santhera

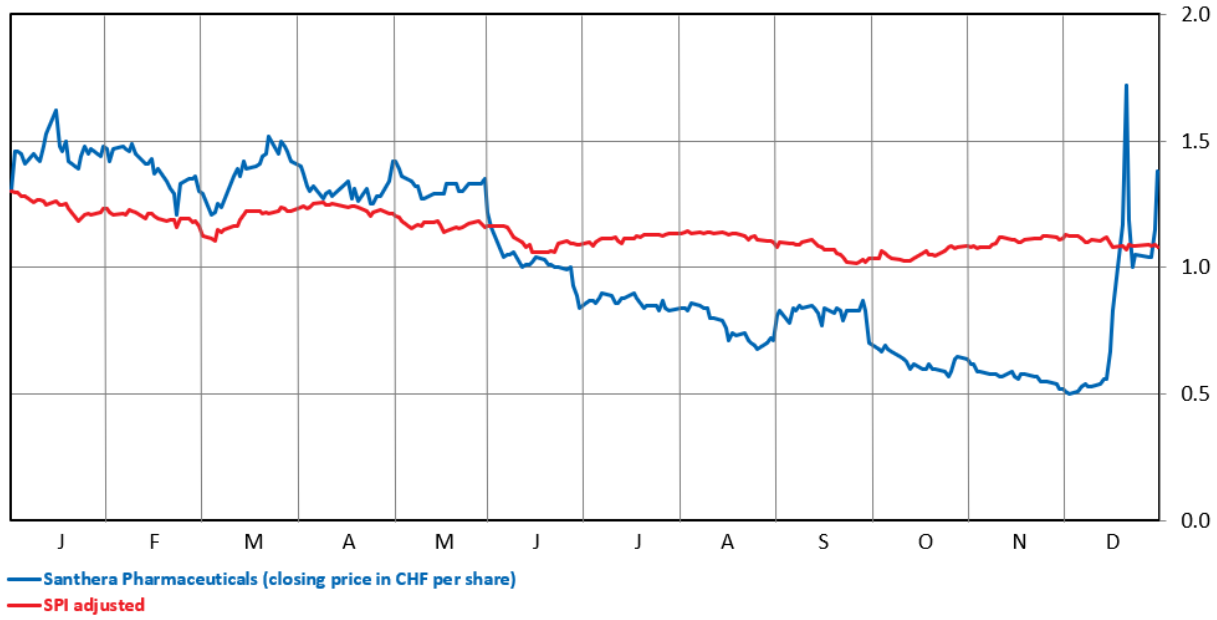
THEIR FUTURE – OUR FOCUS

Annual Report 2022

Financial Key Figures

IFRS consolidated, in CHF thousands	**2022**	2021
Revenue from contracts with customers	**7,473**	(1,595)
Operating expenses	**(56,116)**	(51,872)
Operating result	**(51,976)**	(56,888)
Net result	**(71,076)**	(55,526)
Basic and diluted net result per share (in CHF)	**(1.17)**	(1.62)
Cash and cash equivalents at December 31	**1,353**	21,208
Net change in cash and cash equivalents	**(19,855)**	8,797

Share Price Development in 2022



High	CHF 1.72 (December 20, 2022)
Low	CHF 0.50 (December 2, 2022)
Share price performance in 2022	6.2%
Share price at year-end	CHF 1.38
Market capitalization at year-end	CHF 104 million
Average trading volume	186,223 shares/day

(based on closing share prices)

Contents

Letter to Our Shareholders

Dear Shareholders,

We are pleased to be reaching an important stage in the development of vamorolone, a new treatment for patients with Duchenne muscular dystrophy (**DMD**). Regulatory approval decisions are expected towards the end of 2023 in both the U.S. and Europe, and we will start to bring vamorolone to patients immediately thereafter.

Vamorolone on track for U.S. and European approvals and first launches in late 2023

We are approaching exciting times for Santhera and the Duchenne community. Vamorolone has been developed for patients with DMD who require anti-inflammatory and muscle preserving treatment with an improved safety and tolerability profile to avoid side effects of standard glucocorticoid therapy that often place an additional burden on patients. The data generated across the clinical trial program indicate that vamorolone has the potential to address relevant aspects in patient care that could also enhance treatment outcomes. Once approved, vamorolone will provide an additional treatment option in current standards of care in DMD, potentially addressing unmet medical needs in a majority of Duchenne patients from an early age.

Acceptance of the marketing authorization application (**MAA**) by the European Medicines Agency (**EMA**) in October 2022 and the new drug application (**NDA**) by the U.S. Food and Drug Administration (**FDA**) in January 2023 for vamorolone in DMD were the standout achievements for the Santhera team and the result of many years of work. The MAA submission to the Medicines and Healthcare products Regulatory Agency (**MHRA**) in the UK early this year adds to the regulatory filings.

Notable events along the path to approval include the successful completion of the mid-cycle review meeting with the FDA, which indicated that no significant review or safety concerns were noted up to that point. As part of the ongoing NDA review, the FDA conducted several inspections at various sites, including the contract manufacturer, the sponsor and certain clinical trial sites. All inspections to date were concluded with satisfactory outcomes. The FDA reaffirmed its earlier decision not to request an Advisory Committee Meeting. With an expected PDUFA (Prescription Drug User Fee Act) date confirmed for October 26, 2023, and subject to approval, we anticipate vamorolone becoming available to patients in the U.S. in the final quarter of 2023.

European approval is subject to review and an approval recommendation by the Committee for Medicinal Products for Human Use (**CHMP**) to the European Commission (**EC**). A decision by the EC is expected in the last quarter of 2023 which, if positive, would enable commercialization in the first EU countries before the end of this year and continued roll-out early in 2024. A similar timeline is conceivable for the approval in the UK as in the EU.

We look forward to working closely with regulators for the further advancement of the treatment towards approval and availability to patients. Assuming our justifiable expectations become reality, vamorolone will be the first product approved for the treatment of DMD in both territories, U.S. and EU.

Preparing the path for bringing vamorolone to patients

We have continued to build the relevant commercial functions in the U.S. and begun setting up country-specific commercial activities in major European markets, where we anticipate a staged launch, as we near approval and market entry. The rare disease space lends itself to a targeted and focused commercial approach for a number of reasons.

Care guidelines used at expert reference centers usually recommend that DMD patients be treated with glucocorticoid steroids from the time of diagnosis, which upon approval should include vamorolone. With novel therapies emerging, none of which are currently thought to be curative, we believe that a therapeutic combination approach including standard steroids and vamorolone by treating physicians will likely emerge as the preferred choice, allowing for an individualized treatment approach. Patients with DMD and their families and caregivers are well informed about the latest therapeutic advances and are well organized in local, national and global patient groups. Because patients are usually treated at a limited number of expert reference centers, physicians can frequently be located and targeted efficiently by a small and highly skilled in-house team or by distribution partners.

Upon approval, we envisage launching vamorolone in the U.S. and selected European countries with our own organization. Ensuring prompt availability of vamorolone to patients and a successful implementation of the commercialization plans across regions, we will need to raise additional financial funds and may choose to team up with partners. Discussions are ongoing with various parties on opportunities securing an effective roll-out of vamorolone upon approval, and we are currently evaluating a number of these options.

In addition, Santhera has submitted a request for an early access program for vamorolone for the treatment of DMD in France, namely an AAP (autorisation d'accès précoce) and plans to submit a similar request in the UK, namely an EAMS (early access to medicines scheme), before summer 2023. Such programs allow patients with serious or life-threatening conditions to gain access to investigational drugs that have not yet been approved by regulatory agencies.

Operations financed through to PDUFA date

We recently secured funding that will provide us with liquidity through to the October 2023 PDUFA date and should allow us to progress vamorolone towards market entry. The last financing step included the issuance of 40,000,000 ordinary shares at the end of February 2023, as approved by the Annual General Meeting (**AGM**) held in November 2022. 37,000,000 shares are being held as treasury stock to be used for future equity-based financings and the rest was delivered to Highbridge as part of the most recent financial support provided by our long-standing investor (for more details please see section ‘Financial Review’ on page 13).

Strategy Committee evaluating all strategic options for Santhera

Santhera recently formed a dedicated Strategy Committee to evaluate all strategic options for the Company, and its primary focus is clear: bringing vamorolone to patients as quickly and effectively as possible and assessing the product's potential in additional indications. Beyond this, it will focus on the advancement of potential outlicensing agreements with respect to vamorolone, lonodelestat and Raxone in certain geographies. Additionally, the Strategy Committee supports the evaluation of other options such as the monetization of assets, royalty financing, standby equity distribution agreements and, depending on market conditions, equity-based funding.

