi for the exploitation of Raxone in the agreed territory, as well as an option for the exploitation of Raxone in France upon certain conditions.
- b) Performance obligations recognized over a period of time: Santhera is responsible for the completion of ongoing post authorization measures (PAMs) which were completed during 2021 (in connection with the centralized European Marketing Authorization granted in 2015). Additionally, Santhera provides Chiesi with assistance services regarding market access.

The non-refundable upfront payment of EUR 44 million was analyzed and allocated to the different performance obligations based on stand-alone selling prices, CHF 46.4 million of the transaction price was recognized when the out-licensing transaction was entered into in 2019. Additional variable consideration in the amount of EUR 49 million depends on certain conditions and milestones, which need to be achieved and which based on the constraint guidance in IFRS 15 have not been included in the transaction price at contract inception and at year end.

An amount of CHF 2.7 million is recognized over time and disclosed as contract liability (current and noncurrent) for services, which are carried out in conjunction of the PAMs and market assistance services. As at December 31, 2021 nil (2020: CHF 1.1 million) was included in current contract liabilities to be recognized in future periods. During the year to 31 December 2021, Santhera recognized revenue for such services in the amount of CHF 1.1 million (2020: 2.2 million). The parties also agreed that Chiesi procures from Santhera the manufactured packs of Raxone for selling in the licensed territory (CHF 2.6 million net sales to licensing partner (2020: CHF 2.2 million)).

## 22 Operating Expenses by Nature

	In CHF thousands	2021	2020
External development expenses		-21,382	-25,963
Patent and license expenses		-518	-500
Marketing expenses		-8,513	-3,204
Employee expenses		-15,722	-19,798
<i>Of which non-cash-relevant expenses for equity rights plans</i>		-2,761	-3,029
Other administrative expenses		-1,723	-4,308
Depreciation, impairment and amortization		-3,724	-4,112
Facility related expenses		-146	-241
Lease expenses (offices)		-44	-16
Other operating expenses		-100	-205
<b>Total operating expenses</b>		<b>-51,872</b>	<b>-58,347</b>

## 23 Employee Expenses and Benefits

### Employee expenses

	In CHF thousands	2021	2020
Wages and salaries		-10,285	-13,608
Social security and other personnel-related expenses <sup>1</sup>		-2,676	-3,161
<i>Of which non-cash-relevant adjustments of pension fund</i>		-507	2,106
Expenses for equity rights plans		-2,761	-3,029
<b>Total employee costs</b>		<b>-15,722</b>	<b>-19,798</b>

<b>Average number of full-time equivalents<sup>2</sup></b>	<b>47.1</b>	<b>101.2</b>
<b>Full-time equivalents at year-end</b>	<b>39.4</b>	<b>86.0</b>
<b>Total headcount at year-end</b>	<b>43</b>	<b>91</b>

<sup>1</sup> Thereof TCHF 60 were expensed for defined contribution plans in North America and some European countries (2020: TCHF 283).

<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.

## 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, Pratteln, and Santhera Pharmaceuticals (Schweiz) AG, Pratteln, both in 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, since January 1, 2018, Santhera has an agreement with PKG Pensionskasse (**PKG**). PKG is responsible for the governance of the plan; its board is composed of an equal number of representatives from the employers and employees chosen from all affiliated companies. PKG has set up investment guidelines, defining in particular the strategic allocation with margins. PKG has insured the risks of disability and death before retirement with PKRück AG, Vaduz, Fürstentum Liechtenstein. 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**).

In November 2020 a restructuring was initiated, which led to a curtailment. Additionally, PKG announced in late 2020 a plan amendment (decrease of the conversion factors) which also triggered the calculation of past service costs (income).

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

### *Changes in defined benefit obligations*

	In CHF thousands	2021	2020
<b>Present value of obligation, January 1</b>		<b>22,831</b>	<b>26,358</b>
Current employer service cost		1,355	2,500
Past service cost (plan amendment)		0	-1,216
Past service cost (curtailment due to restructuring)		0	-2,106
Interest cost		20	92
Employee contributions		569	875
Benefits paid / transfer payments		-5,687	-2,667
Insurance premiums		-136	-204
Remeasurements <sup>1</sup>		-1,460	-801
<b>Present value of obligation, December 31</b>		<b>17,492</b>	<b>22,831</b>

<sup>1</sup> Details of remeasurements:

	In CHF thousands	2021	2020
Effect of changes in demographic assumptions <sup>1</sup>		-814	0
Actuarial gain/loss due to changes in financial assumptions		-237	1,111
Actuarial gain/loss due to experience adjustments		-409	-1,912
<b>Subtotal gain/loss</b>		<b>-1,460</b>	<b>-801</b>
Return/loss on plan assets (excluding interest income)		-424	-39
<b>Total remeasurements in other comprehensive income gain/loss</b>		<b>-1,883</b>	<b>-840</b>

<sup>1</sup> Demographic assumptions changed due to increase in lump sum probabilities and reduction of disability probabilities in 2021.

*Changes in plan assets*

	In CHF thousands	2021	2020
<b>Fair value of assets, January 1</b>		<b>16,661</b>	<b>17,242</b>
Interest income on assets		15	64
Employer contributions		853	1,312
Employee contributions		569	875
Benefits paid/transfer payments		-5,687	-2,667
Insurance premiums		-136	-204
Remeasurements (return/loss on plan assets (excluding interest income))		423	39
<b>Fair value of assets, December 31</b>		<b>12,698</b>	<b>16,661</b>

*Net defined benefit asset/obligation*

	In CHF thousands	2021	2020
Present value of obligation, December 31		17,492	22,831
Fair value of assets, December 31		12,699	16,661
<b>Net defined asset/obligation</b>		<b>-4,794</b>	<b>-6,170</b>

*Asset allocation*

	In CHF thousands	2021	2020
Cash		140	167
Debt instruments		4,127	7,664
Equity instruments		4,203	4,948
Property		2,412	3,149
Others		1,816	733
<b>Total value of assets</b>		<b>12,698</b>	<b>16,661</b>

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

	In %	2021	2020
Discount rate		0.2	0.1
Disability probabilities		80.0	80.0
Lump sum probabilities		30.0	30.0
Expected future salary increases		1.5	1.5

*Sensitivity analysis for 2021:*

In CHF thousands	Defined benefit obligation		Gross (net) service cost	
	Increase assumption	Decrease assumption	Increase assumption	Decrease assumption
Discount rate +/-0.25%	-566	605	-64	68
Salary increase +0.25%	105	-	16	-
Life expectancy +1 year	352	-	27	-

*Sensitivity analysis for 2020:*

In CHF thousands	Defined benefit obligation		Gross (net) service cost	
	Increase assumption	Decrease assumption	Increase assumption	Decrease assumption
Discount rate +/-0.25%	-1,035	1,087	-226	-64
Salary increase +0.25%	157	-	-88	-
Life expectancy +1 year	434	-	-118	-

*Mortality rate:*

	2021	2020
Life expectancy at age 65 (in years)		
Male	22.7	22.8
Female	24.5	24.9

The expected employer contributions for fiscal year 2022 amount to approximately TCHF 874 (2021: TCHF 966). Benefit obligations of pensioners amounted to TCHF 1,811 at December 31, 2021 (2020: TCHF 961). The duration of the plan liabilities calculated is 16.6 years as of December 31, 2021 (2020: 18.6 years).

**24 Financial Income/Expenses****Financial income**

	In CHF thousands	2021	2020
Interests on cash and cash equivalents		1	3
Realized and unrealized foreign exchange gains		438	1,052
Change in fair value of financial derivative instruments		9,023	0
Realized gain on exchange of convertible bonds		13,439	0
<b>Total</b>		<b>22,901</b>	<b>1,055</b>



**Financial expenses**

	In CHF thousands	2021	2020
Interest expenses		-16,368	-6,796
Interest expenses on lease liabilities		-55	-95
Change in fair value of financial derivative instruments		-367	-492
Transaction costs of financial instruments		-3,439	-8,256
Realized and unrealized foreign exchange losses		-501	-780
<b>Total</b>		<b>-20,730</b>	<b>-15,435</b>

**25 Income Taxes**

	In CHF thousands	2021	2020
Current income tax income/expense		-62	7
Deferred tax income/expense		-747	-210
<b>Total</b>		<b>-809</b>	<b>-203</b>

The following is a theoretical reconciliation of tax expense and the accounting profit multiplied by expected income tax rate of principal:

	In CHF thousands	2021	2020
Result before taxes		-55,526	-67,456
Tax expense/income at expected group tax rate of 13.45% (2020: 13.45%)		7,468	9,072
Effect of tax rate difference group versus local		81	-725
Effect of nondeductible expenses		-691	-417
Utilization of previously unrecognized tax losses		13	41
Unrecognized deferred taxes		-7,680	-8'174
<b>Effective tax income/expense</b>		<b>-809</b>	<b>-203</b>

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.

## 26 Net Result 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).

	2021	2020
Net result attributable to shareholders (in TCHF)	-55,526	-67,659
Weighted average number of shares issued and outstanding	34,169,858	13,315,912
<b>Basic and diluted net result per share (in CHF)</b>	<b>-1.62</b>	<b>-5.08</b>

Basic and diluted net result per share is based on the weighted average number of Shares issued and outstanding and excludes Shares to be issued upon the future exercise of equity rights and warrants and upon conversion of the convertible bonds, as they would be anti-dilutive. In case Santhera shows a profit in the future, equity rights, warrants, and convertible bonds upon conversion may have a dilutive effect on the net profit per Share and will need to be considered for the purpose of this calculation.

## 27 Related Party Transactions

### Board and Executive Management compensation

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

	In CHF thousands	2021	2020
Compensation (wages, salaries, allowances)		1,783	2,147
Post-employment benefits (pension fund and defined benefit contributions)		513	602
Share-based payment expenses (fair value according to IFRS 2)		2,391	1,303
<b>Total</b>		<b>4,687</b>	<b>4,052</b>

#### *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 2021, no stock options were exercised by members of the Board (2020: no stock options exercised). During 2021, no stock options were exercised by the Executive Management (2020: no stock options exercised).

## 28 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 limit the Group to engage in money market deposits or similar instruments with a maturity beyond 6 months.

### Foreign exchange rate risk

Santhera holds cash amounts in four major currencies CHF, EUR, USD and GBP to cover the majority of future expected expenses. 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>2021</b>	+5%	-12
	-5%	+12
<b>2020</b>	+5%	-2
	-5%	+2

### 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 holds its cash on deposit/current accounts or invests cash through deposits in line with its treasury guidelines to follow its financial needs over time.

The following calculation 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 of the end of 2021, variances of +/-50 basis points were calculated, resulting in fluctuations of +/-TCHF 106 before tax (end of 2020: +/-50 basis points resulting in fluctuations of +/-TCHF 62 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. No investment or contract with any single counterparty, except cash on deposit subject to the criteria above, comprises more than 30% 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. Santhera estimates its expected credit losses (ECL) based on default probabilities and the ageing of outstanding invoices.

### Liquidity risk

Prudent liquidity risk management implies maintaining sufficient cash and cash equivalents. Currently, the Company is financed through equity and convertible bonds (see note 13 “Financial Liabilities”). 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 for financial liabilities*

<b>Year ended December 31, 2021</b> In CHF thousands	On demand	Less than 3 months	3 to 12 months	1 to 5 years	Total	Book value
Convertible bonds <sup>1</sup>	0	15,590	1,296	39,748	56,634	39,676
Exchangeable notes <sup>1</sup>	0	2,000	0	0	2,000	1,488
Trade payables	0	2,412	0	0	2,412	2,412
Accrued expenses	0	9,710	0	16,808	26,518	26,518
Lease liabilities	0	186	550	1,251	1,987	1,812
<b>Total</b>	<b>0</b>	<b>29,898</b>	<b>1,846</b>	<b>57,807</b>	<b>89,551</b>	<b>81,006</b>

<b>Year ended December 31, 2020</b> In CHF thousands	On demand	Less than 3 months	3 to 12 months	1 to 5 years	Total	Book value
Convertible bonds	0	1,500	1,500	61,500	64,500	57,875
Exchangeable notes <sup>1</sup>		750	10,000		10,750	10,595
Trade payables	0	3,803	0	0	3,803	3,803
Accrued expenses	0	8,645	0	0	8,645	8,645
Lease liabilities	0	214	617	2,004	2,835	2,696
<b>Total</b>	<b>0</b>	<b>14,912</b>	<b>12,117</b>	<b>63,504</b>	<b>90,533</b>	<b>83,614</b>

<sup>1</sup> Part of these amounts may be settled in shares subject to certain conditions. For settlement conditions refer to note 13 “Financial Liabilities”.

## Categories of financial instruments

Year ended December 31, 2021 (IFRS 9 measurement categories) In CHF thousands	Book value	Financial as- sets at amor- tized cost	Other liabilities at amortized cost	At fair value through profit or loss
<b>Assets</b>				
Financial assets long-term	468	468	0	0
Trade receivables	962	962	0	0
Cash and cash equivalents	21,208	21,208	0	0
<b>Total</b>	<b>22,638</b>	<b>22,638</b>	<b>0</b>	<b>0</b>
<b>Liabilities</b>				
Convertible bonds	39,676	0	39,676	0
Exchangeable notes	1,488	0	1,488	0
Derivative financial instruments	4,085	0	0	4,085
Warrant liabilities	6,373		0	6,373
Noncurrent lease liabilities <sup>1</sup>	1,203	0	1,203	0
Trade payables	2,412	0	2,412	0
Accrued expenses	26,518	0	26,518	0
Current lease liabilities <sup>1</sup>	609	0	609	0
<b>Total</b>	<b>82,364</b>	<b>0</b>	<b>71,906</b>	<b>10,458</b>
<b>Year ended December 31, 2020 (IFRS 9 measurement categories) In CHF thousands</b>	<b>Book value</b>	<b>Financial assets at amortized cost</b>	<b>Other liabilities at amortized cost</b>	<b>At fair value through profit or loss</b>
<b>Assets</b>				
Financial assets long-term	552	552	0	0
Trade receivables	2,323	2,323	0	0
Cash and cash equivalents	12,411	12,411	0	0
<b>Total</b>	<b>15,286</b>	<b>15,286</b>	<b>0</b>	<b>0</b>
<b>Liabilities</b>				
Convertible bonds	57,875	0	57,875	0
Exchangeable notes	10,595	0	10,595	0
Derivative financial instruments	125	0	0	125
Noncurrent lease liabilities <sup>1</sup>	1,927	0	1,927	0
Trade payables	3,803	0	3,803	0
Accrued expenses	8,645	0	8,645	0
Current lease liabilities <sup>1</sup>	769	0	769	0
<b>Total</b>	<b>83,739</b>	<b>0</b>	<b>83,614</b>	<b>125</b>

<sup>1</sup> Measured in accordance with IFRS 16.