In connection with the recent financing, Bradley Meyer, Senior Advisor at Ducera Partners, has been appointed as Board observer. Santhera will propose him to its shareholders for election as a new Board member at the forthcoming Annual General Meeting of June 27, 2023.

Raxone sales in France resumed

Outside of vamorolone, we are pleased to have secured a final reimbursement agreement with French authorities related to Raxone (idebenone) for the treatment of Leber's hereditary optic neuropathy (**LHON**).

Raxone has been available to patients in France since 2014 for the treatment of LHON and reimbursed under a temporary financing scheme (formerly known as ATU). From August 2021, after the French authorities challenged the temporary pricing and removed Raxone from the list of reimbursed drugs under an ATU, Santhera supplied Raxone to LHON patients free of charge in order to secure uninterrupted access as the Company felt strongly that this was ethically appropriate. Following an agreement reached in February 2023, and the inclusion of Raxone on the list of reimbursed products in France, sales of Raxone have resumed in April 2023.

This now enables Santhera to progress negotiations on completing outlicensing of Raxone and to initiate discussions with the FDA on submitting Raxone for approval for LHON in the U.S., which are further supported by encouraging clinical data from two recent studies with positive results as part of the now completed post-authorization measures (**PAMS**).

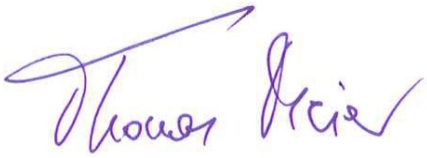
Pursuing portfolio opportunities

We intend to continue actively managing our portfolio of products as an additional source of future non-dilutive income streams and to optimize patient access and commercialization prospects. We aim to develop vamorolone for additional indications with partners to ensure the full potential of this product is made available to the medical community. Having already outlicensed the product in the Greater China region to Sperogenix, we are seeking collaborations with a view of granting sublicensing rights to vamorolone in DMD and potentially in other indications in other jurisdictions. Likewise, we are looking to partner with lonodelestat whose development is currently paused to prioritize our vamorolone strategy.

In 2022, and into 2023, Santhera achieved important milestones with the filing of vamorolone in both the U.S. and Europe. With funding secured into the last quarter 2023, we are reviewing the best path to ensure vamorolone, if approved, reaches patients as quickly and effectively as possible.

We thank our employees for their constant commitment and dedication, and our shareholders for their continued support and patience. The remainder of the year 2023 will be a truly exciting time at Santhera as we approach the finishing line with our ambition of making a novel treatment available to meet the needs of patients living with DMD.

Sincerely,



Thomas Meier, PhD
Chairman

Dario Eklund
Chief Executive Officer

BUSINESS REVIEW

2022/23 in Review — Building the Basis for Future Growth

2022 was a key year, culminating in two important regulatory filings, in the U.S. and the EU, for vamorolone in Duchenne muscular dystrophy (DMD), followed by a third in the UK in early 2023. In parallel, Santhera started expanding its U.S. operations and market entry preparations, concluded first outlicensing agreements which can give rise to non-dilutive cash inflows, and implemented various measures to secure funding and strengthen its capital structure.

The primary operational focus of Santhera was the advancement of the regulatory submissions for vamorolone in the U.S. and Europe towards approval and the preparations for first launches anticipated for late 2023 in both regions. Subject to approval, vamorolone would become the first medication approved for DMD on both continents.

NDA for vamorolone in DMD under review by the U.S. FDA – approval decision by October 2023

Santhera commenced the NDA filing as a rolling submission in March 2022 following a successful pre-NDA meeting with the FDA. In its conclusions from this meeting, the FDA considered the proposed clinical efficacy and safety data sufficient to support an NDA filing of vamorolone for the treatment of DMD. The submission was completed in October 2022, with a delay of four months because a third-party contract manufacturing organization (**CMO**) had postponed achieving FDA inspection readiness which has since been established. Earlier this year, the CMO completed an FDA inspection, having previously passed inspections by EU health authorities.

In January 2023, the FDA accepted the NDA for standard review and set the target date for its decision on approval to October 26, 2023, the date of the Prescription Drug User Fee Act (**PDUFA**). At the recent mid-cycle review meeting, the FDA indicated that no significant review or safety concerns were noted up to that point in its ongoing review and re-affirmed its earlier decision not to request an Advisory Committee Meeting. As part of the ongoing NDA review, the FDA completed several inspections at various sites, including those of the contract manufacturer, the sponsor and certain clinical trial sites, all with satisfactory outcomes. Subject to approval, vamorolone could become available to patients in the U.S. in the final quarter of 2023.

European MAAs for vamorolone in DMD under review in EU and UK – CHMP opinion expected in Q3-2023

In October 2022, the European Medicines Agency (**EMA**) validated the marketing authorization application (**MAA**) for vamorolone for the treatment of DMD submitted in the prior month. The review is on track and Santhera expects the Committee for Medicinal Products for Human Use (**CHMP**) to issue an opinion in the third quarter 2023. Subject to a positive CHMP opinion, the European Commission (**EC**) is expected to decide on a marketing authorization for the EU late in 2023, with a potential launch of vamorolone in first EU countries starting immediately after approval.

BUSINESS REVIEW

In March 2023, Santhera announced that it had submitted a MAA to the UK Medicines and Healthcare products Regulatory Agency (**MHRA**) for vamorolone for the treatment of DMD. A similar timeline is conceivable for the decision on approval in the UK as in the EU.

Findings on bone health published for vamorolone alongside efficacy and safety data

Vamorolone is being developed to provide an anti-inflammatory and muscle preserving treatment with a favorable safety and tolerability profile as an alternative to the current standard of care with glucocorticoids. In addition to long-term efficacy and safety data with vamorolone, recent publications and presentations further characterized vamorolone's differentiated profile with regard to bone health [1-5].

In July 2022, data assessing the **impact of long-term treatment with vamorolone on bone health** were presented at the *10th International Conference on Children's Bone Health* [1]. After 2.5 years of treatment with vamorolone, bone turnover markers were not suppressed, bone age delay was minimal, and the vertebral fracture burden was lower compared with published data on daily prednisolone. Efficacy data showed that vamorolone can maintain muscle function in boys with DMD, similar to standard of care glucocorticoid treatment.

In August 2022, *JAMA Neurology* published the **positive 24-week results from the pivotal VISION-DMD study** evaluating vamorolone in patients with DMD compared to placebo and prednisone [2]. Vamorolone met its primary endpoint by demonstrating statistically significant and clinically relevant improvement in time to stand velocity from floor compared to placebo and showed consistent results across multiple secondary endpoints. The relative efficacy of vamorolone 6 mg/kg/day was comparable to that seen with prednisone 0.75 mg/kg/day across primary and secondary efficacy endpoints. Importantly, no negative impact on biomarkers of bone health and no loss of linear growth were observed with vamorolone. Patients treated with prednisone experienced reductions in serum biomarkers of bone formation, which promptly recovered to baseline values when subjects were switched from prednisone to vamorolone after 24-weeks.

In October 2022, key opinion leaders further highlighted the **bone-related profile of vamorolone** in different presentations at the *World Muscular Society Congress 2022*.

Vamorolone was generally safe and well tolerated in clinical trials. The most commonly reported adverse events versus placebo were cushingoid features, vomiting and vitamin D deficiency. Adverse events were generally of mild to moderate severity. Vamorolone is an investigational medicine and is currently not approved for use by any health authority.

Expanding on areas of unmet needs such as bone health, Santhera has launched the educational website www.Do-MoreForDMD.com. This website is intended to raise awareness about the effects that DMD and the treatment with corticosteroids may have, and highlights the current care considerations from experts in different areas.

BUSINESS REVIEW

Pre-commercialization measures advancing

Santhera's U.S. subsidiary made further progress in establishing launch readiness through hiring into critical roles and focusing on priority projects. These include medical and market access activities, working closely with key clinical opinion leaders to advance education through presentations and scientific publications as well as engaging with patient advocacy groups. A similar program of activities has begun in Europe.

Upon approval, Santhera envisages launching vamorolone in the U.S. and selected European countries with its own organization. Ensuring prompt availability of vamorolone to patients and a successful implementation of the commercialization plans across regions, the Company will need to raise additional financial funds and may consider partnering.

Clinical studies initiated with vamorolone in broader age group of DMD patients and in Becker muscular dystrophy (BMD)

Started Phase 2 study evaluating vamorolone in a wider age range of patients with DMD. Health care professionals routinely prescribe glucocorticoid steroids in DMD to preserve muscle strength and function in ambulant boys, starting at an early stage. In most cases treatment is continued until deleterious side effects prevent further therapy and lead to early discontinuation. The clinical development program for vamorolone until now included patients 4 to <7 years old and, as part of the pediatric investigational plan (**PIP**) requested by EMA, a new Phase 2 study aims at collecting information on vamorolone outside this age range through inclusion of patients starting at an age of 2 years and up to 18 years (more details on page 21).