## 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 only one marketed product, 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, private placements in 2008, 2014, 2015 and 2018, 2019, 2021, SEDA (Standby Equity Distribution Agreement), the sale of Shares by an independent broker, convertible bonds, exchangeable notes as well as funds generated through product sales and revenue from licensing (Chiesi) enabled the Group to be adequately financed.

There were no changes in in goals and policies of the treasury management.

## 29 Events after the Reporting Date

On January 4, 2022 the Company entered into an exclusive license agreement with Sperogenix Therapeutics, a China-based company specializing in orphan diseases. Under this agreement, Sperogenix will in-license vamorolone for rare disease indications for a total consideration of up to USD 124 million, including a double-digit upfront cash compensation and DMD-related U.S.-regulatory milestone payments amounting to a combined USD 20 million, (of which USD 12 million has been received to date) as well as further double-digit royalties on net sales.

In March 2022 the Company increased its issued capital by issuing 3,100,000 treasury shares from authorized capital and a further issuance of 15,500,000 treasury shares in an ordinary capital increase, in order to support future financing activities.

On June 2, 2022 the Company entered into an amendment to the timing of an upcoming milestone payment to partner ReveraGen, thereby reducing near-term financial obligations of the Company by CHF 20 million. The Company also upsized its existing financing arrangement with certain funds managed by Highbridge Capital Management, LLC (Highbridge) which provides up to CHF 40 million of additional financing including the first tranche of CHF 20 million that was drawn on June 3, 2022, of which CHF 8.5 million will be used to refinance currently outstanding exchangeable notes. Santhera expects the combination of these events to extend its liquidity runway into Q1-2023 or up to approval of vamorolone in the U.S. which, subject to priority review being granted, is expected in Q1-2023.



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To the General Meeting of  
Santhera Pharmaceuticals Holding Ltd, Pratteln

Basle, June 9, 2022

## Statutory auditor's report on the audit of the consolidated financial statements



### Opinion

We have audited the consolidated financial statements of Santhera Pharmaceuticals Holding Ltd and its subsidiaries (the Group), which comprise the consolidated statement of financial position as at 31 December 2021 and the consolidated statement of income, consolidated statement of comprehensive income, consolidated statement of changes in equity and consolidated statement of cash flows for the year then ended, and notes to the consolidated financial statements, including a summary of significant accounting policies.

In our opinion, the consolidated financial statements (pages 26 to 78) give a true and fair view of the consolidated financial position of the Group as at 31 December 2021, and its consolidated financial performance and its consolidated cash flows for the year then ended in accordance with International Financial Reporting Standards (IFRS) and comply with Swiss law.



### Basis for opinion

We conducted our audit in accordance with Swiss law, International Standards on Auditing (ISAs) and Swiss Auditing Standards. Our responsibilities under those provisions and standards are further described in the Auditor's Responsibilities for the Audit of the Consolidated Financial Statements section of our report.

We are independent of the Group in accordance with the provisions of Swiss law and the requirements of the Swiss audit profession, as well as the *International Code of Ethics for Professional Accountants (including International Independence Standards) of the International Ethics Standards Board for Accountants (IESBA Code)* and we have fulfilled our other ethical responsibilities in accordance with these requirements.

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



### Material uncertainty related to going concern

We draw attention to note 2 of the consolidated financial statements, which indicates the existence of a material uncertainty which casts significant doubt about the Group's ability to continue as a going concern in connection with the ability to raise additional funds. This fact together with other matters disclosed in note 2 indicates that a material uncertainty exists that may cast significant doubt about the Group's ability to continue as a going concern. Our conclusion is not modified in respect of this matter.



### Key audit matters

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the consolidated financial statements of the current period. In addition to the matters described in the Material uncertainty related to going concern section of our report, we have determined the matters described below to be the key audit matters to be communicated in our report. These matters were addressed in the context of our audit of the consolidated financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters. For each matter below, our description of how our audit addressed the matter is provided in that context.

We have fulfilled the responsibilities described in the *Auditor's responsibilities for the audit of the consolidated financial statements* section of our report, including in relation to these matters. Accordingly, our audit included the performance of procedures designed to respond to our assessment of the risks of material misstatement of the consolidated financial statements. The results of our audit procedures, including the procedures performed to address the matters below, provide the basis for our audit opinion on the consolidated financial statements.

### Accounting treatment and valuation of financing transactions

**Area of focus** During 2021, under the financing agreement with Highbridge, the Group issued exchangeable notes in several tranches amounting to CHF 22.0 million in total, of which CHF 20.8 million was converted into equity as of 31 December 2021. The outstanding liability for exchangeable notes as of 31 December 2021 amounted to CHF 1.5 million.

In May 2021, the Group completed a convertible bond exchange process whereby the public 2017 / 2022 convertible bond of CHF 60.0 million nominal value was partially exchanged, effectively resulting in two separate public bonds – with the one bond being a CHF 15.2 million remainder portion of the original bond (not exchanged and maturing in February 2022), and the other bond being a new convertible bond of CHF 30.3 million in nominal value maturing in August 2024. The Group recorded a net gain of CHF 13.4 million in connection with the exchange. In addition, in September 2021, the Group issued a private convertible bond to Highbridge at a nominal value of CHF 15.0 million. As of 31 December 2021, the carrying amount of the private and the two public bonds amounted to CHF 39.7 million and the value of the related derivatives amounted to CHF 4.6 million. Further, to cover the amendment and commitment fees for financing transactions, including the equity injection of CHF 20.3 million, the Group issued a total of 9'819'807 warrants valued at CHF 6.4 million as of 31 December 2021.

These financing transactions are considered a key audit matter based on the magnitude of the transaction values, the complexity of the accounting treatment and the inherent judgment in the valuation of level 3 fair value financial instruments.

Refer to note 2 "Summary of Significant Accounting Policies", note 3 "Critical Accounting Estimates, Assumptions and Judgments", and note 13 "Financial liabilities".



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**Our audit response** We analyzed the underlying contractual agreements and the accounting position papers prepared by management and management specialists. We evaluated the appropriateness of the accounting treatment under the requirements of IAS 32 and IFRS 9. We assessed the valuation approach and the reasonableness of the assumptions applied to determine the value of the financial instruments. We further evaluated sensitivities in the valuation of the warrants and the derivatives resulting from changes to key assumptions applied as well as the different presentation and disclosure aspects.

Our audit procedures did not lead to any reservations regarding the accounting for these financing transactions in 2021.

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**Impairment assessment of intangible assets not yet available for use**

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**Areas of focus** The Group has capitalized intangible assets not yet available for use in the amount of CHF 53.4 million. Based on the requirements of IAS 36, such intangible assets need to be tested for impairment at least annually.

The impairment assessment of the intangible assets not yet available for use is a key audit matter based on the magnitude of the balances and the inherent judgement in the respective model and assumptions used as part of management's impairment assessment, especially those related to the probabilities of future success (e.g., probability to obtain regulatory approval), the timing and magnitude of future cash flows and to the determination of the respective discount rate.

*Refer to note 2 "Summary of Significant Accounting Policies", note 3 "Critical Accounting Estimates, Assumptions and Judgments", and note 7 "Impairment Test for Intangible Assets".*

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**Our audit response** We evaluated the Group's valuation model for the intangible assets not yet available for use and analyzed the underlying key assumptions and discount rates, including risk adjustments for the probabilities of development success. We assessed the assumptions regarding future revenues and margins, and we evaluated sensitivity in the valuation resulting from changes to the key assumptions applied. With respect to the discount rates applied, we evaluated the reasonableness of the discount rates determined by management by assessing the cost of capital for the Group and comparable organizations, as well as considering territory specific factors.

Our audit procedures did not lead to any reservations regarding the measurement of intangible assets not yet available for use.

### Reimbursement status and reference price of Raxone in France

**Areas of focus** Raxone for the treatment of patients with Leber's hereditary optic neuropathy (LHON) historically was reimbursed by the French Social Security under a so-called *autorisation temporaire d'utilisation (ATU)* and a so-called *post-autorisation temporaire d'utilisation* (post-ATU) financing scheme. However, because Raxone did not get registered on the lists of reimbursed products in France, Santhera may need to refund to the French Social Security the difference between the price at which Santhera sold Raxone in the past and a reference price to be set by the Comité économique des produits de santé (CEPS).

In 2021 there was a decision that Raxone would be officially taken off the list of reimbursed products, as a result of which Santhera decided to provide Raxone to LHON patients in France free of charge to ensure the continued supply of Raxone to LHON patients in France. Further, in 2021 and 2022, Santhera had further communications with the CEPS to try to identify a comparator drug. Several different comparator drugs have been suggested by both parties, with the pricing of some of these drugs being higher than the price at which Santhera sold Raxone in France in the past, and others with prices that are lower.

Despite several rounds of communication between Santhera and the CEPS, no comparator drug has yet been determined. Santhera is of the view that due the difficulty identifying a single comparator drug, the final reference price will likely be based on a so-called basket approach (basket of possible comparator drugs). Based on such basket, and a basket reference price that is expected to be less than the price that Raxone has been sold at in France in the past, the Group has recorded a liability of CHF 16.8 million as of 31 December 2021.

*Refer to note 3 "Critical Accounting Estimates, Assumptions and Judgments", and note 18 "Commitments and Contingent Liabilities".*

**Our audit response** We obtained copies of the communication between the Group and the CEPS and the Commission de la Transparence (CdT) in 2021 and 2022 up to the date of our auditor's report, to assess the status of the discussions, including the likelihood of a comparator drug being identified. We obtained letters from both the internal and external legal counsel to understand the facts and reimbursement process in France. Additionally, we involved our internal specialist to confirm our understanding of the pricing and regulatory processes in France and asked for their assessment of the situation as well as the likelihood of a comparator drug being identified, and a reference price being set.

Further, we evaluated the Group's determination of the liability (presented within accrued expenses) and analyzed the underlying key assumptions, including an assessment of the drugs included in the basket, both in terms of completeness and the pricing of such drugs.

Our audit procedures did not lead to any reservations regarding the accounting and disclosure of such liability as of 31 December 2021.



### **Other information in the annual report**

The Board of Directors is responsible for the other information in the annual report. The other information comprises all information included in the annual report, but does not include the consolidated financial statements, the stand-alone financial statements, the compensation report and our auditor's reports thereon.

Our opinion on the consolidated financial statements does not cover the other information in the annual report and we do not express any form of assurance conclusion thereon.

In connection with our audit of the consolidated financial statements, our responsibility is to read the other information in the annual report and, in doing so, consider whether the other information is materially inconsistent with the consolidated financial statements or our knowledge obtained in the audit, or otherwise appears to be materially misstated. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.



### **Responsibility of the Board of Directors for the consolidated financial statements**

The Board of Directors is responsible for the preparation of the consolidated financial statements that give a true and fair view in accordance with IFRS and the provisions of Swiss law, and for such internal control as the Board of Directors determines is necessary to enable the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the consolidated financial statements, the Board of Directors is responsible for assessing the Group's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the Board of Directors either intends to liquidate the Group or to cease operations, or has no realistic alternative but to do so.



### **Auditor's responsibilities for the audit of the consolidated financial statements**

Our objectives are to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with Swiss law, ISAs and Swiss Auditing Standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these consolidated financial statements.

A further description of our responsibilities for the audit of the consolidated financial statements is located at the website of EXPERTsuisse: <http://www.expertsuisse.ch/en/audit-report-for-public-companies>. This description forms part of our auditor's report.



**Report on other legal and regulatory requirements**

In accordance with article 728a para. 1 item 3 CO and the 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/ Frederik Schmachtenberg  
Licensed audit expert  
(Auditor in charge)

/s/ Diana Vejina  
ACCA

# Statutory Financial Statements of Santhera Pharmaceuticals Holding AG

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## Balance Sheet

	As of December 31, in CHF thousands	Notes	2021	2020
<b>Assets</b>				
Cash and cash equivalents			6,441	6,625
Other receivables from third parties			77	76
Other receivables from shareholdings			214	189
Prepaid expenses and accrued income			8	5
Loans to shareholdings			8,936	0
<b>Current assets</b>			<b>15,676</b>	<b>6,895</b>
Loans to shareholdings		3.1	161,904	142,466
Investments in shareholdings		3.2	404	404
<b>Noncurrent assets</b>			<b>162,308</b>	<b>142,870</b>
<b>Total assets</b>			<b>177,984</b>	<b>149,765</b>
<b>Liabilities and equity</b>				
Trade accounts payable to third parties			247	226
Other accounts payable to third parties			8	44
Other short-term liabilities			1,271	0
Accrued expenses			1,743	1,660
Senior unsecured convertible bonds <sup>2</sup>			13,945	0
Senior unsecured exchangeable notes <sup>1</sup>		2	0	10,000
<b>Current liabilities</b>			<b>17,214</b>	<b>11,930</b>
Senior unsecured convertible bonds <sup>2</sup>		2	34,564	60,000
<b>Noncurrent liabilities</b>			<b>34,564</b>	<b>60,000</b>
<b>Total liabilities</b>			<b>51,778</b>	<b>71,930</b>
Share capital		3.3	54,608	19,430
<i>Reserves from capital contributions<sup>3</sup></i>			19,188	12,080
<i>Other capital reserves</i>			2,850	3,712
Statutory capital reserves			22,038	15,792
<i>Accumulated result</i>			-41,414	-39,801
<i>Results carried forward</i>			-39,801	-32,377
<i>Net result for the period</i>			-1,613	-7,424
<i>Other voluntary reserves (free reserves)</i>			95,995	83,994
Voluntary accumulated result and other reserves			54,581	44,193
Treasury shares		3.4	-5,020	-1,580
<b>Total equity</b>			<b>126,206</b>	<b>77,835</b>
<b>Total liabilities and equity</b>			<b>177,984</b>	<b>149,765</b>

1 Non-interest bearing

2 Interest bearing

3 Value as per December 31, 2021, to be confirmed by Swiss Federal Tax Administration (SFTA).

## Income Statement

For the year ended December 31, in CHF thousands	Notes	2021	2020
Income from shareholdings	3.5	0	537
Other operating income		0	0
<b>Total operating income</b>		<b>0</b>	<b>537</b>
General and administrative expenses	3.6	-6,184	-2,877
Employee expenses		-192	-480
Other operating expenses		-9	-90
<b>Total operating expenses</b>		<b>-6,385</b>	<b>-3,447</b>
<b>Operating result</b>		<b>-6,385</b>	<b>-2,910</b>
Financial income		14,727	79
Financial expenses		-9,956	-4,714
<b>Financial result</b>		<b>4,771</b>	<b>-4,635</b>
Reversal on allowance of investment		0	121
<b>Result before and after taxes/net result</b>		<b>-1,613</b>	<b>-7,424</b>
Direct taxes		0	0
<b>Net result</b>		<b>-1,613</b>	<b>-7,424</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 Hohenrainstrasse 24 in 4133 Pratteln, Switzerland.

#### Material uncertainties and ability to continue operations

Cash and cash equivalents amounted to CHF 21.2 million as of December 31, 2021, of which CHF 13.9 million was used for the repayment of the 2017/22 convertible bond on maturity in February 2022. However, because the funds as of December 31, 2021 and as of the date of these financial statements are insufficient to allow the Company to reach the value inflection points after the completion of vamorolone regulatory filing, material uncertainties remain as to the Company's ability to continue as a going concern until December 31, 2022. Executing the Company's strategy significantly depends on the following

- The acceptance by the U.S. FDA of the NDA submission for vamorolone expected in Q3-2022
- Further funding to ensure the continuation of its operations through December 31, 2022
- No material adverse advents as it relates the reimbursement status of Raxone in France (see note 17 Commitments and Contingent Liabilities)
- Ability to settle current debt obligations

The U.S. NDA submission for vamorolone in ambulant patients with DMD, is in progress and expected to be completed during Q2-2022, with the acceptance of the submission by the FDA expected in Q3-2022. In the event of acceptance, the Management and Board of Directors plan to raise additional funds through a capital increase in the second half of 2022 in order to finance further development to support a European submission and pre-commercialization activities. Should further funding not be available, pending approval of the submission, the Company may review further organizational restructuring measures and reduction in business activities as well as consider the monetization of assets (e.g., out-licensing rights of Ionodelestat or outlicensing rights in certain geographic markets of vamorolone).

On June 2, 2022, the Company increased its financing facility with Highbridge Capital to provide up to CHF 40 million to increase the cash runway to the next key inflection point, namely the approval of vamorolone in DMD in the U.S. which is expected in Q1-2023 subject to priority review, and to allow for additional time to raise additional finance after the vamorolone results. The respective agreement with Highbridge Capital provides for a tranche of CHF 20 million, which is unconditional and which Santhera has requested immediately upon signing. These CHF 20 million have been received on June 3, 2022, of which CHF 8.5 million was used to refinance outstanding exchangeable notes. The remaining balance (CHF 20 million) is divided into two tranches, each amounting to CHF 10 million, and each drawdown is subject to Highbridge Capital's consent.

In addition, on June 2, 2022, the Company announced an amendment to the agreement with ReveraGen, resulting in a reduction of the milestone payment due upon FDA approval (expected in Q1-23) by USD 20 million in exchange for an increase of the sales milestone by USD 20 million (due when vamorolone annual revenue reaches USD 100 million).

Shareholders should note that whilst the Management and Board of Directors consistently continue to apply best efforts to evaluate and execute available options, there is no guarantee that the development studies will be suc-



cessful, regulatory approvals obtained, that there are no material adverse events as it relates to the reimbursement status of Raxone in France and any transaction can be realized or that such transaction would generate sufficient funds to finance operations through December 31, 2022. These material uncertainties may cast significant doubts about ability of the Company to continue as a going concern. If going concern cannot be supported, consolidated financial statements would have to be prepared using liquidation values.

However, the Management and the Board of Directors of Santhera are of the view that it is more likely than not that the Company will continue to secure additional funds needed in order to operate its business as planned with the objective to meet all of its obligations until December 31, 2022. Hence, the consolidated financial statements have been prepared on a going concern basis.

## 2 Principles

### General

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**). Since Santhera prepares consolidated financial statements in accordance with International Financial Reporting Standards (**IFRS**) of the International Accounting Standards Board (**IASB**), 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.

### Financial assets short-term

Financial assets (units in a fund) are held for trading and measured at fair value. In case of gains and losses from such assets are recognized through the income statement as financial income or financial expense.

### 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. Investments in subsidiaries are evaluated for impairment annually and an impairment loss is recorded when the carrying amount of such assets exceeds the fair value. Fair value estimates of investments are predominantly based on the income approach.

## Convertible bonds

In February 2017, Santhera issued senior unsecured 2017/22 convertible bonds in the nominal amount of CHF 60 million. The bonds, listed on the SIX, are interest bearing (5%) with a maximum term of 5 years and are convertible into registered Shares of Santhera with a nominal value of CHF 1 each. The initial conversion price was fixed at CHF 86.4006 and was reset in accordance with the terms of the bond in February 2018 to CHF 64.80. In addition, Santhera may call the convertible bonds at any time on or after the second anniversary of the issue date at par, plus accrued interest, if any, if the volume weighted average price (VWAP) of the Shares is at least 160% of the conversion price.

On March 25, 2021 Santhera announced an exchange offer for the 2017/22 convertible bonds due in 2022. The holders of the 2017/22 bonds who accepted the exchange offer received, for each of their 2017/22 bonds, one new bond issued in 2021 with a maturity in 2024 (2021/24 convertible bonds) and 26 shares on exchange. The 2021/24 convertible bonds were offered as consideration for the 2017/21 convertible bonds. Santhera did therefore not receive any cash proceeds for the issue of 2021/24 bonds. The nominal amount of the new convertible bond is CHF 30.3 million. The bonds, listed on the SIX, are interest bearing (7.5%) with a maximum term of 39 months and are convertible into registered Shares of Santhera with a nominal value of CHF 1 each. The initial conversion price is fixed at CHF 3.0029. In addition, Santhera may call the convertible bonds at any time on or after the second anniversary of the issue date at par, plus accrued interest, if any, if the VWAP of the Shares is at least 150% of the conversion price. To the extent that the Company does not repurchase or redeem these 2017/22 Bonds, such 2017/22 Bonds continue to be outstanding and will become due for redemption on February 17, 2022.

On October 14, 2021, Santhera issued new senior unsecured private convertible bonds to Highbridge with an aggregate principal amount of CHF 15 million (the "21/24 Private Bonds"). The terms of the Private Convertible Bonds are substantially similar to those of the 2021/24 Bonds, except that the conversion price is CHF 1.76 and that the floor price for purposes of interest payments in shares by the Company is CHF 1.25. The net proceeds from the Private Convertible Bonds will be used to redeem the 2017/22 Bonds remaining amount of CHF 14.0 million on maturity in February 2022. The Private Convertible Bonds are currently not listed.

As consideration for its commitment to subscribe for New Term Loan Notes, Highbridge received 1.5 million new warrants, each of which is exercisable for one Share at an exercise price of CHF 2.00 at any time until September 22, 2026. These new warrants were issued in combination with the 1.0 million warrants related to the new money tranches for a total of 2.5 million warrants issued to Highbridge.

## Exchangeable notes

During 2021, Santhera issued exchangeable notes in the amount of CHF 22.0 million to Highbridge. Each note is convertible at the discretion of its holder into a number of shares. All exchangeable notes have been converted into shares of Santhera stock with the exception of tranche 9, of which CHF 2.0 million is outstanding as of December 31, 2021.

During 2021, the Company has amended different equity-linked financing agreements in order to receive additional liquidity in support of the Company's ongoing development pipeline. Commitment fees for the amendments to Highbridge facilities, warrants, equal to 15% of the total aggregate amount of the remaining existing facility and new money tranches, were issued and are exercisable into Santhera Shares at the discretion of Highbridge. A total of 984,769 warrants with a fair value of CHF 1.58 per warrant, were issued in May and 1.0 million warrants with a fair value of 1.05 per warrant were issued in September.

In July, 2020, Santhera issued exchangeable notes in the amount of CHF 7.5 million to Highbridge. Each note is convertible at the discretion of its holder into a number of shares. Between November 1, 2020, and December 31, 2020, a second tranche of CHF 5 million and a third tranche of CHF 2 million have been issued. The first and the

second tranches have been fully converted into shares of Santhera, a balance of CHF 0.75 million from the third tranche is outstanding as of December 31, 2020.

### Treasury shares

Treasury shares are recognized at acquisition cost and deducted from shareholders' equity at the time of acquisition. Santhera holds treasury shares for market making which is maintained by an external bank. In case of a resale, the gain or loss is recognized through the income statement as financial income or financial expenses.

Starting in 2020 Santhera created treasury shares from its authorized capital in order to use them for finance activities of the Group (exchangeable notes) and as payment in the connection of the transaction with Idorsia.

### Related parties

In the meaning of the Swiss Accounting Law, related parties are only considered to be 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 are granted to shareholdings primarily to fund the development and marketing activities of the Santhera Group (December 31, 2021: CHF 334.2.8 million; December 31, 2020: CHF 314.8 million). Until the end of 2015 the balance consisted of fully impaired and subordinated loans to Santhera Pharmaceuticals (Schweiz) AG. To finance the activities in development and the commercialization of LHON, in 2016 the loan granted to Santhera Pharmaceuticals (Schweiz) AG was increased (with the additional loans also being subordinated). As part of the annual reassessment as of December 31, 2021, Executive Management concluded that approximately 48% of the total loan balance is recoverable considering a more positive outlook, in terms of market success of the development progress in different indications (mainly vamorolone in DMD).

### 3.2 Investments in shareholdings

In 2021 and 2020 the following companies are direct subsidiaries of Santhera Pharmaceuticals Holding AG (100% ownership and 100% voting rights):

	Share capital at December 31	2021	2020
Santhera Pharmaceuticals (Schweiz) AG Pratteln, Switzerland	CHF	125,000	125,000
Santhera Pharmaceuticals (Deutschland) GmbH Lörrach, Germany	EUR	25,000	25,000
Santhera Pharmaceuticals (USA), Inc. Burlington, 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.

The following companies are 100% direct subsidiaries (100% voting rights) of Santhera Pharmaceuticals (Schweiz) AG:

	Share capital at December 31	2021	2020
Santhera Pharmaceuticals (Liechtenstein) AG Ruggell, Fürstentum Liechtenstein	CHF	50,000	50,000
Santhera (Italy) S.r.l. - <i>in liquidation</i> Milano, Italy	EUR	50,000	50,000
Santhera (Germany) GmbH München, Germany	EUR	50,000	50,000
Santhera (Netherlands) B.V. Nieuwegein, The Netherlands	EUR	50,000	50,000
Santhera (UK) Limited London, United Kingdom	GBP	50,000	50,000
Santhera Pharmaceuticals (Spain), S.L.U Irun, Spain	EUR	50,000	50,000

### 3.3 Share capital

During 2021, the share capital was increased by a total amount of CHF 35,178,114 to CHF 54,607,810 as of December 31, 2021 (2020:19,429,696); The increase consisted of 1) increases through the issuance of 16,980,658 Shares from authorized share capital for equity financing purposes (e.g., convertible notes) and 2) increases through the issuance of 7,912,954 Shares from the conditional share capital and 3) and an ordinary capital increase of 10,284,502 Shares.

### 3.4 Treasury shares

The movement of treasury shares held by Santhera was as follows:

	No of Shares	TCHF
<b>December 31, 2019</b>	<b>54,892</b>	<b>745</b>
<i>Purchase for market making</i>	137,327	922
<i>Sale for market making</i>	-134,228	-1,330
<b>Subtotal</b>	<b>57,991</b>	<b>337</b>
<i>Shares created for financing purposes</i>	4,569,291	4,569
<i>Shares used for financing purposes</i>	-3,326,207	-3,326
<b>Subtotal</b>	<b>1,243,084</b>	<b>1,243</b>
<b>December 31, 2020</b>	<b>1,301,075</b>	<b>1,580</b>

<i>Shares created for financing purposes</i>	17,135,083	17,135
<i>Shares used for financing purposes</i>	-13,695,267	-13,695
<b>Subtotal</b>	<b>3,439,816</b>	<b>3,440</b>
<b>December 31, 2021</b>	<b>5,019,879</b>	<b>5,020</b>

### 3.5 Income from shareholdings

Income from shareholdings represents reimbursement for management services provided by the Company to its major shareholding Santhera Pharmaceuticals (Schweiz) AG.

### 3.6 General and administrative expenses

	In CHF thousands	2021	2020
Administrative expenses		1,557	1,668
Consulting expenses		4,627	1,209
<b>Total</b>		<b>6,184</b>	<b>2,877</b>

## 4 Other Information

### 4.1 Full-time equivalents

The number of full-time equivalents at period end was not above 10 in 2021 and 2020.