First patient dosed in FDA-funded study with vamorolone in BMD. Vamorolone has shown efficacy in the pivotal VISION-DMD study in DMD, a more severe but related disease, and, based on these findings and its mechanisms of action, this developmental compound may show a benefit in BMD. A Phase 2 pilot study is evaluating the safety, tolerability and exploratory clinical efficacy on motor function outcomes of vamorolone compared to placebo in males aged ≥18 and <65 years with BMD (more details on page 21). The study is funded by 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.

Lonodelestat development paused to focus on vamorolone advancement

Santhera's focus in the near-term is on advancing vamorolone through the regulatory process towards approval and on preparations for market entry. Consequently, and as previously communicated, Santhera has paused the development program for lonodelestat, its second clinical development candidate targeting pulmonary indications. Preparations for Phase 2 studies in acute respiratory distress syndrome (**ARDS**) and in cystic fibrosis (**CF**) are far advanced, however, continuation of the program will be subject to funding. Santhera explores various opportunities via collaboration and/or partnerships to resume the project as quickly as possible.

BUSINESS REVIEW

Raxone in LHON – Completion of post-authorization measures (PAMS) and French pricing agreement

Last part of PAMS completed in July 2022. Under the EU marketing authorization for Raxone (idebenone) in the treatment of Leber's hereditary optic neuropathy (**LHON**), Santhera was required to conduct PAMS, among others two Phase 4 studies. The *LEROS* study met the primary endpoint, the proportion of eyes with clinically relevant benefit after 12 months treatment with Raxone, with high statistical significance (p=0.002). *PAROS*, a prospective non-interventional study in routine clinical settings in LHON patients treated with Raxone, suggested a maintenance of treatment effect and showed a similar safety profile observed to that from the LEROS study. This clinically robust evidence of long-term effectiveness and safety confirms and extends previous findings and is expected to facilitate market access, allowing patients to benefit where currently no effective treatments alternatives are available. The last part of the PAMS has been completed in July 2022.

Sales resume in France after settlement of pricing and reimbursement negotiations. In 2019, Santhera outlicensed rights for the product outside North America and France to Chiesi Group. Since mid-2021 and until the recent settlement of reimbursement matters, Santhera has provided Raxone for LHON to patients in France for free. Following an agreement reached in February 2023 and the inclusion of Raxone on the list of reimbursed products, sales of Raxone have resumed in April 2023.

These important achievements open up opportunities for future life cycle management, which will include discussions with partners on expanding outlicensing to include North America and with drug regulators regarding U.S. approvability.

Strategic licensing agreements to further pipeline potential and raise non-dilutive funding

Santhera continues to pursue outlicensing agreements in the rare disease space to further the potential of its pipeline products, and for securing additional funding. Two agreements were closed in 2022:

Exclusive license agreement with Sperogenix for vamorolone in Greater China region. In January 2022, the Company entered into an exclusive license agreement for the Greater China area with Sperogenix Therapeutics, a China-based company specializing in orphan diseases. Under this agreement, Sperogenix has inlicensed 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 US-regulatory milestone payments amounting to a combined USD 20 million, as well as further double-digit royalties on net sales. Payments received to date include an upfront cash compensation received upon closing of the transaction in January 2022 and a subsequent tranche in April 2023. 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 in early 2025.

BUSINESS REVIEW

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 (**CMD**). 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 lonodelestat in cystic fibrosis (**CF**), halt the further development of omigapil, and pursue partnering to exploit the potential of it's the CMD gene therapy approach.

Evaluation of additional indications and partnering for vamorolone and lonodelestat

Santhera continues the pursuit of partnering opportunities for vamorolone and sees potential in additional indications outside DMD. Available data 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 in DMD, and the Company believes such features to be features of vamorolone's mechanism of action and therefore potentially beneficial in other diseases. 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. In parallel, the Company is open to collaborations with partners to assess and exploit the potential of lonodelestat in additional pulmonary diseases beyond ARDS and CF.

Santhera's next steps

Santhera's key objectives for the remainder of the year and into 2024 are approvals and launches of vamorolone in DMD in the U.S. and Europe along with raising additional financing to fund the Company's operations and ambitious commercialization plans.

References:
[1] Guglieri M et al (2022). JAMA Neurol. 2022;79(10):1005-1014. doi:10.1001/jamaneurol.2022.2480. Link.
[2] Mah JK et al (2022). JAMA Netw Open. 2022;5(1):e2144178. doi:10.1001/jamanetworkopen.2021.44178. Link.
[3] Guglieri M et al (2022) JAMA. doi:10.1001/jama.2022.4315
[4] Heier CR et al (2019). Life Science Alliance DOI: 10.26508
[5] Liu X et al (2020). Proc Natl Acad Sci USA 117:24285-24293

FINANCIAL REVIEW

Financial Performance, Activities & Outlook

In 2022, Santhera reported revenue of CHF 7.5 million and a net loss of CHF 71.1 million. Impacting top- and bottom-line results is a pricing and reimbursement agreement for Raxone which was reached with the French authorities. It allowed the Company to resume sales to be used for a staggered repayment of a liability resulting from a drug pricing dispute. Liquid funds (cash and cash equivalents) at year-end amounted to CHF 1.4 million. Throughout 2022, Santhera implemented several financing initiatives to secure operations and will continue to require significant amounts of cash for launch preparations for vamorolone and advancing its business.

Settlement reached on pricing and reimbursement for Raxone in France

Since its launch in 2015, Raxone was reimbursed in France for the treatment of patients with LHON under a temporary financing scheme. From August 2021, Santhera has supplied Raxone free of charge based on an agreement reached with the *Direction de la Sécurité sociale* (**DSS**) in France after the temporary pricing was challenged and Raxone was removed from the list of reimbursed drugs. Pricing and reimbursement discussions with the *Comité économique des produits de santé* (**CEPS**) started in 2021 and were still ongoing by the end of 2022. Due to uncertainties around the outcome of these negotiations, the Company accrued an additional CHF 8.1 million in 2022 towards a settlement, of which CHF 6.0 million was recognized against net sales and CHF 2.1 million as marketing and sales expenses. As of December 31, 2022, Santhera had recognized a total accrual amount of CHF 24.9 million in noncurrent provisions.

In February 2023, Santhera concluded the negotiations with the CEPS securing a final pricing reimbursement. The newly agreed price for Raxone in France is lower than the price applied under the temporary pricing scheme, leading to a settlement payment of approximately EUR 25 million (CHF 24.9 million), with 30% due in mid-2024 and the remainder one year later. The first payment is currently expected to be covered by the direct sales generated in France until mid-2024, while the second payment will be covered by direct sales thereafter. Outside of France and North America, Santhera has outlicensed Raxone to Chiesi Group.

2022 full-year revenue

In 2022, Santhera reported revenue from contracts with customers of CHF 7.5 million (2021: CHF -1.6 million). Net sales amounted to CHF -5.6 million (2021: CHF -5.0 million). The negative sales are attributable to an additional CHF 6.0 million that has been accrued and offset against sales in the context of reimbursement negotiations in France, as described above. In 2022, Santhera recognized revenue from outlicensing transactions in the amount of CHF 11.2 million (2021: CHF 1.1 million). This largely reflects an upfront milestone payment from the outlicensing of vamorolone for the Greater China Region with Sperogenix.

Cost of goods sold

Cost of goods sold amounted to CHF 3.6 million (2021: CHF 3.8 million) and represents continuing supply of Raxone and amortization of intangibles.

FINANCIAL REVIEW

Operating expenses and result

Operating expenses of CHF 56.1 million (2021: CHF 51.9 million) were higher, primarily due to additional intangible impairment and increased expenses related to vamorolone

Development expenses amounted to CHF 30.5 million (2021: CHF 29.7 million). The increase was primarily due to the additional intangible impairment expense of CHF 6.2 million related to lonodelestat. The remaining amount includes third-party clinical and regulatory services for finalizing data analysis and the assembly of the regulatory dossiers for vamorolone in DMD to U.S., EU and UK authorities.

Marketing and sales expenses were CHF 10.9 million (2021: CHF 9.3 million). The increase was a result of the additional accrual of CHF 2.1 million in relation to ongoing reimbursement negotiations in France, as described above, which was partially offset by lower pre-commercialization activities for vamorolone. The remaining amount includes market readiness preparations for vamorolone in the U.S.

General and administrative expenses of amounted to CHF 14.6 million (2021: CHF 12.7 million), for which the increase year-on-year reflects the addition of personnel in key functions in view of market readiness preparations for vamorolone in the U.S.