### 4.2 Significant shareholders (>5%)

Pursuant to information from the Company's share register and the disclosure of participations made to the Company in accordance with applicable stock exchange regulation, the following shareholders owned 5% or more of the Company's share capital as registered in the commercial register at December 31, 2021: 54,607,810 shares (December 31, 2020: 18,983,321 shares):

	2021 Shares	2021 %	2020 Shares	2020 %
Idorsia Pharmaceuticals Ltd., Switzerland	7,482,259	13.7	1,700,000	8.7

#### 4.3 Disclosure of shares and equity rights (share appreciation rights and stock options) held by members of the Board and Executive Management (and their respective related party)

<i>As of December 31, 2021:</i>	<b>Number of shares</b>	<b>Number of stock options (vested)</b>	<b>Number of stock options (un- vested)</b>	<b>Number of SAR (vested)</b>	<b>Number of SAR (un- vested)</b>	<b>Number of RSU (vested)</b>	<b>Number of RSU (un- vested)</b>
<i>Board of Directors</i>							
Elmar Schnee	6,000	0	0	63,264	24,569	0	100,000
Philipp Gutzwiller	7,100	0	0	44,522	17,287	0	86,250
Thomas Meier	84,222	14,875	0	92,223	22,505	0	83,750
Patrick Vink	1,000	0	0	50,420	18,965	0	86,250
<b>Total</b>	<b>98,322</b>	<b>14,875</b>	<b>0</b>	<b>250,429</b>	<b>83,326</b>	<b>0</b>	<b>356,250</b>
<i>Executive Management</i>							
Stephanie Brown	0	0	117,500	0	0	0	117,500
Dario Eklund	0	0	50,000	0	184,248	0	450,000
Günther Metz	10,000	19,120	30,000	70,503	24,125	0	130,000
Andrew Smith	0	0	35,000	0	162,138	0	285,000
Oliver Strub	0	11,241	30,000	71,968	24,284	0	130,000
<b>Total</b>	<b>10,000</b>	<b>30,361</b>	<b>262,500</b>	<b>142,471</b>	<b>394,795</b>	<b>0</b>	<b>1,112,500</b>

<sup>1</sup> Member of the BoD until June 22, 2021 (AGM 2021)

<i>As of December 31, 2020:</i>	<b>Number of shares</b>	<b>Number of stock op- tions (vested)</b>	<b>Number of stock options (un- vested)</b>	<b>Number of SAR (vested)</b>	<b>Number of SAR (un- vested)</b>	<b>Number of RSU (vested)</b>	<b>Number of RSU (un- vested)</b>
<i>Board of Directors</i>							
Elmar Schnee	12,000	0	0	31,688	56,145	0	0
Martin Gertsch <sup>1</sup>	38,109	6,281	0	29,339	45,865	0	0
Philipp Gutzwiller	7,100	0	0	22,300	39,509	0	0
Thomas Meier	82,902	14,875	0	60,720	54,008	0	0
Patrick Vink	1,000	0	0	25,571	43,814	0	0
<b>Total</b>	<b>141,111</b>	<b>21,156</b>	<b>0</b>	<b>169,618</b>	<b>239,341</b>	<b>0</b>	<b>0</b>
<i>Executive Management</i>							
Dario Eklund	0	0	0	0	184,248	0	0
Günther Metz	0	19,120	0	40,151	54,477	0	0
Andrew Smith	0	0	0	0	162,138	0	0
Oliver Strub	0	11,241	0	41,283	54,969	0	0
<b>Total</b>	<b>0</b>	<b>30,361</b>	<b>0</b>	<b>127,117</b>	<b>522,742</b>	<b>0</b>	<b>0</b>

#### 4.4. Disclosure of the allocation of equity rights for Board of Directors, Executive Management and employees of Santhera Group

	2021	2021	2020	2020
	Quantity	Value (in TCHF) <sup>1</sup>	Quantity	Value (in TCHF) <sup>1</sup>
Board of Directors	356,250	409	165,332	551
Executive Management	1,375,000	560	283,127	901
Employees of Santhera Group	1,415,450	677	719,008	2,386
<b>Total</b>	<b>3,146,700</b>	<b>1,646</b>	<b>1,167,467</b>	<b>3,838</b>

<sup>1</sup> Value of the equity rights calculated in accordance with the Monte Carlo model in 2021 and Hull-White model in 2020 at the date of allocation in accordance with the terms of the award. The tax value of equity rights is 0 until they would be exercised. Such equity rights 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 equity rights plans, see note 18 "Equity Rights 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 General Meeting in 2023.

##### *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 Events after the reporting date

On January 4, 2022 the Company entered into an exclusive license agreement with Sperogenix Therapeutics, a China-based company specializing in orphan diseases. Under this agreement, Sperogenix will in-license vamoro-lone for rare disease indications for a total consideration of up to USD 124 million, including a double-digit upfront cash compensation and DMD-related US-regulatory milestone payments amounting to a combined USD 20 million, (of which USD 12 million has been received to date) as well as further double-digit royalties on net sales.

In March 2022 the Company increased in issued share capital by issuing 3,100,000 treasury shares from authorized capital and a further issuance of 15,500,000 treasury shares in an ordinary capital increase, in order to support future financing activities.

On June 2, 2022 the company entered into an amendment to the timing of an upcoming milestone payment to partner ReveraGen, thereby reducing near-term financial obligations of the Company by CHF 20 million. The Com-

pany also upsized its existing financing arrangement with certain funds managed by Highbridge Capital Management, LLC (**Highbridge**) which will provide up to CHF 40 million of additional financing. Santhera expects the combination of these events to extend its liquidity runway into 2023 or up to approval of vamorolone in the U.S. which, subject to priority review being granted, is expected in Q1-2023. The first tranche of CHF 20 million was drawn on June 3, 2022.



## Proposal of the Board of Directors to the Annual General Meeting

**Proposal of the Board for the result to be carried forward, subject to the approval of the Annual General Meeting**

	In CHF	2021	2020
Result carried forward		-39,801,095	32,377,063
Net result of the year		-1,613,379	-7,424,032
<b>Accumulated result</b>		<b>-41,414,474</b>	<b>-39,801,095</b>
<b>Result to be carried forward</b>		<b>-41,414,474</b>	<b>-39,801,095</b>

**The Board of Directors requests the approval of the Annual General Meeting for the following release and transfer from reserves from capital contribution:**

	In CHF
Reserves from capital contribution after Annual General Meeting (June 22, 2021)	79,559
Share premium of capital increases during 2021	19,108,084
<b>Reserves from capital contribution</b>	<b>19,187,643</b>
Transfer from reserves from capital contribution to other voluntary reserves (free reserves)	19,000,000
<b>Reserves from capital contribution</b>	<b>187,643</b>

**Subject to approval by the Annual General Meeting, the other voluntary reserves (free reserves) develop as follows:**

	In CHF
<b>Other voluntary reserves (free reserves) after Annual General Meeting (June 22, 2021)</b>	<b>95,994,714</b>
Transfer to free reserves from capital contribution	19,000,000
<b>Free reserves</b>	<b>114,994,714</b>



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To the General Meeting of  
Santhera Pharmaceuticals Holding Ltd, Pratteln

Basle, June 9, 2022

## Report of the statutory auditor on the financial statements

As statutory auditor, we have audited the financial statements of Santhera Pharmaceuticals Holding Ltd, which comprise the balance sheet, income statement and notes (pages 86 to 97), for the year ended December 31, 2021.



### Board of Directors' responsibility

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



### Auditor's responsibility

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

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



### Opinion

In our opinion, the financial statements for the year ended December 31, 2021 comply with Swiss law and the company's articles of incorporation.



### Emphasis of matter

We draw attention to note 1 of the financial statements, which indicates the existence of a material uncertainty which casts significant doubt about the Company's ability to continue as a going concern in connection with the ability to raise additional funds. This fact together with other matters disclosed in note 1 indicates that a material uncertainty exists that may cast significant doubt about the

Company's ability to continue as a going concern. Should the going concern assumption no longer be appropriate, the financial statements would have to be prepared based on liquidation values. In this case, a serious concern of over-indebtedness in the sense of article 725 para. 2 CO would exist and the relevant provisions would have to be complied with. Our conclusion is not modified in respect of this matter.



#### **Report on key audit matters based on the circular 1/2015 of the Federal Audit Oversight Authority**

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the financial statements of the current period. In addition to the matters described in the *Emphasis of matter* section of our report, we have determined the matters described below to be the key audit matters to be communicated in our report. These matters were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters. For each matter below, our description of how our audit addressed the matter is provided in that context.

We have fulfilled the responsibilities described in the Auditor's responsibility section of our report, including in relation to these matters. Accordingly, our audit included the performance of procedures designed to respond to our assessment of the risks of material misstatement of the financial statements. The results of our audit procedures, including the procedures performed to address the matters below, provide the basis for our audit opinion on the financial statements.

#### **Valuation of investments in and long-term receivables from shareholdings**

<b>Area of focus</b>	Santhera Pharmaceuticals Holding Ltd holds investments in subsidiaries and grants loans to subsidiaries for financing purposes, both of which are assessed for impairment as of the balance sheet date. Management's assessment requires estimation and judgement around assumptions used, including prospective financial information, probability of success (e.g., obtaining regulatory approvals for a drug), and discount rates. Changes to assumptions could lead to significant changes in the estimated recoverable amount, impacting both potential impairment charges as well as potential reversals of impairment. As such, we considered this matter to be significant to our audit.
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*Refer to note 3.1 and 3.2 related to the investment in and the long-term receivables from shareholdings.*

<b>Our audit response</b>	We evaluated management's impairment assessment, which is based on an income approach, and analyzed the underlying key assumptions in relation to prospective financial information, probability of success, as well as discount rates used. We evaluated the historical accuracy of the Group's previous estimates on prospective financial information. We tested the sensitivity of the assessment due to changes to key assumptions and compared these assumptions to externally available information in order to assess management's impairment conclusion. Our audit procedures did not lead to any reservations regarding the valuation of investments and long-term receivables from shareholdings.
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#### **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 para. 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/ Frederik Schmachtenberg

Licensed audit expert

(Auditor in charge)

/s/ Diana Vejina

ACCA

# Compensation Report

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## Introduction

This Compensation Report (**Report**) describes the principles of the compensation system of Santhera's Board of Directors (**Board**) and Executive Management (**EM**) members (**Executives**) and how the respective decisions are made. Furthermore, the Report discloses the compensation made to the Board and EM for 2021, as well as shareholdings of the members of the Board and EM members.

## Compensation Governance

### The Role and Powers of the Compensation Committee

The Compensation Committee (**CC**) currently consists of the two members of the Board, Patrick Vink as Chairman and Elmar Schnee as Member. 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 Ordinance against Excessive Compensation (**OaEC**), the SIX Swiss Exchange, as well as Swiss and international best corporate governance practices.

According to the Company's Articles and the CC Charter, the CC reviews and recommends for approval by the Board:

- The shareholders' resolutions with regard to the total compensation (annual cash fees and annual grant of Restricted Share Units) for the Board members;
- The respective shareholders' resolutions with regard to the compensation of the members of Executive Management. The compensation shall include a fix base salary, a variable cash bonus, equity compensation, pensions and any other benefits;
- Board candidates for election or re-election at the annual general meeting;
- Executive Management candidates for hiring or dismissal;
- A total compensation policy which fairly rewards Company non-executives and executives for performance benefiting the shareholders and which effectively attracts and retains the executive resources necessary to successfully lead and manage the Company and ensures long-term business success;
- The Company's equity compensation plans;
- The annual report on executive and non-executive compensation for inclusion in the Company's financial statements and in accordance with Corporate Governance regulations.

The CC reviews and approve






- Executive employment agreements;
- Salary increases, bonus payments and equity grant pools (e.g., SAR) given to all employees (other than members of Executive Management) on a total Company basis;
- Any management position, any board mandate or any similar position in third party companies.

The Board may assign other tasks to the CC. The CC generally meets 4 to 6 times in a calendar year and met 7 times in the calendar year 2021.

### Compensation Periods and Approvals by Shareholders

For the Board, the compensation period starts after the Annual General Meetings (**AGM**) and ends on the day before the AGM of the subsequent year.

For Executive Management, the compensation period starts on January 1 of a given year and ends on December 31 of such year. With respect to the fixed compensation, the approval of the shareholders is prospective and with respect to the variable cash compensation, such approval is retrospective, allowing the Board to base its respective motions to the shareholders on the achievement of goals by the Executives.

	Previous Year	Current Year	Next Year
Advisory Vote on the Compensation Report	Compensation Framework		
Total Board Compensation			Compensation Period
Fixed EM Compensation			Compensation Period
Variable EM Compensation Cash bonus	Compensation Period		
Variable EM Compensation Long-Term Incentive		 Compensation Period	

 AGM voting

### Voting procedures at the AGM 2022

The Board will propose the following votes on compensation for shareholder approval:

1. Consultative vote on the Compensation Report 2021.
2. Board

The maximum total amount of the compensation for the period between the AGM 2022 and the AGM 2023.

3. Executive Management

3.1. The maximum total amount of the fixed compensation for the period from January 1, 2023 to December 31, 2023.

3.2. The maximum total amount of the variable compensation for the cash bonus for the period from January 1, 2021 to December 31, 2021.

3.3. The maximum total amount of the variable compensation under the Long-Term Incentive Plan for the period from January 1, 2022 to December 31, 2022.

The invitation to the AGM contains the text of agenda items, motions and the explanations thereto in detail.

## Compensation Principles

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 market 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. The compensation system shall ensure compliance and best practice. In addition, compensation elements are focused on rewarding the delivery of outstanding and sustainable results without inappropriate risk-taking.

### Market competitiveness

The compensation structure and level of the EM members is reviewed locally on a regular basis in order to ensure market competitiveness. Such review takes into consideration comparable functional and financial responsibilities. The Company will benchmark the remuneration of EM members again in the year 2022. Three out of five EM members have joined the Company since December 2019 and their compensation offers were based on market conditions. EM members did not receive a salary increase in the last two years. In the calendar year 2021 in preparation to the annual shareholder meeting, the Compensation Committee conducted a benchmark on BoD remuneration on publicly available information. As a result of such benchmark, it suggested a decrease in the ordinary compensation for the BoD.

With respect to total compensation (fixed EM compensation and variable EM compensation), we position ourselves at the market median at target.

## Compensation Elements

### Board of Directors Compensation Elements

The compensation for members of the Board consists of:

- Annual cash fees (50% of the total compensation)
- Annual grant of Restricted Share Units (**RSU**; 50% of the total compensation)

Both components, cash fees and RSU allocation, do not depend on the achievement of corporate goals or the individual performance of a Board member. Additionally, the Company pays employer's social security contributions due on the annual cash fees and assumes the payment of employer's social security contributions due on Restricted Share Units. Board members do not receive any variable compensation.

Annual RSU grants typically vest one day prior to the date of the AGM following the AGM of election or re-election. Such shares are restricted for trade for a period of 2 years following the vesting date.

In addition, each BoD member has the option, to convert up to 100% of the approved annual cash fees into restricted share units, which vest one day prior to the date of the AGM following the AGM of election or re-election. Such shares are restricted for trade for a period of 5 years following the vesting date.

For more information about the underlying Plan, see note 19 "*Equity Rights Plans*" in the consolidated financial statements.



## Executive Management Compensation Elements

The compensation for members of Executive Management generally consists of:

- Fixed compensation
- Variable compensation
  - Annual cash bonus
  - Annual equity grant under the Long-Term Incentive Plan (LTI)

### Fixed compensation

The fixed compensation for the EM members includes base salary, allowances, 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.

### Annual cash bonus

The annual cash bonus is based on the achievement of Company and individual goals and will be paid after the AGM until end of December of the same year, subject to the shareholders' approval. The target bonus, i.e., cash bonus to be paid if Santhera's financial situation allows for a cash bonus and corporate and individual goals are met, is determined individually for each EM member as percentage of the base salary, ranging from 25% to 50%. Corporate goals are discussed at the beginning of each calendar year by the Compensation Committee and proposed for approval by the Board of Directors. The CEO decides on individual goals for his direct reports.

The cash bonus of each EM member is determined at the discretion of the Compensation Committee, which takes into account when making the decision (i) the financial situation of the Company, (ii) the achievement of corporate objectives in the past year and the individual performance of the EM member.

### Long-Term Incentive Plan

Until the financial year 2020 and under the Long-Term Incentive Plan members of the EM received Share Appreciation Rights (**SAR**) annually. The Company has amended the LTI plan with regard to the share-based instrument and has discontinued the Share Appreciation Rights (SAR) program, which has been replaced since 2021 with a forward-looking, time- and performance- based plan, a combination of options and Performance Share Units (PSU). The combination of options and PSUs is decided annually by the Compensation Committee when issuing the annual grant under the Long-Term Incentive Plan.

The PSUs will only be converted into shares after 3 years depending on the achievement of predefined performance targets; the respective rights (PSUs), like the options and similar to the previous SARs, will be allocated in 3 tranches over a period of 3 years, and one tranche will vest after each year.

The objective of this long-term incentive compensation is to align the variable long-term compensation of the Management with Santhera's strategy. The LTI program is designed to motivate participating executives to promote the achievement of medium- and long-term value-based objectives through their actions and decisions. Santhera strives to align the interests of the Management and the Company with those of shareholders beyond share price appreciation. In addition, the LTI program aims to strengthen executives' loyalty to Santhera, their identification with the Company and their motivation to stay with the Company. The Board of Directors intends to raise the necessary shares from the Company's conditional capital for employee participations (Article 3b of the Articles of Incorporation).

For more information about the underlying Plan, see note 18 “*Equity Rights Plans*” in the consolidated financial statements.

## Compensation awarded to the Board of Directors in 2021

### Comparison of the approved and paid and or payable Board compensation during the approval period from one AGM to the next

At the AGM 2021, the shareholders approved the compensation awarded to the Board of Directors in 2021 for the period from the AGM 2021 to the AGM 2022 of in Total CHF 1,025,000 (excl. social security contributions) composed of the ordinary compensation of CHF 625,000 (excl. social security contributions), which is granted 50% in cash and 50% in RSU, and an extraordinary compensation of CHF 400,000 (excl. social security contributions) to be granted in RSU.

### Annual cash fees

At the AGM 2021, the shareholders approved a total cash compensation for the entire Board of a maximum of CHF 312,500 for the period between the AGM 2021 and the AGM 2022, excluding social security contributions. The annual cash fees paid or payable are lower than the approved amount due to BoD members electing to receive a portion of their cash fees in Restricted Share Units.

### Restricted Share Units (RSU)

At the AGM 2021, the shareholders approved a total maximum amount of CHF 312,500 to be granted in RSU for the period until the AGM 2022. In accordance with the Board Share Appreciation Rights Plan (**BSARP 2017**), RSUs were granted to the Board members as of June 23, 2021 based upon a fair market value of the Instrument of CHF 2.00 per RSU.

The table below represents the approved maximum compensation for the Board, the actual amounts paid in 2021 and those still payable until AGM 2022.

	Approved AGM 2021 – AGM 2022 <sup>3</sup>	Paid/payable AGM 2021 – AGM 2022 <sup>3</sup>
Board fees (CHF) cash		223,125
Board fees (CHF) cash converted into RSU <sup>1</sup>		89,375
<b>Total Board fees (CHF) cash or foreseen for conversion</b>	<b>312,500</b>	<b>312,500</b>
RSU <sup>2</sup> (CHF)	312,500	312,500
<b>Total ordinary compensation (CHF)</b>	<b>625,000</b>	<b>625,000</b>
Extraordinary compensation (CHF) <sup>4</sup>	400,000	400,000
<b>TOTAL compensation</b>	<b>1,025,000</b>	<b>1,025,000</b>
RSU <sup>2</sup> (number)	n/a	356,250

- 1 The Board fees earmarked for conversion into RSU will convert into a number of RSU based on the fair market value of the instrument at the day of grant, which is one day prior to the AGM 2022.
- 2 The shareholders approved a fix amount in CHF which was converted into a number of RSU based on the fair market value of such RSU (CHF 2.00) excluding assumed social security contributions on the first trading day immediately following the AGM 2021.
- 3 Excluding social security contributions. The Company pay mandatory social security contributions of 4% on the total compensation (expected for the period from AGM 2021 to AGM 2022 at a level of CHF 26,522).
- 4 The Annual Shareholder Meeting in June approved a one-off grant of restricted shares to current members of the BoD to achieve equality between the current members of the BoD and any new members.

**Disclosure of compensation of members of the Board for the financial years 2021 and 2020 (audited)**

In CHF	Annual cash fees	RSU <sup>1</sup>	Total compensation <sup>2</sup>	Number of RSU granted
<b>2021</b>				
Elmar Schnee	68,563	200,000	268,563	100,000
Martin Gertsch	13,389	0	13,389	0
Philipp Gutzwiller	48,364	172,500	220,864	86,250
Thomas Meier	61,250	167,500	228,750	83,750
Patrick Vink	49,639	172,500	222,139	86,250
<b>Total</b>	<b>241,205</b>	<b>712,500</b>	<b>953,705</b>	<b>356,250</b>
In CHF	Annual cash fees	SAR <sup>1</sup>	Total compensation <sup>2</sup>	Number of SAR granted
<b>2020</b>				
Elmar Schnee	92,813	137,717	230,530	41,333
Martin Gertsch	71,996	107,114	179,110	32,148
Philipp Gutzwiller	60,532	96,912	157,444	29,086
Thomas Meier	67,662	102,013	169,674	30,617
Patrick Vink	65,630	107,114	172,745	32,148
<b>Total</b>	<b>358,632</b>	<b>550,870</b>	<b>909,502</b>	<b>165,332</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 unvested stock options (SAR or RSU) is CHF 0 until the vesting date of the RSU respectively when the SAR are exercised. SAR values are theoretical values and do not reflect income tax values and do also take into consideration certain vesting provisions.

<sup>2</sup> The Total compensation does not include mandatory employer social security contributions on the annual cash fees and the RSU or SAR (2021: CHF 26,794; 2020: CHF 73,503). 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 market value of allocated options/SAR. For all RSUs and SARs held by Board members as of December 31, 2021, the social security contribution is CHF 0 since the SARs have not been exercised and the RSUs have not vested. The total value of social security payments on options/SAR exercised by members of the Board during 2021 is CHF 0 (2020: CHF 0).

**Compensation awarded to the members of the Executive Management in 2021**

The compensation awarded to the members of the Executive Management in 2021 consisted of 3 components, (i) fixed compensation as approved at the AGM 2020, (ii) variable compensation as approved at the AGM 2021 and (iii) one-time compensation as approved at the EGM in March 2021.

**Comparison of the approved and paid EM fixed compensation**

At the AGM 2020, shareholders approved a maximum total compensation for the EM for 2021 as follows: CHF 4,100,000 for the fixed compensation in cash.

In CHF	Approved 2021	Paid 2021
Fixed Compensation	4,100,000	2,112,453

**Comparison of the approved and paid EM variable compensation**

The AGM 2021 has approved a maximum total amount of variable compensation of the members of the Executive Management for the period from January 1, 2020, to December 31, 2020, of CHF 1,550,000, to be settled only in the form of PSUs and Options given the difficult financial situation following the restructuring of the Company in the year 2020. The AGM approved the BoD's proposal, not to pay a cash bonus to EM members for the year 2020. The EM members did not receive a cash bonus in two consecutive years.

In CHF	Approved 2021	Paid 2021
Maximum amount Variable Compensation	1,550,000	554,219 <sup>1</sup>
Thereof		
Cash Bonus	0	0
Allocation of PSU / Options	1,550,000	554,219 <sup>1</sup>
- Number of Options		145,000
- Number of PSUs		145,000

<sup>1</sup> Included in the amounts are social security payments on the fair market value of allocated PSU.

**Comparison of the approved and paid EM one-time compensation**

The EGM in March 2021 has approved a maximum total amount of one-time compensation of the members of the Executive Management in the form of Performance Share Units (PSU) to retain members of the Executive Management to execute the Company's new strategy, strengthen their loyalty and identification with the Company and align the interests of the members of the Executive Management with those of its shareholders.

	Approved 2021	Paid 2021
Maximum amount one-time Compensation (CHF)	2,300,000	1,066,848 <sup>1</sup>
Maximum number of PSU (number)	850,000	850,000

<sup>1</sup> Included in the amounts are social security payments on the fair market value of allocated PSU.

**Disclosure of compensation of members of the Executive Management for the years 2021 and 2020 (audited)**

In CHF	Base salary	Allowances	Cash bonus	SU/ Options <sup>1</sup>	Social security and pension <sup>2</sup>	Total compensation	Number of PSU/ Options granted
<b>2021</b>							
Dario Eklund	500,004	43,272	0	632,466	172,123	1,347,864	500,000
Other 4 members of EM	955,637	43,260	0	1,046,249	340,509	2,385,656	875,000
<b>Total</b>	<b>1,455,641</b>	<b>86,532</b>	<b>0</b>	<b>1,678,715</b>	<b>512,632</b>	<b>3,733,520</b>	<b>1,375,000</b>

In CHF	Base salary	Allowances	Cash bonus	SAR <sup>1</sup>	Social security and pension <sup>2</sup>	Total compensation	Number of SAR granted
<b>2020</b>							
Andrew Smith <sup>4</sup>	240,030	32,445	0	500,001 <sup>3</sup>	94,032	866,508	162,138 <sup>2</sup>
Dario Eklund	500,004	66,177	0	0	114,870	681,050	0
Other 3 members of EM	950,040	0	0	400,752	254,528	1,605,320	120,989
<b>Total</b>	<b>1,690,074</b>	<b>98,622</b>	<b>0</b>	<b>900,753</b>	<b>463,430</b>	<b>3,152,879</b>	<b>283,127</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 unvested stock options (SAR, Options or PSU) is CHF 0 until when the SAR or Options are exercised respectively when PSUs are converted into shares of the Company. SAR values are theoretical values and do not reflect income tax values and do also take into consideration certain vesting provisions.

<sup>2</sup> Included in the amounts are social security payments on the fair market value of allocated SAR/PSU/Options.

<sup>3</sup> The amount represents an initial grant number of 162,138 SAR at a fair market value of CHF 3.0838 as of the grant date of April 1, 2021 (the first day of employment) to attract and retain the CFO for a period of three years. The initial grant is forfeited in case the employment agreement terminates prior to April 1, 2023.

<sup>4</sup> Highest paid in the year 2021 due to the one-time SAR grant.

**Changes in the Executive Management in 2021**

President NA: Stephanie Brown was appointed President North America of the Company effective December 1, 2021.

Chief Medical Officer (CMO): Kristina Sjöblom Nygren, Chief Medical Officer and Head of Development, resigned in October 2020. Her employment ended on April 30, 2021.

Event	Date	Number of Executives
Resignation Kristina Sjöblom Nygren (CMO)	April 30, 2021	4 <sup>1</sup>
Appointment of Stephanie Brown as President NA	December 1, 2021	5

<sup>1</sup> As of January 1, 2021 Kristina Sjöblom Nygren functioned not as an EM member anymore until the Termination Date of April 30, 2021.

## **Executive Contracts**

The employment contracts with the EM members are compliant with the OaEC and no EM member has a notice period of longer than 12 months and the Company's Articles of Incorporation. Any noncompeting 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.

## **Indirect Benefits**

The Company contributes to pension plans which are based on defined contributions, for old age pension, disability and death. The risk portion provides benefits for widowers (spouse), orphans and long-term disability in case of sickness. In addition, there is a lump sum will be paid in case of death due to accident or sickness. The amount of pension benefits depends on the employee's age and insured compensation. Both employee and employer contribute to the aforementioned pension plans.

## **Loans and Credits**

In accordance with the Articles of Incorporation, 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 2021, no loans or credits were made to the members or former 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 payment of CHF 0 (2020: CHF 0) for such payments in 2021.

Disclosure of compensation of former Board members for the years 2021 and 2020 (audited)

In CHF	Total payment
<b>2021</b>	
n/a	–
<b>Total</b>	<b>0</b>
<b>2020</b>	
n/a	–
<b>Total</b>	<b>0</b>

With regard to the former EM members, Santhera made payments of CHF 160,922 in 2021 (2020: CHF 322,573).

Disclosure of compensation of former EM members for the years 2021 and 2020 (audited)

In CHF	Total payment
<b>2021</b>	<b>160,922</b>
Kristina Sjöblom Nygren <sup>1)</sup>	160,922
<b>Total</b>	
<b>2020</b>	<b>322,573</b>
Thomas Meier <sup>2)</sup>	322,573

<sup>1</sup> The amount reflects gross payments made in the year including social security cost. K. Sjöblom Nygren left the Executive Management team at December 31, 2020 and received ongoing compensation until the termination date on April 30, 2021 in accordance with contractual obligations.