The operating result amounted to a loss CHF 52.0 million which is in a similar range year-on-year (2021: loss CHF 56.9 million).

Financial income and expenses

Financial income of CHF 5.9 million (2021: CHF 22.9 million) was lower than in the previous year due to a non-recurring recognized gain on exchange of 2017/22 Bonds in 2021. Financial expenses of CHF 24.6 million (2021: CHF 20.7 million) increased year-on-year due to the recognition of a higher change in fair value of financial instruments (net) which was only partially compensated by lower financing transaction costs, together with an increase in interest expense.

The net financial expense amounted to CHF 18.6 million (2021: financial income of CHF 2.2 million).

Net result

The net result 2022 was a loss of CHF 71.1 million or a basic net result of CHF -1.17 per share, compared to a net loss of CHF 55.5 million or CHF -1.62 per share for the year 2021.

Cash balance and cash flows

As of December 31, 2022, the Company had cash and cash equivalents of CHF 1.4 million compared to CHF 21.2 million as of December 31, 2021.

FINANCIAL REVIEW

Net cash outflow for operating activities was slightly lower year-on-year and amounted to CHF 29.8 million (2021: CHF 37.4 million). Net cash inflow from financing activities was lower year-on-year and amounted to CHF 14.0 million (2021: CHF 46.0 million). The increase in net additional proceeds from exchangeable notes were largely offset by the repurchase of convertible bonds. In comparison, 2021 saw a one-time income from a capital increase (2022: nil).

Shareholders' equity

Total consolidated net equity deficit as of December 31, 2022, amounted to CHF -43.7 million compared to total equity of CHF 1.3 million as of December 31, 2021, as a result of the net loss incurred for the period.

Equity-linked financings and share capital

In a difficult market environment throughout 2022 and to date, Santhera managed to reduce the balance sheet debt through repayment of a convertible bond and engaged in equity-linked financings to provide sufficient funding for operations and advancing its lead product towards approval. Presently, the Company still has treasury stock available for placement, subject to adequate market conditions.

Bond instruments. In February 2022, the senior unsecured convertible bonds (**2017/22 Bonds**) with a remaining amount of CHF 13.9 million were fully repaid and delisted from the SIX Swiss Exchange. Of the senior unsecured convertible bonds (**2021/24 Bonds**) maturing in August 2024, an aggregate amount of CHF 13.6 million was still outstanding at December 31, 2022,with CHF 6.0 million being repurchased during the year. Of the private convertible bonds (**2021/24 Private Bonds**) in the amount of CHF 15.0 million issued to Highbridge, CHF 3.0 million were converted into shares during the period, leaving a remainder of CHF 12.0 million at December 31, 2022. In summary, this significantly reduced total of convertible bonds during 2022 from CHF 48.5 million to approximately CHF 25.5 million, now maturing in August 2024.

Share capital and treasury stock. The Annual General Meeting (**AGM**) of June 30, 2022, approved a reduction of the nominal value of the shares from CHF 1.00 to CHF 0.01 per share. During 2022, a total of 20,712,700 new shares were issued for financing transactions and share-based compensation, with the unused portion held as treasury shares. In order to provide additional fundraising flexibility, the Extraordinary General Meeting (**EGM**) of November 29, 2022, approved an ordinary share capital increase by up to 40,000,000 registered shares by February 28, 2023, none of which were placed during the period under review. In summary and as of December 31, 2022, Santhera's issued shares amounted to CHF 753,205.10 and the Company held 9,438,017 treasury shares.

Post balance sheet date, in February 2023, Santhera completed the ordinary capital increase resolved by its shareholders on November 29, 2022, by issuing 40,000,000 shares. Santhera delivered 3,000,000 of these shares at CHF 0.75 per share. The remaining 37,000,000 shares were kept as treasury stock. As of April 26, 2023, the Company held 38,514,652 treasury shares to satisfy the ongoing facilities provided by Highbridge and to facilitate future equity-based financings.

FINANCIAL REVIEW

Authorized and conditional share capitals. During the year ended December 31, 2022, the Company's shareholders approved the increase of authorized and conditional capitals at the AGM and EGM, held in June and November, respectively. Shares were issued out of both capitals for financing transactions and to treasury shares. On the balance sheet date (December 31, 2022), Santhera's authorized capital amounted to 36,860,687 shares and its conditional capital amounted to 35,191,205 shares, each with a nominal value of CHF 0.01 per share. Santhera plans to use these shares for financing activities, if required.

Amendments of Highbridge facility to satisfy near-term cash requirements

In June 2022, the Company upsized its existing financing arrangement with certain funds managed by Highbridge Capital Management, LLC (Highbridge) by up to an additional CHF 40 million, allowing for periodic drawdowns (subject to certain conditions) and exchangeable by Highbridge for shares at a discount to the volume-weighted average price (**VWAP**). An initial drawdown tranche of CHF 20 million was received on June 3, 2022.

In September 2022, Santhera and Highbridge amended the existing financing arrangement to provide for the immediate drawdown of a CHF 10 million tranche. As part of this new money financing and further commitments, Santhera agreed on a new conversion price of CHF 1.20 for the remaining outstanding private convertible bond issued to Highbridge in 2021 and a new exercise price of CHF 0.80 per share for the existing warrants held by Highbridge. A further tranche of CHF 10 million available for drawdown is conditional on management achieving certain milestones and other conditions.

Post balance sheet date, in February 2023, Santhera and Highbridge further amended the existing financing arrangement. Under the amended agreement, Highbridge will provide up to CHF 22.2 million, thereof around CHF 2.2 million through the purchase of 3 million shares at CHF 0.75 per share and up to CHF 20 million through the existing financing arrangement, subject to conditions. This is intended to fund Santhera through to the PDUFA date in October 2023 when an FDA decision on vamorolone in the U.S. is expected.

The Company had outstanding exchangeable instruments as of December 31, 2022, in the aggregate amount of CHF 28 million (December 31, 2021: CHF 2 million), reflecting an issue during the year 2022 of CHF 40 million offset by repayments through exchange for shares.

Funding outlook

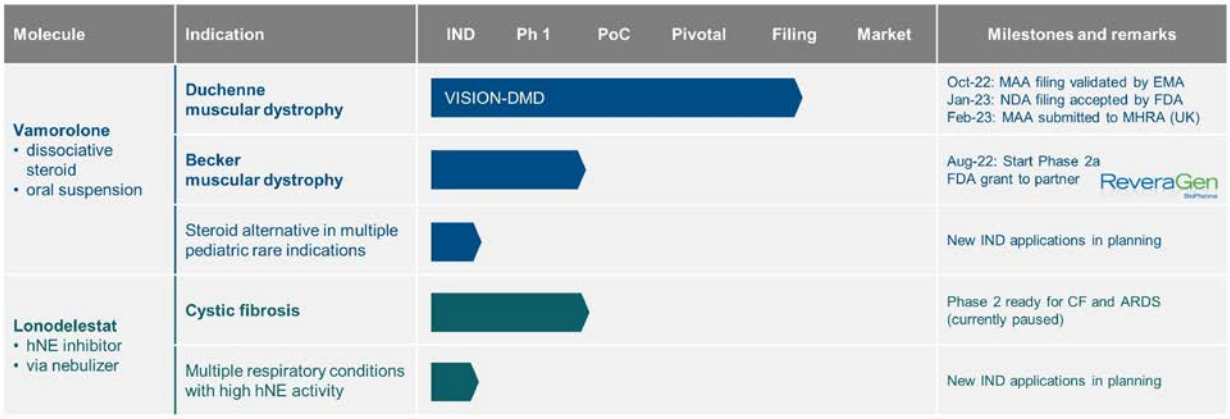
Santhera has treasury shares, conditional and authorized capitals which are available for future placement or issue, subject to market conditions. This, in combination with the recent drawdown from the amended Highbridge facility, is expected to provide a liquidity runway for operations into Q4-2023, or through to the PDUFA-date (October 26, 2023), when approval of vamorolone in the U.S. is expected.

In order to support the preparation and execution of the launch plans for vamorolone in the U.S. and Europe, Santhera will need to secure additional funds. Santhera is pursuing strategic options including but not limited to non-dilutive funding in the form of outlicensing agreements and/or the monetization of assets and, in parallel, is also evaluating debt financing, royalty financing, standby equity distribution agreement or, depending on market conditions, equity-based funding.

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.



Vamorolone worldwide license from ReveraGen in Sep 2020; Lonodelestat worldwide license from now Spexis in Feb 2018; Lonodelestat formerly POL6014
PoC: proof of concept; EMA: European Medicines Agency; MHRA: Medicines and Healthcare products Regulatory Agency

Vamorolone, our lead pipeline candidate, is under regulatory review for the treatment for Duchenne muscular dystrophy (**DMD**) in the U.S. and Europe. In January 2023, the U.S. Food and Drug Administration (**FDA**) accepted the filing of a new drug application (**NDA**) and Santhera expects an approval decision by October 26, 2023, the PDUFA target decision date. In the EU and the United Kingdom, corresponding marketing authorization applications (**MAA**) were submitted in September 2022 and February 2023, respectively, and approval decisions are expected in both regions in late 2023.

Lonodelestat, in early clinical stage, is an innovative new investigational drug for which Phase 2a studies are ready in the prime indication acute respiratory distress syndrome (**ARDS**) and in cystic fibrosis (**CF**). Owing to financial and human resource constraints, further work is currently paused.

Both vamorolone and lonodelestat represent **platform-type pipeline molecules**, each with potential for outlicensing or development in a range of additional indications beyond DMD, ARDS and CF, respectively, in collaboration with partners. For vamorolone, an FDA-funded Phase 2 clinical trial is ongoing in Becker muscular dystrophy (**BMD**), a progressive muscle wasting disease similar to DMD but usually milder. In addition, the product is being evaluated as a steroid alternative for multiple pediatric rare diseases in the planning phase. Beyond neuromuscular diseases like DMD and BMD, Santhera believes vamorolone to have the potential to treat certain other inflammatory diseases with high unmet medical need. 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.

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Vamorolone Highlights

Vamorolone, proposed as a dissociative steroid, has been developed for patients with Duchenne muscular dystrophy (DMD) who require an anti-inflammatory, muscle preserving treatment with a potentially differentiated safety and tolerability profile, starting at an early stage. The successfully completed clinical program aims at offering an alternative to the standard of care in DMD and culminated in the filing of a new drug application (NDA) to the U.S. FDA and marketing authorization applications (MAA) to health authorities in the EU and the UK. Subject to regulatory approvals, which are expected in late 2023, Santhera plans to launch vamorolone in the U.S. and first markets in Europe shortly thereafter. Vamorolone is an investigational medicine and is currently not approved for use by any health authority.

Duchenne muscular dystrophy

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, caused by mutations in specific regions (so-called exons) of the gene that encodes dystrophin in the cell nucleus, and primarily affects boys starting at an age between three and five years on average. DMD is characterized by a loss of a protein called dystrophin, which links the muscle cytoskeleton and extracellular matrix to maintain muscle integrity, acting as a shock absorber preventing muscle cell damage when muscle fibers contract and relax with use. This results in progressive muscle weakness, loss of muscle tissue and early illness and death due to cardio-respiratory failure. Patients are commonly unable to walk by their teenage years. Progressive respiratory muscle weakness leads to a need for mechanical ventilation to prolong the life of the patient beyond the late teenage years.

Current and emerging treatment options for DMD

Numerous potential treatments using different therapeutic approaches are in clinical development. Physicians can expect new options to treat DMD to emerge, allowing them to tailor therapies to individual needs including combining treatments to create the 'best mix' for each patient.

Glucocorticoids are effective anti-inflammatory agents and current standard of care in DMD. They are prescribed in order to slow the decline in muscle strength and function caused by DMD regardless of the genetic mutation underlying DMD. There is currently growing evidence to suggest that continued use of glucocorticoids may be beneficial beyond the time of loss of ambulation and in later stages of disease. 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 subtherapeutic doses to manage tolerability issues and eventually premature discontinuation of treatment. There is a high medical need for a treatment providing steroidal efficacy with a more benign tolerability and safety profile.

Non-steroid therapies include several approaches targeting the genetic defect or treating symptoms. Exon skippers (available to patients) aim to restore functional dystrophin. They work by 'skipping' over the mutated exon, thereby enabling the production of a truncated partially functional dystrophin protein. As exon skippers are specific for certain mutations, they typically only work in subpopulations of DMD-patients. Gene therapy approaches

NEUROMUSCULAR

aim to deliver functional copies of a shortened dystrophin ('mini- or micro-dystrophin') gene to the affected muscles. In clinical development programs, gene therapy is commonly evaluated in addition to a base therapy with glucocorticoids. While gene therapy holds promise for treating DMD, no such treatment has as of today gained marketing authorization. A range of developmental therapies address DMD disease symptoms with treatments focusing on muscle development and protection being most advanced.

All approaches share one objective: slow the progression of muscle weakness, improve quality of life and prolong life expectancy for individuals with this devastating disease. It is the combination of these different mechanistic approaches that may lead to improved and/or synergistic treatment strategies, possibly also altering the current standard of care. Glucocorticoids have long been a staple in the treatment of DMD and are expected to continue playing a vital role in combination therapies.

Novel mode of action of vamorolone drives its potentially differentiated clinical profile

Vamorolone is proposed as a first-in-class, dissociative steroidal anti-inflammatory drug candidate with a novel mechanism of action and pharmacological profile, i.e. it aims at having the structural properties required for its desired clinical action, but structural properties which are believed to limit side effects or safety concerns. Preclinical studies have shown that like other glucocorticoids vamorolone induces transrepression, thus retaining steroid-like anti-inflammatory properties. However, unlike glucocorticoids, vamorolone minimizes transactivation, the main cause of undesirable side effects of glucocorticoid drugs, through subtle modification to the steroidal backbone.

Collectively, this potentially 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 which, unlike other glucocorticoids, may translate into additional benefits that require further investigation.

Vamorolone was well tolerated in clinical studies, and its potentially differentiated safety profile may allow treating physicians to initiate and maintain treatment with vamorolone for longer than current standard of care. Based on its distinct structure, as well as its pharmacologic and clinical differences, vamorolone has been proposed as a new pharmacological class.

Positive pivotal VISION-DMD study establishing efficacy with statistical significance

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 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).

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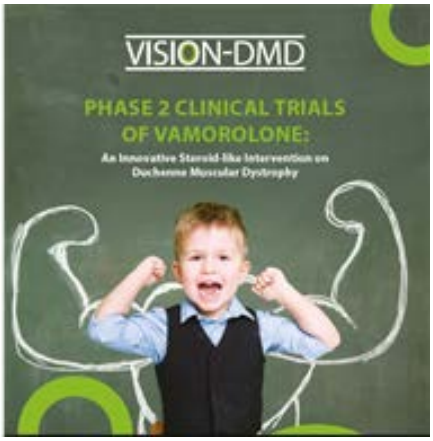

Vamorolone 6 mg/kg/day also met its secondary efficacy endpoints – including six-minute walk test (**6MWT**), time to run/walk 10 meters (**TTRW**) – and no statistically significant differences were observed between vamorolone and prednisone.

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 data indicate a potentially favorable and differentiated safety and tolerability profile of vamorolone

Based on the available clinical data, vamorolone is believed to offer the efficacy of glucocorticoids with a favorable safety and tolerability profile, which would allow physicians to maintain chronic treatment for longer and could therefore represent 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, the available clinical data shows clinically important differences indicating an improved safety profile:

- *Absence of deleterious effects on bone metabolism with the potential to reduce vertebral fractures.* Vamorolone has shown that it does not depress bone biomarkers, allows for bone biomarkers that were depressed because of prednisone treatment to recover after switching to vamorolone, and results also indicate fewer and less severe spinal fractures after long-term treatment with vamorolone compared to an external control study.
- *No stunting of growth.*
  No growth stunting has been observed in the pivotal VISION- DMD study and over the 30 months duration of extension treatment with vamorolone.
- *Reduced incidence, frequency and severity of behavior-related events.*
  Results showed a lower risk for developing clinically relevant behavior problems affecting the psychosocial adjustment of children with DMD compared with the current standard of care.
- *Lower frequency and severity of overall treatment emergent adverse events compared to prednisone.* While vamorolone and prednisone show comparable powerful anti-inflammatory properties, findings from clinical studies to date indicate a more benign tolerability and safety profile of vamorolone.

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Potential benefits of vamorolone in broader age groups of DMD patients studied in Phase 2 trial

An ongoing open-label, multiple dose Phase 2 study (VBP-006, ClinicalTrials.gov ID: NCT05185622) is evaluating the safety, tolerability, pharmacokinetics, pharmacodynamics, and exploratory efficacy of vamorolone 2 or 6 mg/kg/day over a treatment period of 12 weeks in steroid-naïve boys aged 2 to <4 years as well as boys aged 7 to <18 years who are currently untreated but may have taken glucocorticoids before. The study, which aims to enroll 54 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 2024. Defeat *Duchenne Canada*, a patient advocacy group providing leadership in research, advocacy and support in the fight to defeat DMD, is supporting the study.