<sup>2</sup> The amount reflects gross payments made in the year including social security cost. T. Meier did not receive the 2019 cash bonus, which amounted to CHF 176.060 (excl. social security cost). The approved 2019 cash bonus for EM members, which was intended to be paid out only upon meeting short term inflection points, was not paid out in the year 2021 due to not achieving the short-term inflection points.

## Shareholdings of Members of the Board and Executive Management

Disclosure of shareholdings in the Company of Board members for the years 2021 and 2020 (audited)

<b>December 31, 2021</b>	<b>Number of shares</b>	<b>Number of stock options (vested)</b>	<b>Number of stock options (unvested)</b>	<b>Number of SAR (vested)</b>	<b>Number of SAR (unvested)</b>	<b>Number of RSU (vested)</b>	<b>Number of RSU (unvested)</b>
Elmar Schnee	6,000	0	0	63,264	24,569	0	100,000
Philipp Gutzwiller	7,100	0	0	44,522	17,287	0	86,250
Thomas Meier	84,222	14,875	0	92,223	22,505	0	83,750
Patrick Vink	1,000	0	0	50,420	18,965	0	86,250
<b>Total</b>	<b>98,322</b>	<b>14,875</b>	<b>0</b>	<b>250,429</b>	<b>83,326</b>	<b>0</b>	<b>356,250</b>

<b>December 31, 2020</b>	<b>Number of shares</b>	<b>Number of stock options (vested)</b>	<b>Number of stock options (unvested)</b>	<b>Number of SAR (vested)</b>	<b>Number of SAR (unvested)</b>	<b>Number of RSU (vested)</b>	<b>Number of RSU (unvested)</b>
Elmar Schnee	12,000	0	0	31,688	56,145	0	0
Martin Gertsch <sup>1</sup>	38,109	6,281	0	29,339	45,865	0	0
Philipp Gutzwiller	7,100	0	0	22,300	39,509	0	0
Thomas Meier	82,902	14,875	0	60,720	54,008	0	0
Patrick Vink	1,000	0	0	25,571	43,814	0	0
<b>Total</b>	<b>141,111</b>	<b>21,156</b>	<b>0</b>	<b>169,618</b>	<b>239,341</b>	<b>0</b>	<b>0</b>

<sup>1</sup> Member of the BoD until June 22, 2021 (AGM 2021)



**Disclosure of shareholdings in the Company of Executive Management members for the years 2021 and 2020 (audited)**

<b>December 31, 2021</b>	<b>Number of shares</b>	<b>Number of stock options (vested)</b>	<b>Number of stock options (unvested)</b>	<b>Number of SAR (vested)</b>	<b>Number of SAR (unvested)</b>	<b>Number of PSU (vested)</b>	<b>Number of PSU (unvested)</b>
Stephanie Brown	0	0	117,500	0	0	0	117,500
Dario Eklund	0	0	50,000	0	184,248	0	450,000
Günther Metz	10,000	19,120	30,000	70,503	24,125	0	130,000
Andrew Smith	0	0	35,000	0	162,138	0	285,000
Oliver Strub	0	11,241	30,000	71,968	24,284	0	130,000
<b>Total</b>	<b>10,000</b>	<b>30,361</b>	<b>262,500</b>	<b>142,471</b>	<b>394,795</b>	<b>0</b>	<b>1,112,500</b>

<b>December 31, 2020</b>	<b>Number of shares</b>	<b>Number of stock options (vested)</b>	<b>Number of stock options (unvested)</b>	<b>Number of SAR (vested)</b>	<b>Number of SAR (unvested)</b>	<b>Number of PSU (vested)</b>	<b>Number of PSU (unvested)</b>
Dario Eklund	0	0	0	0	184,248	0	0
Günther Metz	0	19,120	0	40,151	54,477	0	0
Andrew Smith	0	0	0	0	162,138	0	0
Oliver Strub	0	11,241	0	41,283	54,969	0	0
<b>Total</b>	<b>0</b>	<b>30,361</b>	<b>0</b>	<b>127,117</b>	<b>522,742</b>	<b>0</b>	<b>0</b>

**Outlook****Outlook for Board compensation**

The Board will continue with the Audit Committee (**AC**), Compensation Committee (**CC**) and the Scientific Committee (**SC**). All committee chairmanships as well as memberships of the Board and its committees are proposed to be remunerated as follows:

<b>Function</b>	<b>Compensation (CHF)</b>	<b>Number</b>	<b>Total (CHF)<sup>1)</sup></b>
Chairman of the Board ( <b>COB</b> )	180,000	1	180,000
Member of the Board	115,000	4	460,000
Chairman of the AC	30,000	1	30,000
Member of the AC	10,000	1	10,000
Chairman of the CC or SC	20,000	2	40,000
Member of the CC or SC	10,000	2	20,000
<b>Total</b>			<b>740,000</b>

<sup>1</sup> Excluding employer contributions to AHV/IV/ALV that does not form part of remuneration

At minimum, 50 percent of the total compensation is made in the form of restricted shares. The Board of Directors proposes that the 2022 ordinary AGM approves Board remuneration totaling not more than CHF 950,000 (excluding legally required employer's contributions to AHV/IV/ALV) for the period ending at the 2023 ordinary AGM. The amount includes an amount of CHF 210,000 in the form of restricted share units for the attraction of new Board members on a one-time basis based upon 75% of the normalized total annual compensation.

### Outlook for EM compensation

#### Outlook for fixed compensation

The AGM 2021 has already approved the fix compensation for 2022 in the amount of CHF 4,100,000.

For the fix compensation for 2023, the Board will propose an amount of CHF 2,950,000 to the AGM 2022 which is based on the existing six Executives, including a reserve amount which would allow increasing the fix compensation of the EM if deemed appropriate by the Board.

#### Outlook for Variable compensation

The Variable compensation of the members of the EM consist of an annual cash bonus and an annual grant under the companies' LTI program. Following two successive years of no cash bonus payments and materially reduced LTI grants relative to the amounts approved by the shareholders, the BoD proposes a total maximum variable compensation to the members of the EM of CHF 3,600,000.

In CHF	For Approval in 2022	2021	2020
<b>Maximum amount Variable Compensation</b>	<b>3,600,000</b>	<b>554,219</b>	<b>427,549</b>
Thereof:			
Cash Bonus	1,200,000 <sup>1</sup>	0	0
Stock Options / PSU	2,400,000	554,219	427,549

<sup>1</sup> Excluding a sign on bonus for Stephanie Brown, which will be only paid out in the year 2022 and reported as Fixed Compensation in the year 2022

### Annual cash bonus

The annual cash bonus for 2021 is based on the achievement of Company and individual goals. The Company goals included the successful completion of a financing, achieving milestones to pursue the development of vamorolone as well as to prepare partnering on vamorolone in China.

Overall Company targets were substantially achieved. The Company was successfully turned around in 2021 following the futility of the Phase 3 SIDEROS study with Puldysa (idebenone) and the subsequent restructuring in the year 2020. The existing debt of CHF 60 million was successfully restructured. Following the acquisition of the rights for vamorolone on a cash free basis, the development of vamorolone was diligently pursued to enable the start of the filing process of vamorolone in DMD in the U.S. and the EU in 2022 and subsequent commercialization in 2023.

The proposal to the shareholders at the AGM 2022 is for a maximum cash bonus payment of CHF 1,200,000 (incl. social security contributions).

**Long-Term Incentive Plan – annual grant**

The Company has discontinued the SAR program and replaced it with a time and performance dependent equity-based plan, a combination of options and Performance Share Units (PSU) from the year 2021 onwards.

The objective of the variable long-term remuneration is to align manager's long-term compensation with the strategy of Santhera. The Long-Term Incentive (LTI) program shall be designed to motivate eligible managers to ensure that their actions and decisions promote the achievement of the medium- and long-term value-based targets. Santhera seeks to align the interests of management and the Group with the interests of its shareholders beyond share price appreciation. In addition, the LTI program aims to strengthen the loyalty of its managers to Santhera, identification with the Company and motivation among its key talents to stay with the Company.

The Board intends to propose to shareholders at the AGM 2022 to issue stock options and PSUs as the annual grant under the LTI program in aggregate up to a total value of CHF 2,400,000 to EM members.



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To the General Meeting of  
Santhera Pharmaceuticals Holding Ltd, Pratteln

Basle, June 9, 2022

## Report of the statutory auditor on the compensation report

We have audited the compensation report of Santhera Pharmaceuticals Holding Ltd for the year ended December 31, 2021. 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 107 to 113 of the compensation report.



### Board of Directors' responsibility

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 December 31, 2021 of Santhera Pharmaceuticals Holding Ltd complies with Swiss law and articles 14 – 16 of the Ordinance.

Ernst & Young Ltd

/s/ Frederik Schmachtenberg  
Licensed audit expert  
(Auditor in charge)

/s/ Diana Vejina  
ACCA

# Corporate Governance Report

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## General Information

The Company's corporate governance principles are laid out in its articles of incorporation (**Articles**), the organizational rules (**Organizational Rules; Organisationsreglement**), by-laws of the Company's Audit, Compensation and Scientific Committees adopted by the Board of Directors (**Board**) and a comprehensive set of Group directives, including 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. All the above documents can be downloaded from: <http://www.santhera.com/investors-and-media/investor-toolbox/governance>.

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.

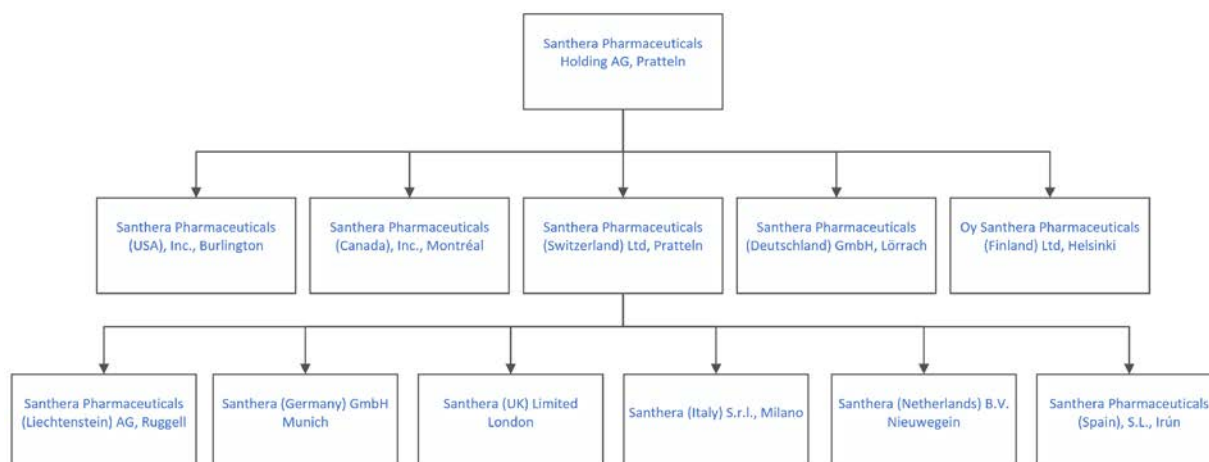
## Group Structure and Shareholders (DCG 1)

### Group structure (DCG 1.1)

#### Listed company

Name	Santhera Pharmaceuticals Holding AG ( <b>Company</b> , together with its affiliates, <b>Santhera</b> )
Legal domicile	Hohenrainstrasse 24, 4133 Pratteln, Switzerland
Register number	CHE-105.388.338
Listing	SIX Swiss Exchange SIX Swiss Exchange SIX Swiss Exchange
Symbol	SANN
Security ID	2714864
ISIN	CH0027148649
Market capitalization	CHF 53 million (December 30, 2021)
Website	<a href="http://www.santhera.com">www.santhera.com</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	Share Capital	Domicile	Activities
Santhera Pharmaceuticals (Schweiz) AG	CHF 125,000	Pratteln, CH	Headquarters; development of pharmaceutical drugs, administrative functions
Santhera Pharmaceuticals (Liechtenstein) AG	CHF 50,000	Ruggell, LI	Logistics/distribution
Santhera (Germany) GmbH	EUR 50,000	München, DE	Dormant
Santhera (Netherlands) B.V.	EUR 50,000	Nieuwegein, NL	Dormant
Santhera (UK) Limited	GBP 50,000	London, GB	Dormant
Santhera (Italy) S.r.l.	EUR 50,000	Milano, IT	In voluntary liquidation
Santhera Pharmaceuticals (Spain), S.L.U	EUR 50,000	Irún, ES	Dormant
Santhera Pharmaceuticals (Canada), Inc.	CAD 1,000	Montréal, CA	Development of pharmaceutical drugs
Santhera Pharmaceuticals (USA), Inc.	USD 1,000	Burlington, Massachusetts, US	Pre-commercial activities/advocacy/patient liaison
Santhera Pharmaceuticals (Deutschland) GmbH	EUR 25,000	Lörrach, DE	Regulatory and development in the EU
Oy Santhera Pharmaceuticals (Finland) Ltd	EUR 2,500	Helsinki, FI	Administrative (liquidation under evaluation)

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 mostly performed in Switzerland, the EU and the U.S. (DCG 1.1.1).

Each subsidiary has exactly one direct parent company which holds 100% of the shares or the quota of such subsidiary.

As a result of the restructuring of its operations following the decision to discontinue the further development of Puldysa in 2020, the majority of this subsidiaries in the EU have become dormant or are being liquidated.

**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, 2021, 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>	54,607,810	100.0	54,617,810	100.0		3
<b>Authorized capital</b>	27,303,905	50.0	27,303,905	50.0	December 14, 2023	3a
<b>Conditional capital for warrants/option rights granted in connection with debt instruments</b>	21,878,228	40.1	21,878,228	40.1	For conversion rights: 10 years from issue date. For options: 7 years from issue date.	3c
<b>Conditional capital for ESOP/BSOP/EIP</b>	5,425,677	9.9	5,415,677	9.9		3b

For details with regard to terms and conditions of potential share issues under the Company’s authorized and conditional share capital, see sections 3a, 3b and 3c of the Company’s Articles, which can be downloaded from <https://www.santhera.com/investors-and-media/investor-toolbox/governance>, and the section on DCG 2.7 below.

For details with regard to the Company’s ESOP, BSOP, ESARP, BSARP, ELTIP and EIP, see note 19 “Equity Rights Plans” to the consolidated financial statements.