Vamorolone in regulatory review – first U.S. and EU launches anticipated in late 2023

In the U.S., the Food and Drug Administration (**FDA**) has set October 26, 2023, as the Prescription Drug User Fee Act (**PDUFA**) target action date upon which approval of the new drug application (**NDA**) for vamorolone in DMD is expected. In the EU, a corresponding MAA has been validated and is under review by the European Medicines Agency (**EMA**) with an expected approval in late 2023. Subject to approvals, Santhera plans to launch vamorolone in both the U.S. and the EU in late 2023. In February 2023, post balance sheet date, Santhera submitted an MAA for vamorolone in DMD to the UK Medicines and Healthcare products Regulatory Agency (**MHRA**).

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 designations by the U.S. FDA and Promising Innovative Medicine (**PIM**) status from the UK MHRA for DMD.

Vamorolone in Becker muscular dystrophy – additional indications under evaluation

In August 2022, the first patient was dosed in a Phase 2a clinical trial of vamorolone in Becker muscular dystrophy (**BMD**). The trial is a randomized, double-blind, placebo-controlled study that intends to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and exploratory clinical efficacy on motor function out-comes of daily vamorolone compared to placebo over a treatment period of 24 weeks in 39 males with BMD between 18 and under 65 years of age (ClinicalTrials.gov ID: NCT05166109). Two thirds of participants will receive vamorolone and one third will receive placebo. Partner ReveraGen received a USD 1.2 million grant from the FDA to fund this Phase 2a clinical trial.

BMD is an inherited condition that 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, BMD has high clinical variability with patients of various ages. Some BMD patients lose the ability to walk as the disease progresses, while others do not. The severity of BMD ranges from nearly as severe as DMD to asymptomatic.

NEUROMUSCULAR

With regards to additional indications, Santhera will focus its development plan on rare pediatric conditions where a product profile such as displayed by vamorolone is expected to represent clear clinical benefit over current standards of care. In parallel, Santhera is evaluating vamorolone's potential in treating certain other inflammatory and non-inflammatory diseases with high unmet medical need beyond DMD and BMD, to be pursued with partners.

Achievements

- Feb 27, 2023: Submission of MAA to the UK MHRA for vamorolone in DMD.
- Jan 9, 2023: U.S. FDA accepted the NDA filing for vamorolone in DMD with October 26, 2023, PDUFA date.
- Oct 31, 2022: EMA validated the MAA for vamorolone in DMD.
- Oct 27, 2022: Completion of NDA submission to the U.S. FDA for vamorolone in DMD.
- Oct 3, 2022: Submission of a MAA to the EMA for vamorolone in DMD.
- Aug 22, 2022: First patient dosed in a Phase 2 pilot study to assess vamorolone in BMD.
- Mar 29, 2022: Start of rolling submission of NDA with the FDA for vamorolone in DMD.
- Jan 4, 2022: Exclusive license agreement for vamorolone in rare diseases in Greater China with Sperogenix Therapeutics

Near-term milestones

- Q3-2023: CHMP opinion on the vamorolone MAA to the EMA
- Oct 26, 2023: PDUFA target action date; U.S. FDA approval of the NDA for vamorolone in DMD expected.
- Late 2023: EU approval subject to a positive CHMP opinion.
- Late 2023: Subject to approvals, Santhera plans to launch vamorolone in both the U.S. and in Europe.

PULMONARY

Lonodelestat Highlights

Lonodelestat is a selective inhibitor of an enzyme called human neutrophil elastase (hNE). The compound is expected to provide a benefit for patients by addressing the acute or chronic inflammation caused by hNE which destroys pulmonary tissue over time. Following the successful completion of the Phase 1 program, Santhera prepared for Phase 2a studies in cystic fibrosis (CF) and acute respiratory distress syndrome (ARDS) but had to pause further work with lonodelestat for the time being due to financial and human resource constraints. Santhera is open to partnering for program continuation and/or outlicensing of lonodelestat.

Lung diseases associated with increased hNE activity

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 U.S. and Europe combined have been diagnosed with CF. Whereas CFTR-modulating therapies (a class of drugs that target specific defects in the CFTR protein so that the protein can work properly) 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 well as for many patients treated with CFTR modulators.

Acute respiratory distress syndrome (**ARDS**) is a serious pulmonary condition in which fluid builds up inside the tiny air sacs of the lungs, and surfactant breaks down. Surfactant is a foamy substance made by the body that keeps the lungs fully expanded so one can breathe. This fluid build-up and lack of surfactant prevent the lungs from properly filling with air and moving enough oxygen into the bloodstream and throughout the body. The lung tissue may scar and become stiff. ARDS may develop over a few days, or it can get worse very quickly, and supplying oxygen is the main treatment. [1]

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.

Lonodelestat targets elastase, a protease responsible for pulmonary damage

Lonodelestat, licensed from Spexis, is a selective inhibitor of hNE and is believed to have the potential to treat lung diseases associated with increased neutrophil elastase activity. Activated neutrophils (a type of white blood cell)

[1] https://www.nhlbi.nih.gov/health/ards

PULMONARY

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. Furthermore, inflammation is present in chronic and acute lung diseases which are associated with increased neutrophil elastase activity. In chronic diseases, inhibition of hNE may stop or slow damage to lung tissue, may help preserve lung function and may help improve the overall quality of life for affected individuals.

Lonodelestat 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.

Successful Phase 1 completion – development program paused

In two single dose studies completed for the treatment of CF, lonodelestat showed high drug concentrations in sputum and within the lung, complete inhibition of hNE after inhalation (via an optimized eFlow® nebulizer developed by PARI Pharma GmbH) as well as good tolerability. Results of a multiple ascending dose (**MAD**) study with lonodelestat in 32 patients 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. Lonodelestat demonstrated a good tolerability and no serious or severe (grade 3 or higher) adverse events were reported by the patients. To date, the 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 these studies, Santhera has prepared for two Phase 2a clinical trials with lonodelestat in ARDS and CF. Due to financial and human resource constraints, further work has been paused and continuation of the program will be subject to the Company having partnered and/or secured the requisite funding.

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 in broad range of indications

Chronic inflammation related to pathologically hNE levels is associated with a number of additional indications which provides a rationale for pipeline expansions and opportunities beyond CF and ARDS for a very potent and selective elastase inhibitor directly delivered to the lung via inhalation such as lonodelestat.

Next steps

- Partnering, granting licensing rights to lonodelestat or securing funding to resume and advance the development program for lonodelestat.

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 [2] with a vast background in the pharmaceuticals and biotech industry, from small and large companies.

Board of Directors

Thomas Meier, PhD, Chairman (from June 30, 2022)

Philipp Gutzwiller

Patrick Vink

Executive Committee

Dario Eklund, CEO

Andrew Smith, CFO

Stephanie Brown, President North America

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

Günther Metz, PhD, Head Business Development

Oliver Strub, General Counsel

Extended Management Team

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

[2] Details on the profiles of Board and Executive Committee 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

In CHF thousands	Notes	**December 31, 2022**	**December 31, 2021**
Assets			
Tangible assets	5	1,008	1,324
Intangible assets	6	59,206	64,596
Financial assets long-term		444	468
Deferred tax assets	8	3	88
Noncurrent assets		**60,661**	**66,476**
Prepaid expenses		513	1,069
Inventories	9	108	428
Trade and other receivables	10	1,091	1,936
Cash and cash equivalents	11	1,353	21,208
Current assets		**3,065**	**24,641**
Total assets		**63,726**	**91,117**
Equity and liabilities			
Share capital	12	753	54,608
Capital reserves and share premium		581,116	509,513
Retained deficit		(627,501)	(556,425)
Employee benefit reserve		2,722	(437)
Treasury shares	12	(94)	(5,020)
Translation differences		(682)	(911)
Total equity		**(43,686)**	**1,328**
Noncurrent convertible bonds	13.2	21,080	25,796
Noncurrent derivative financial instruments	13	4,335	3,683
Noncurrent warrant financial instruments	13	5,171	4,723
Noncurrent lease liabilities	15	607	1,203
Noncurrent provisions	16	24,961	16,808
Pension liabilities	25.2	1,844	4,794
Noncurrent liabilities		**57,998**	**57,007**
Trade and other payables	17	7,583	4,585
Accrued expenses	18	10,852	9,710
Income tax payable		553	266
Current lease liabilities	15	623	609
Current exchangeable notes	13.1	22,127	1,488
Current convertible bonds	13.2	0	13,880
Current derivative financial instruments	13	5,440	402
Current warrant financial instruments	13	2,225	1,650
Current provisions	19	11	192
Current liabilities		**49,414**	**32,782**
Total liabilities		**107,412**	**89,789**
Total equity and liabilities		**63,726**	**91,117**

Consolidated Income Statement

In CHF thousands (except per share data)	Notes	Year ended December 31,	
		2022	**2021**
Net sales	22.1,23	(5,578)	(4,963)
Revenue from out-licensing transactions	23	11,190	1,126
Net sales to licensing partner	22.1	1,861	2,242
Revenue from contracts with customers		**7,473**	**(1,595)**
Cost of goods sold		(3,592)	(3,767)
Of which amortization intangible assets		*(3,040)*	*(3,040)*
Other operating income		259	346
Development	24	(30,536)	(29,715)
Marketing and sales	24	(10,857)	(9,332)
General and administrative	24	(14,565)	(12,725)
Other operating expenses	24	(158)	(100)
Operating expenses		**(56,116)**	**(51,872)**
Operating result		**(51,976)**	**(56,888)**
Financial income	26.1	5,984	22,901
Financial expenses	26.2	(24,624)	(20,730)
Result before taxes		**(70,616)**	**(54,717)**
Income taxes	27	(460)	(809)
Net result		**(71,076)**	**(55,526)**
Basic and diluted net result per share	28	(1.17)	(1.62)

Consolidated Statement of Comprehensive Income

In CHF thousands	Notes	Year ended December 31, 2022	2021
Net result		**(71,076)**	**(55,526)**
Items that will not be reclassified to profit or loss in subsequent periods:			
Actuarial gains/(losses) on defined benefit pension plans	25.2	3,159	1,883
Items that may be reclassified to profit or loss in subsequent periods:			
Foreign currency translation differences		229	79
Other comprehensive result		**3,388**	**1,962**
Total comprehensive result		**(67,688)**	**(53,564)**

Consolidated Statement of Cash Flows

In CHF thousands	Notes	Year ended December 31,	
		2022	**2021**
Result before taxes		**(70,616)**	**(54,717)**
Depreciation and impairment of tangible assets		608	634
Amortization and impairment of intangible assets		9,250	3,090
Share-based compensation	21	5,452	2,761
Change in fair value of financial instruments, net		198	(8,656)
Realized gain on exchange of convertible bonds		0	(13,439)
Realized gain on repurchase of convertible bonds		(1,504)	0
Change in pension liabilities		104	507
Reversal of current provisions	19	(67)	(589)
Change in noncurrent provisions	16	8,153	16,808
Income taxes paid		(78)	(70)
Change in net working capital		1,394	1,767
Total financial result		19,793	16,485
Interest received		0	1
Interest paid		(2,530)	(1,941)
Net cash flow from/(used in) operating activities		**(29,843)**	**(37,359)**
Investments in tangible assets	5	(53)	(2)
Investments in intangible assets	6	(3,903)	(13)
Change in financial assets long-term		24	84
Net cash flow from/(used in) investing activities		**(3,932)**	**69**
Proceeds from capital increase		0	20,272
Proceeds from sale of treasury shares		474	81
Purchase of treasury shares		0	(56)
Proceeds from exercise of equity rights		37	0
Proceeds from exchangeable notes	13.1	33,000	22,000
Repayment of exchangeable notes	13.1	0	(3,500)
Proceeds from convertible bonds	13.2	0	13,792
Repayment of convertible bonds	13.2	(13,935)	0
Repurchase of convertible bonds	13.2	(4,511)	0
Financing transaction costs		(153)	(3,439)
Cost of issuance of capital		(273)	(2,389)
Payment of lease liabilities		(646)	(739)
Net cash flow from/(used in) financing activities		**13,993**	**46,022**
Effects of exchange rate changes on cash and cash equivalents		(73)	65
Net increase/(decrease) in cash and cash equivalents		**(19,855)**	**8,797**
Cash and cash equivalents at January 1		21,208	12,411
Cash and cash equivalents at December 31		**1,353**	**21,208**

Consolidated Statement of Changes in Equity

In CHF thousands	Notes	Share capital	Capital reserves and share premium	Retained earnings / (deficit)	Employee benefit reserve	Treasury shares	Translation differences	**Total**
Balance, January 1, 2021		19,430	480,005	(500,899)	(2,320)	(1,580)	(990)	**(6,354)**
Net result		0	0	(55,526)	0	0	0	**(55,526)**
Other comprehensive result		0	0	0	1,883	0	79	**1,962**
Total comprehensive result		**0**	**0**	**(55,526)**	**1,883**	**0**	**79**	**(54,241)**
Share-based compensation	21	0	2,465	0	0	0	0	**2,465**
Capital increase for financing transactions		33,512	1,133	0	0	(20,841)	0	**13,804**
Delivery of shares on conversion of Idorsia loans	13.1	0	2,905	0	0	3,595	0	**6,500**
Delivery of shares on conversion of exchangeable notes into shares	13.1	1,666	17,289	0	0	8,400	0	**27,355**
Delivery of shares on conversion of convertible bonds into shares	13.2	0	8,356	0	0	4,501	0	**12,857**
Delivery of shares for financing facility		0	0	0	0	233	0	**233**
Change in treasury shares		0	(251)	0	0	672	0	**421**
Cost of issuance of capital		0	(2,389)	0	0	0	0	**(2,389)**
Balance, December 31, 2021		**54,608**	**509,513**	**(556,425)**	**(437)**	**(5,020)**	**(911)**	**1,328**
Balance, January 1, 2022		54,608	509,513	(556,425)	(437)	(5,020)	(911)	**1,328**
Net result		0	0	(71,076)	0	0	0	**(71,076)**
Other comprehensive result		0	0	0	3,159	0	229	**3,388**
Total comprehensive result		**0**	**0**	**(71,076)**	**3,159**	**0**	**229**	**(67,688)**
Share-based compensation	21	0	5,452	0	0	0	0	**5,452**
Shares issued		19,134	0	0	0	(19,120)	0	**14**
Delivery of shares on conversion of exchangeable notes into Shares	13.1	0	6,878	0	0	3,264	0	**10,143**
Delivery of shares on conversion of convertible bonds into shares	13.2	0	2,582	0	0	2,192	0	**4,775**
Delivery of shares on settlement of convertible bonds interest expense	13.2	0	(202)	0	0	2,085	0	**1,884**
Delivery of shares for financing transactions		0	10	0	0	77	0	**87**
Delivery of shares for exercises of share-based compensation		0	105	0	0	0	0	**105**
Sale of treasury shares		0	490	0	0	3	0	**487**
Cost of issuance of capital		0	(273)	0	0	0	0	**(273)**
Adjustment for reduction of share nominal value to CHF 0.01		(72,989)	56,561	0	0	16,425	0	**0**
Balance, December 31, 2022		**753**	**581,116**	**(627,501)**	**2,722**	**(94)**	**(682)**	**(43,686)**

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 the 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 authorized for issue by the Board of Directors (**Board**) on May 31, 2023. They are subject to approval by the Annual General Meeting of Shareholders (**AGM**) on June 27, 2023.

2. Summary of Significant Accounting Policies

2.1 Basis of presentation

The Group's consolidated financial statements are prepared in accordance with International Financial Reporting Standards (**IFRS**). Except as described in 2.2 below, the accounting policies applied in these consolidated financial statements are consistent with those applied in the audited consolidated financial statements for the year ended December 31, 2021.

The presentation currency is Swiss francs (**CHF**). Amounts shown are rounded to the nearest CHF 1,000 unless otherwise indicated. Certain reclassifications have been made to prior years' amounts or balances in order to conform to the current year presentation.

The preparation of consolidated 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 Group may undertake in the future, however, actual results ultimately may differ from those estimates.

2.2 Changes in accounting policies

In 2022, there were no new IFRS standards that required adoption by the Group. The adoption of various amendments to existing standards and interpretations that became effective in 2022 had no material impact on the Group's overall results and financial position. The Group has not voluntarily early adopted new standards, interpretations or amendments that have been issued but are not yet effective. Among them is the amended International Accounting Standard (IAS) 1, specifically with respect to the classification of liabilities as current or non-current. This amendment is effective for annual reporting periods beginning on or after January 1, 2024.

This amendment to IAS 1 clarifies that the classification of liabilities as current or non-current should be based on rights that are in existence at the end of the reporting period and aligns the wording in all paragraphs to refer to the 'right' to defer settlement by at least twelve months and makes explicit that only rights in place 'at the end of the reporting period' should affect the classification of a liability.

The Company is currently evaluating the impact of this amendment on the financial statements. The change in policy will be applied retrospectively as required by the standard, meaning it will affect both the current and comparative figures.

2.3 Material uncertainties and ability to continue operations

The consolidated financial statements have been prepared under the going concern assumption despite material uncertainties present as of December 31, 2022, that may be perceived to be contrary to this assumption. In order to support ongoing operating activities including preparation for the launch of vamorolone, the Group's lead pipeline candidate, the Group requires additional funds subsequent to the expected regulatory approvals in late 2023 of vamorolone in the U.S., the EU, and UK.