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

For changes in capital that occurred in 2019 and 2020, see the Company’s Annual Reports for 2019 and 2020, which can be downloaded at [http://www.santhera.com/assets/files/financial\\_reports/2020-Santhera-Annual-Report\\_final.pdf](http://www.santhera.com/assets/files/financial_reports/2020-Santhera-Annual-Report_final.pdf) and [http://www.santhera.com/assets/files/financial\\_reports/2019-Santhera-Annual-Report\\_final.pdf](http://www.santhera.com/assets/files/financial_reports/2019-Santhera-Annual-Report_final.pdf). For changes that took place in 2021, 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, 2021, 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 AGM 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 Group General Counsel (**GC**) who may cancel registration of shareholders if such registration was based on false information and if the GC 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 bonds - 2017/2022 Bonds*

On February 10, 2017, the Company had placed CHF 60 million senior unsecured convertible bonds (**2017/22 Bonds**) due 2022. In early 2021, after year-end closing, Santhera proposed to the holders of the 2017/22 Bonds a restructuring thereof. At the respective bondholders' meeting, a large majority of 89% of represented bondholders, equaling 58% of the total bonds outstanding, voted in favor of the resolutions proposed by the Company, however, the required threshold of 2/3 of all bonds outstanding to pass such resolutions to exchange all bonds was not met. On March 18, 2021, Santhera convened an Extraordinary General Meeting (**EGM**) where the Board announced to shareholders – inter alia - the intended restructuring of the 2017/22 Bonds. Santhera's shareholders supported all motions by the Board. Separately, the Company, on March 25, 2021, launched a bond exchange offer (**Exchange Offer**) which was settled on May 4, 2021, when the Company repurchased 2017/22 Bonds with an aggregate principal amount of CHF 44,845,000, corresponding to 74.7% of all 2017/22 Bonds then in circulation. The holders of the 2017/22 Bonds who accepted the Exchange

Offer received, for each of their 2017/22 Bond, one 2021/24 Bond and 26 Shares. On the maturity date of the 2017/22 Bonds, i.e., February 17, 2022, the Company redeemed all out-standing 2017/22 Bonds at their principal amount, together with unpaid accrued interest.

#### *Convertible bonds - 2021/2024 Bonds*

On May 4, 2021, the Company issued an aggregate of CHF 30,270,375 Senior Unsecured Convertible Bonds due 2024, which are listed on the SIX Swiss Exchange (ISIN CH0563348744, Ticker Symbol SAN21) and governed by Swiss law (**2021/24 Bonds**). The nominal value of each 2021/24 Bond is CHF 3,375.

The Company issued the 2021/24 Bonds in the above-mentioned Exchange Offer, with respect to 100% of its now redeemed 2017/22 Bonds. The 2021/24 Bonds carry interest at 7.5% per annum payable semi-annually in arrears on February 17 and August 17. The 2021/24 Bonds are senior and unsecured obligations of the Company and rank pari passu with all its other non-subordinated debt and will become due for redemption on August 17, 2024, unless previously converted, redeemed or purchased and canceled under their terms and conditions. The Company may repurchase the 2021/24 Bonds at any time and may also have the repurchased 2021/24 Bonds canceled. Under the terms of the 2021/24 Bonds, the Company may pay all or part of any interest in Shares, valued at 90% of the then-prevailing volume-weighted average price ("VWAP").

The 2021/24 Bonds are convertible between May 4, 2021, and their date of maturity, i.e., on August 17, 2024, at a conversion price of CHF 3.0029. The prevailing conversion price is subject to anti-dilution and other adjustments in certain events, as further set forth in the terms and conditions of the 2021/24 Bonds.

#### *Senior Unsecured Private Convertible Bonds due 2024*

On October 14, 2021, the Company issued new senior unsecured private convertible bonds to Highbridge with an aggregate principal amount of CHF 15,001,875 (**Private Convertible Bonds**). The terms of the Private Convertible Bonds are substantially similar to those of the 2021/24 Bonds, except that the conversion price is CHF 1.76 and that the floor price for purposes of interest payments in shares by the Company is CHF 1.25.

The net proceeds from the Private Convertible Bonds were used to redeem the 2017/22 Bonds. The Private Convertible Bonds are currently not listed. If, however, the Company and Highbridge, after discussions, come to the conclusion to list the Private Convertible Bonds, they shall use their reasonable efforts to ensure such listing on a securities exchange within 30 days.

As consideration for its commitment to subscribe for the Private Convertible Bonds, Highbridge received 1.5 million new warrants, each of which is exercisable for one Share at an exercise price of CHF 2.00 at any time until September 22, 2026.

#### *Options, warrants*

See the statutory financial statements of the Company and note 19 "*Equity Rights Plans*" to the consolidated financial statements.

## Board of Directors (DCG 3)

### Board and committee memberships (DCG 3.1/3.2/3.3/3.4 and 3.5.2)

Composition of the Board of Directors (**BoD**), the Audit Committee (**AC**), the Compensation Committee (**CC**) and the Scientific Committee (**SC**):

	Year of birth	Nationality	First elected	BoD	AC	CC	SC
Elmar Schnee <sup>1</sup>	1959	CH	2017	●	○	○	
Martin Gertsch <sup>4</sup>	1965	CH	2006	(○)	(●)		
Philipp Gutzwiller <sup>1</sup>	1968	CH	2017	○	●		
Thomas Meier <sup>1, 2</sup>	1962	DE	2017	○			●
Patrick Vink <sup>1, 3</sup>	1963	NL	2017	○		●	○

● = Chairman      ○ = Member

1 Elected for the first time at the 2017 AGM on April 4, 2017.

2 Thomas Meier was also Delegate of the Board and CEO of Santhera until November 30, 2019. Thereafter, he remained an employee of the Company until December 31, 2020 and acted as an advisor to the CEO.

3 In the time between September 2016 and the 2017 AGM, Patrick Vink had served as an advisor to the Board.

4 Martin Gertsch did not stand for re-election at the 2021 AGM. After the AGM, the Board of Directors constituted the AC as follows: Philipp Gutzwiller: Chairman; Elmar Schnee: member.

### Elmar Schnee

Elmar Schnee, born 1959, Swiss citizen, is Santhera's Chairman of the Board and Member of the Compensation Committee since 2017. He is both a non-executive and an independent Board Member.

Elmar Schnee has a Master Degree in Marketing and General Management from SIB Zurich.

Elmar served as Advisor to Management of MindMaze Group SA, a neuro-technology company spun off from the Swiss Federal Institute of Technology in Lausanne (EPFL). 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 in marketing, licensing, strategy, business development, and as Managing Director with UCB Pharma, Sanofi-Synthelabo, Migliara Kaplan and Fisons. Elmar Schnee currently serves as chairman of the board of the listed companies Calliditas SA (Sweden), and Clinigen Group plc (UK) and of the privately held companies Genkyotex SA (France and Switzerland), Moleac Pte Ltd (Singapore), ProComRx SA (Switzerland) and Noorik Biopharmaceuticals AG (Switzerland). He also serves as member of the board of the privately held companies Damien AG (Switzerland), Genpharm (UAE) and MindMaze Group SA (Switzerland), Kuste SA (France) and acts as managing director for Caljem GmbH (Switzerland). Until 2021, he was chairman of the Board of Directors of Advanz Pharma Corp Limited (UK) and a member of the Board of Directors of Jazz Pharmaceuticals (Ireland). Until 2020, he was a member of the Board of Directors of Stallergenes Greer Plc (UK).

### Martin Gertsch

Martin Gertsch, born 1965, Swiss citizen, was a member of Santhera's Board and Chairman of the Audit Committee since 2017 until the 2021 AGM. He had been Santhera's Chairman of the Board from 2006 to 2017 and Santhera's Vice Chairman of the Board from 2017 until the 2020 AGM. He was both a non-executive and an independent Board Member. Martin Gertsch is Certified Public Accountant, economics/audit, Kammerschule Basel/Zurich.

From 2013 to 2014 he was Chief Financial Officer of Acino Pharma AG, from 2011 to 2013 Vice-President Head of Finance EMEA of Synthes. From 2009 to 2010 he served as Chief Operating Officer/Chief Financial Officer of Delenex Therapeutics AG, from 2007 to 2009 as Chief Financial Officer of ESBA Tech AG and from 1997 to 2006 as Chief Financial Officer and previously Head Group Controlling and Reporting, Straumann Holding AG.

At the time of his resignation, he served as board member and chairman of the audit committee the University Center of Dentistry (Switzerland) and is chairman of the board of Artidis AG (Switzerland).

#### *Philipp Gutzwiller*

Philipp Gutzwiller, born 1968, Swiss citizen, is a Member of Santhera's Board and its Audit Committee since 2017. He is both a non-executive and an independent Board Member. Philipp Gutzwiller has an MSc (Finance and Economics), University of Basel.

Philipp is a Managing Director at Mizuho Bank, leading the European coverage effort for large Consumer and Healthcare clients. Before joining Mizuho, he spent over 20 years in various Investment and Commercial Banking roles working for UBS, DC Advisory and Lloyds Bank, always with a focus on corporate clients. Philipp started his career at Roche where he held positions in financial controlling as well as in the corporate M&A team. He has no other activities and vested interests.

#### *Thomas Meier*

Thomas Meier, born 1962, German citizen, became a Member of Santhera's Board in 2017. Since December 1, 2019, when he stepped down as CEO, he is no longer an executive Board Member; as per the Swiss Code of Best Practice for Corporate Governance, he is not considered an independent Member as a consequence of his former role as CEO. Thomas Meier chairs the Board's Scientific Committee.

Thomas Meier holds a PhD in Biology from the University of Basel and carried out post-doctoral training at the University of Colorado Health Sciences Center (USA) and Lecturer for Neurosciences at the Biozentrum, University of Basel, where he became group leader and lecturer in Neurosciences before joining the industry. He has a distinguished scientific track record in the field of neuromuscular research. From 2004 to 2019 he was Santhera's Chief Executive Officer (2011 to 2019), Chief Scientific Officer (2004 to 2019). He is a founder of Santhera. From 2000 to 2004, he was founder and Chief Executive Officer of MyoContract AG.

As entrepreneur, he established MyoContract in 2000, a research company focused on orphan neuromuscular diseases and the first start-up company originating from the Biozentrum. Thomas is managing partner of Viopas Venture Consulting GmbH (Switzerland). He currently is a member of the Board of Directors of the privately held companies Novaremed AG (Switzerland) and Visgenx Inc. (USA). Previously and he acted as chairman of the privately held company Pharmabiome AG (Switzerland) until 2021.

#### *Patrick Vink*

Patrick Vink, born 1963, Dutch citizen, is Member of Santhera's Board and Chairman of the Compensation Committee since 2017. He is both a non-executive and an independent Board Member.

Patrick Vink has an MD from Leiden University and an MBA from Rotterdam School of Management and University of Rochester.

From 2012 to 2015 Patrick Vink served as Chief Operating Officer (2015) and General Manager International Business (2012-2014) of Cubist Pharmaceuticals. From 2007 to 2012 he was Head Global Institutional Business of Mylan Inc. and from 2002 to 2006 Global Head Biopharmaceuticals of Sandoz. From 2000 to 2002 he was Vice President International of Biogen Idec Inc. and from 1997 to 2000 in Strategic Marketing Cardio-Thrombosis of Sanofi-Synthelabo.

Until 2020, Patrick served as chairman of the listed company Acacia Pharma Group plc (UK), from 2017 to 2020 he served as chairman of the listed company Targovax ASA (Norway), and from 2017 to 2019 he served as Board member of the listed company Arch BioPartners Inc. (Canada). He also serves as chairman of the privately held company NMD Pharma A/S (Denmark), Chairman of privately held F2G Ltd, is a member of the Board of Directors of Amryt Pharma Plc, Board member of several privately held life science companies and is an advisor to private equity and venture capital funds. Business connections between Board members and the Company (DCG 3.1.c).

See note 27 “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. All members of the Board, including the Chairman in his function as a chairman, are appointed or removed exclusively by a resolution of the shareholders. The Board members are elected on an individual basis for a term of office which must not exceed one year, whereby a year means the period between two AGMs. The terms of the Board members end at the 2022 AGM. There are no rules in the Company’s Articles that differ from legal provisions with regard to the appointment of the Chairman, the members of the Compensation Committee and the independent proxy.

#### **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 GC, who also acts as the Secretary to the Board, he decides on agenda items and motions. The other Board members 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)*

The Compensation Committee consists of two Board members, Patrick Vink (Chairman) and Elmar Schnee (member). The members of the Compensation Committee are elected individually by the AGM for a term of office until the end of the next AGM. The CC's Chairman is elected the Board.

The Audit Committee consists of two Board members, Philipp Gutzwiller (Chairman) and Elmar Schnee (member), both since after the 2021 AGM. Chairman and member of the AC are elected by the Board.

The Scientific Committee consists of two Board members, Thomas Meier (Chairman) and Patrick Vink (member). Chairman and member of the SC are elected by the Board.

## **Board - organizational structure 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 Executive Management. The Board's nontransferable and inalienable duties include the following:

- The ultimate management of the Company, by determining the strategy of the Company based on discussions with Executive Management, e.g., whether to evaluate, pursue or execute a financing, M&A or licensing transaction or a strategy before regulatory authorities such as the European Medicines Agency (**EMA**) and the U.S. Food and Drug Administration (**FDA**).
- The determination of the organizational structure of the Company, in terms of both organization by departments and organization through the legal structure of the Group.
- The oversight of the accounting system, financial control (including the Company's internal control system, risk management as well as financial planning), through structured processes of budgeting/forecasting (both bottom up and top down), variance analyses, regular latest estimates and invoice approvals.
- The appointment, recall and supervision of the Executive Management, the determination of their areas of responsibility and their signing authorities.

The Board is also responsible for the preparation of the Annual Report, AGM and EGMs (if any), carrying out shareholders' resolutions, and notification to the judge in case of overindebtedness of the Company.

The Board has delegated the execution of the strategies defined by it and the day-to-day management of the Company to the Executive Management under the leadership of the CEO. The Executive Team is supported by a Management Team where major functions are represented (commercial operations, communications, technical development, People & Culture, clinical operations, medical affairs).

### *Work methods of the Board and its Committees (DCG 3.5.3)*

#### *Board*

The adoption of resolutions and elections by the Board requires 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 tele- or videoconference and resolutions may be taken by circular. This can be the case where the BoD is very familiar with the project (e.g., if it has been continuously updated before taking such resolution).

#### *Audit Committee*

The Audit Committee (**AC**) reviews, discusses with management and recommends for approval by the BoD the financial statements and the financial information contained in news releases that. It reviews and discusses with management significant financial reporting issues, significant changes to the accounting principles, the adequacy of the internal controls, any special audits, and the effect of regulatory and accounting initiatives. The AC can invite the Company's auditors, consultants and legal advisers to any of its meetings and discuss any AC related topic with such parties. The AC 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 AC has the authority to suggest to the whole BoD the appointment or replacement of the auditors.

*Compensation Committee*

The tasks of the Compensation Committee are described in the Compensation Report under “Compensation Governance”.

*Scientific Committee*

The purpose of the SC is to assist the Board in its oversight of the Company’s research and development strategy. CEO and Head Development/Head Medical Affairs, Head Business Development and Secretary to the Board participate in such meetings. The SC reports its actions and recommendations to the Board at the meeting of the Board following each SC meeting. Its core tasks include to provide strategic advice to the Board regarding current and planned research and development programs and activities, to evaluate the effectiveness of the Company’s R&D Operations and activities, to evaluate in-licensing or partnering opportunities and monitor compliance with the Company’s standards of scientific integrity.

*Meetings in 2021*

<b>Corporate Body</b>	<b>In person meetings</b>	<b>Tele- and Videoconferences</b>	<b>Circular resolutions</b>	<b>Average duration in hrs</b>
Board of Directors	0	21	8	Ca. 1½
Audit Committee	1	3	0	More than 1½
Compensation Committee	0	7	0	Almost 1½
Scientific Committee	0	2	0	Ca. 4½

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

As a rule, all Executives participate in the Board meetings and report to the Board on the current course of business and all significant issues and transactions. Other members of senior management may be invited to attend to present and discuss 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 or legal advisors to its meetings.

In the year under review, the Board discussed the Company’s strategy, major projects and risks. It put in place two equity-linked financings, restructured its 2017/22 Convertible Bonds, called for an AGM, two EGMs and a bondholders’ meeting. It extensively discussed the regulatory and CMC strategy of vamorolone and approved the out-licensing of vamorolone rights for Greater China.

Among the key risks identified at the beginning of 2021 were the financial situation of the Company, the regulatory risk in the U.S. with respect to vamorolone, potential loss of key personnel, compliance (GxP compliance and compliance with respect to interactions with healthcare professionals and qualification and validation of computerized systems). For all these risks, mitigation strategies had been put in place.

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 2021, the Executive Management consisted of five Executives<sup>1</sup>.

Executive	Function	Nationality	Year of Birth
<b>Dario Eklund</b>	CEO	AT/FI	1968
<b>Stephanie Brown<sup>2</sup></b>	President North America	CA	1960
<b>Günther Metz</b>	Head Business Development, EVP	DE	1958
<b>(Kristina Sjöblom Nygren<sup>3</sup>)</b>	Chief Medical Officer & Head Development, EVP	SE	1961
<b>Andrew Smith</b>	CFO	GB	1962
<b>Oliver Strub</b>	Group General Counsel & Secretary to the Board, EVP	CH	1963

<sup>1</sup> As of May 1, 2022, Shabir Hasham was appointed Chief Medical Officer (**CMO**).

<sup>2</sup> As of December 1, 2021.

<sup>3</sup> On garden leave since January 1, 2021. The effective date of termination was April 30, 2021.

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.

During the Board and Board committee meetings, the CEO reports to the Board as well as whenever required on an ad hoc basis.

The CEO, together with Executive Management, is responsible for implementation of the strategy and the decisions taken by the Board and its Committees within the approved budget. With the support of the management team - consisting of the members of Executive Management, the Chief of Staff, the Head Region Western Europe, the Head Technical Development & Operations and the Interim Head Santhera US & Global Launch Lead Vamorolone - he prepares the business strategy and business plan for decision by the Board. 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, alliance management, 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.

### *Dario Eklund*

Dario Eklund, born 1968, Finnish and Austrian citizen, is Santhera's CEO since December 1, 2019. He has an MSc in Economics and graduated from the Swedish School of Economics and Business Administration in Helsinki (Finland).

From 2014 to 2019, Dario Eklund was Chief Commercial Officer of Vifor Pharma, from 2005 to 2014 Vice President, member of Executive Committee of Organogenesis, a Nasdaq-listed world leading company in regenerative medicine and cell therapy with three approved products, from 2002 to 2004 General Manager Switzerland of Sanofi. From 1994 to 2002 he served as Global Commercial Director, Biotechnology (1999 to 2002), Area Director, Eastern Europe & Israel (1997 to 1999) and Area Manager, Eastern European countries (1994 to 1996) of Novartis.



He has no other activities and vested interests.

*Günther Metz*

Günther Metz, born 1958, German citizen, is Santhera's Head Business Development, EVP. He has a PhD in Biophysics from University of Freiburg (Germany) and was a post-doctoral fellow at Yale University, New Haven (USA).

Since 2015, he is Head Business Development at Santhera. From 2008 to 2015, he served as Director Business Development at Santhera and from 2004 to 2008, he held various research positions at Santhera. From 1999 to 2004, he was Group Leader Computational Discovery at Graffinity Pharmaceuticals (start-up in Heidelberg, Germany) and from 1994 to 1998 Group Leader Research at Fournier Pharma (Heidelberg, Germany).

He has no other activities and vested interests.

*Kristina Sjöblom Nygren*

Kristina Sjöblom Nygren, born 1961, Swedish citizen, joined Santhera as Chief Medical Officer (CMO) and Head of Development and member of Santhera's Executive Management effective January 1, 2017. Since January 1, 2021, she is on garden leave. The effective date of termination was April 30, 2021.

Kristina Sjöblom Nygren holds an MD from Karolinska institutet (KI) in Stockholm (Sweden) and a Diploma in Pharmaceutical Medicine from KI.

From 2008 to 2016 she was Head Clinical Development (2016), Medical Head Global Brands and Evidence Generation (2015-2016), Medical Therapy Area Head Neonatology (2013-2015) and Medical Program Director (2008-2013) of Sobi/Swedish Orphan Biovitrum AB and from 2003 to 2008 early development Group Director (2007-2008) and Senior Clinical Research Physician (2003-2007) of AstraZeneca. From 1998 to 2003 she served as Medical Manager, Medical Director of Pfizer.

Kristina Sjöblom Nygren is a board member of Infant Bacterial Therapeutics, Sweden.

*Andrew Smith*

Andrew Smith, born 1962, British citizen, joined Santhera as Chief Financial Officer (CFO) on April 1, 2020.

Andrew is a Fellow of the Chartered Institute of Management Accountants and a Chartered Global Management Accountant. He studied business and accounting at Liverpool John Moores University and Durham University Business School.

He joined Santhera with broad experience in corporate and operational finance in the pharmaceutical and biotech industry and public accounting. Prior to joining Santhera (2017-2020) he was CFO and COO at Allegra Therapeutics GmbH a clinical-stage biopharmaceutical company developing novel therapies to combat antibiotic resistance. Previously, Andrew was CFO (2015-2017) and VP Finance (2011-2014) of NASDAQ-listed Sucampo Pharmaceuticals Inc., based in the US, Finance Director (2009-2010) Sucampo UK, (2006-2009) for Retroscreen Virology Ltd., a contract virology company assisting in development of influenza vaccines, and the Finance Director (2004-2006) of Clearlab Europe, following its acquisition of VisionTec CL, contact lens developer, of which he was co-founder and member of its Board of Directors (2001-2004). In addition, between 1989-2001 he held senior financial management positions at Biocompatibles plc, Hydron Ltd and Allergan Inc. and in public accounting from 1981-1989.

He has no other activities and vested interests.

*Oliver Strub*

Oliver Strub, born 1963, Swiss citizen, joined Santhera in 2006 as Group General Counsel & Secretary to the Board. He is also responsible for IT and facility management.

Oliver Strub has a MLaw (lic. iur.) from the University of Basel.

From 1995 to 2006, Oliver Strub was with Ciba-Geigy, then Ciba Specialty Chemicals (now part of BASF), Basel, Switzerland, where he was Head Corporate Law and Chief Compliance Officer. From 1990 to 1992, he worked for Crown Obrist AG and M&D Computerberatung where he was writing software and building networks.

He has no other activities and vested interests.

#### *Shabir Hasham*

Shabir Hasham, born 1970, British citizen, joined Santhera in 2015. Shabir has been appointed as Chief Medical Officer and Member of the Executive Management Team, effective May 1, 2022.

Shabir completed his medical studies with an MBBS (Bachelor of Medicine and Surgery) degree from St Bartholomew's School of Medicine, equivalent to a Doctor of Medicine (MD) in other jurisdictions. Prior to that, Shabir obtained a Bachelor of Science degree (Hons) in Immunopathology and Basic Medical Science from Imperial College London. After subsequently working as a physician with the UK NHS for a number of years, Shabir augmented his education by completing an MPhil in Bioscience Enterprise (MBE), a Master's degree in biotechnology and strategic models of commercialization, a joint program from University of Cambridge Institute of Biotechnology and The Judge School of Management, for which he was awarded a full scholarship. In 2003, he joined the pharmaceutical industry.

Shabir has served as Santhera's Global Development Program Lead & Global Head Medical Affairs for the past three years. In this role, he was primarily responsible for overseeing the clinical development and regulatory submission of vamorolone for the treatment of Duchenne muscular dystrophy (DMD) and for supporting launch preparations for this lead product candidate. He previously served as Santhera's Head of Medical Affairs EU & RoW.

Before joining Santhera in 2015, Shabir held various positions at Novartis including EU Medical Director and Global Associate Brand Director for the Neuroscience franchise at Novartis Pharma, and Senior Medical Manager at Novartis Oncology, contributing to global and regional clinical development, medical affairs and launch plans for new products. Earlier in his career, Shabir held medical manager and advisor roles within the neuroscience franchise at Biogen Idec and Pfizer's cardiovascular business.

He has no other activities and vested interests.

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

Other than described above, 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 of this Annual Report.

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

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

Subject to the provisions with respect to nominees in the Company's Articles (Article 5), there are no voting rights restrictions, and 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.

For details, see Section on DCG 2.6.

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. There are no provisions in the Company's Articles of Incorporation that differ from statutory provisions where the participation of shareholders in the AGM is concerned (DCG 6.1.5).

### **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 agenda items and motions of the AGM. 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 AGM, are entitled to attend such AGM and to exercise their votes.

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

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

Santhera's shareholders resolved to cancel the opting out provision at the 2019 AGM. As a result, art. 135 FMIA applies, according to which anyone who acquires 33 1/3% of the voting rights of a company must make an offer to acquire all listed equity securities of such company.

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

The ESOP 2004, 2008, 2010, 2015, the BSOP 2011 and 2015, the BSARPs, ESARPs and ELTIPs, under which most options, share appreciation rights to receive Shares, PSU (performance share units) and RSU (restricted share units) have been granted, contain clauses according to which all instruments granted under these plans vest immediately upon a sale of more than 50% of the Shares.

Other than that, as of December 31, 2021, 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 (DCG 8.1.1). The Shareholders' Meeting elects the Company's auditors for a term of office of one year. The auditor in charge is Frederik Schmachtenberg. He assumed his responsibility in 2017 (DCG 8.1.2).

**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 (audit-related fees have been incurred in connection with capital increases and related comfort letters and review procedures):

	In CHF thousands	2021	2020
Audit services		698	416
Audit-related services		84	108

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 news releases, the AGMs, the Annual Report, the Interim Reports and the website [www.santhera.com](http://www.santhera.com). In addition, Santhera communicates on social media, including LinkedIn, Twitter, Facebook and Instagram.

Investors and other parties interested in subscribing to the Company's news service may do so by registering themselves on [www.santhera.com/investors-and-media/news-and-media-center/news-subscriptions](http://www.santhera.com/investors-and-media/news-and-media-center/news-subscriptions). For contact details, see [www.santhera.com/contact](http://www.santhera.com/contact).

## Corporate events 2022

The 2022 Annual General Meeting will be held on June 30, 2022 where personal attendance will be impossible. See also [www.santhera.com/investors-and-media/corporate-calendar](http://www.santhera.com/investors-and-media/corporate-calendar).

## Quiet Periods (DCG 10)

The Company has a policy according to which every Santhera director, officer and employee must obtain pre-clearance from the Group General Counsel before engaging in a transaction with respect to any Santhera security (which, e.g., includes Santhera shares and Convertible Bonds). During Quiet Periods, no pre-clearance request shall be granted. Quiet Periods begin two weeks before the public release of Santhera's financial statements and end at the close of business one day after such release. For the 2021 annual Report, the Quiet Period has started on May 24, 2022 and will end on June 14, 2022, at close of business. As at the date of this report, no decision has been made with respect to subsequent reporting dates, it is not possible to determine the related Quiet Periods.

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## About Santhera

Santhera Pharmaceuticals (SIX: SANN) is a Swiss specialty pharmaceutical company focused on the development and commercialization of innovative medicines for rare neuromuscular and pulmonary diseases with high unmet medical need. Santhera has an exclusive license for all indications worldwide to vamorolone, a dissociative steroid with novel mode of action, which was investigated in a pivotal study in patients with DMD as an alternative to standard corticosteroids. The Company plans to complete the rolling submission of its filing for approval for vamorolone with the US FDA in June 2022. The clinical stage pipeline also includes lonodelestat to treat cystic fibrosis (CF) and other neutrophilic pulmonary diseases. Santhera out-licensed rights to its first approved product, Raxone® (idebenone), outside North America and France for the treatment of Leber's hereditary optic neuropathy (LHON) to Chiesi Group. For further information, please visit [www.santhera.com](http://www.santhera.com).

*Raxone® is a trademark of Santhera Pharmaceuticals.*

## 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.

**Their Future. Our Focus.**

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