Cash at hand and additional funds available as of December 31, 2022, and as of the date of issuance of these consolidated financial statements are sufficient to allow the Group to reach the value inflection point of expected FDA approval on the PDUFA date of October 26, 2023. However, material uncertainties remain as to the Group's ability to continue as a going concern after the PDUFA date and until December 31, 2023. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

Executing the Group's strategy significantly depends on the following:

- Notification by the European Medicines Agency (**EMA**) on whether the Marketing Authorization Application (**MAA**) submission for vamorolone in Duchenne muscular dystrophy (**DMD**) is approved, which is expected in late Q3-2023
- Notification by the U.S. Food and Drug Administration (**FDA**) on whether the New Drug Application (**NDA**) submission for vamorolone in DMD is approved, which is expected in Q4-2023
- Notification by the UK Medicines and Healthcare products Regulatory Agency (**MHRA**) on whether the MAA submission for vamorolone in DMD is approved, potentially in Q4-2023
- Additional funding to ensure the continuation of operations through to December 31, 2023
- Ability to settle current debt obligations

In October 2022, the EMA validated the MAA for vamorolone for the treatment of DMD. Validation confirms that the submission is complete and that the review by the EMA's Committee for Medicinal Products for Human Use (**CHMP**) has begun. Santhera expects the CHMP to complete the review and issue an opinion regarding approval to EMA's European Commission (**EC**) in late Q3-2023. Subject to EC approval, vamorolone will receive marketing authorization in all member states of the European Union, as well as in Norway, Liechtenstein, and Iceland. Pending approval, Santhera plans to launch vamorolone in the EU in Q4-2023.

In January 2023, the FDA formally accepted the NDA for vamorolone for the treatment of DMD for filing. The FDA has set October 26, 2023, as the Prescription Drug User Fee Act (**PDUFA**) target action date. The PDUFA date is the target date for the FDA to complete its review of the NDA. Furthermore, the FDA stated that it does not currently plan to hold an advisory committee meeting to discuss the application. Subject to approval, Santhera plans to launch vamorolone in the U.S. in Q4-2023.

In the event of approval, management and the Board plan to raise additional funds to finance ongoing development and may consider partnering to support commercialization activities in the U.S. and the EU. Should sufficient further funding not be available, the Group may review further organizational restructuring measures and reduction in business activities as well as consider the monetization of assets.

However, to ensure the execution of the Group's operating plan through to December 31, 2023, and beyond, additional funding will be needed. If the Group is unable to obtain the required funding to run its operations and to develop and commercialize its product candidates, the Group could be forced to delay, reduce or stop some or all of its research and development programs with the objective to ensure it remains solvent. The Group may seek additional funding through public or private financings or licensing agreements. The sale of additional equity may dilute existing shareholders.

Shareholders should note that whilst management and the Board 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, and that any transaction can be realized or that such transaction would generate sufficient funds to finance operations through to December 31, 2023. These material uncertainties may cast significant doubt about the ability of the Group to continue as a going concern.

However, management and the Board are of the view that it is more likely than not that the Group will continue to secure the additional funds needed in order to operate its business as planned with the objective to meet all of its obligations until December 31, 2023. Therefore, the consolidated financial statements have been prepared on a going concern basis.

2.4 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 (Deutschland) GmbH, Lörrach, Germany; Santhera Pharmaceuticals (USA), Inc., Burlington, US; Santhera Pharmaceuticals (Canada), Inc., Montréal, Canada; and Oy Santhera Pharmaceuticals (Finland) Ltd, Helsinki, Finland (in liquidation, expected to be dissolved during 2023). 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. (in liquidation, expected to be dissolved during 2023), Milano, Italy; 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.

2.5 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 Leber's hereditary optic neuropathy (**LHON**), outlicensing transactions and sales to licensing partners. Geographic revenue information is based on location of the customer or licensee.

2.6 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 consolidated 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 consolidated 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 consolidated statements of comprehensive income/equity.

2.7 Intangible assets

Patents, licenses, sublicenses, 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 lifetime of their patent or orphan drug protection (up to 20 years).

Inlicensing agreements or similar arrangements which require milestone payments dependent on the achievement of agreed objectives or performance targets as defined in the contracts are recognized as intangible assets when they become probable.

2.8 Software

Acquired software licenses are for internal use and are capitalized as intangible assets on the basis of the costs incurred to acquire and implement the specific software. Capitalized costs are amortized on a straight-line basis over their estimated useful lives (2 to 5 years).

2.9 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 (leased assets that meet criteria for capitalization)	2 to 6 years
Leasehold improvements	2 to 10 years

2.10 Impairment of assets

Assets include intangible assets not yet available for use, intangible assets with finite useful lives, tangible assets, and right-of-use assets. Assets not yet available for use are 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 and intangible assets with definite useful lives is performed at the end of each reporting period.

2.11 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. Credit risk arises from the possibility that counterparties to transactions may default on their obligations causing financial losses for the Group. Receivables are written off (either partly or in full) when there is no reasonable expectation of recovery. Where receivables have been written off, the Group continues to engage in enforcement activities to attempt to recover the receivable due.

2.12 Inventories

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

2.13 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 two categories:

Financial assets at fair value through profit or loss

This category includes 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 consolidated income statement in the period in which they arise.

Financial assets 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, which are initially measured at fair value plus transaction costs. Trade receivables are measured at the transaction price established. 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.

2.14 Interest income

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

2.15 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 assessments.

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 (below CHF 5 thousand). Lease payments on short-term leases and leases of low-value assets are recognized as expense over the lease term.

2.16 Cash and cash equivalents

Cash and cash equivalents include 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.

2.17 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.

2.18 Treasury shares

Treasury shares are purchased at cost and recognized as a deduction from equity. Gains or losses from subsequent sales is presented in equity.

2.19 Financial liabilities

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 consolidated income statement in the period the changes occur.

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

- the host contract is not an asset in the scope of IFRS 9 *Financial Instruments*
- 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 initially and subsequently measured at fair value, with all changes in fair value recognized in profit or loss.

Other financial liabilities measured at amortized cost

This category principally covers debt instruments and trade and other payables. The debt instruments are initially recognized at fair value less transaction costs and subsequently measured at amortized cost 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 consolidated income statement.

2.20 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 (or liabilities) in the consolidated 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.

2.21 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 exercise of warrants, equity rights plans, or conversion of Exchangeable Notes and the convertible bonds, were dilutive.

2.22 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 consolidated balance sheet for defined benefit pension plans is the present value of the defined benefit obligation at the consolidated 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 scheme

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

Share-based compensation

Santhera has established 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.

2.23 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.

2.24 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. To date, customer returns have not been material.

Revenue from outlicensing, including revenue from royalties

Outlicensing 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

Revenue associated with upfront payments or performance milestones is recognized in accordance with respective agreements.

2.25 Development expenses

Development expenses are charged to the consolidated income statement as incurred. Development costs are capitalized as intangible assets when it is probable that future economic benefits will flow to Santhera. Capitalized development costs 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. Intangible assets not available for use are tested annually for impairment.

3. Critical Accounting Estimates, Assumptions and Judgments

The preparation of consolidated 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 and in developing 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, which is derived primarily from licensing fees, estimates related to the refund of sales in France achievement of specified milestones and research services
- Estimates and assumptions used to test impairment of intangible assets not yet available for use
- Valuation of financial instruments measured at fair value through profit or loss
- Defined benefit pension schemes actuarial valuations where various assumptions on discount rates, salary increase rates and mortality rates, etc. bear significant uncertainties due to the long-term nature of the plans
- Provisions and accrued expenses are reasonably estimated based upon currently available information. However, given the inherent difficulties in estimating liabilities relating to clinical development, variable consideration, taxes, and possible litigation due to the uncertainty concerning both the amount and timing of future expenditures, additional costs may be incurred materially beyond the amounts accrued. The Company records a provision for its contingent obligations when it is probable that an outflow of resources will be required to settle the obligation and the amount can be reasonably estimated

4. Principal Currencies Translation Rates

	Average rates for year ended		Year-end rates	
	Dec 31, 2022	**Dec 31, 2021**	**Dec 31, 2022**	**Dec 31, 2021**
1 Euro (**EUR**)	1.0038	1.0823	0.9839	1.0339
1 US dollar (**USD**)	0.9548	0.9144	0.9233	0.9127
1 British pound (**GBP**)	1.1800	1.2559	1.1108	1.2330
1 Canadian dollar (**CAD**)	0.7339	0.7275	0.6814	0.7176

5. Tangible Assets

5.1 Movements in carrying value of tangible assets

In CHF thousands	Right-of-use assets vehicles	Right-of-use assets offices	Equipment	IT hardware	Leasehold improvements	**Total 2022**
Cost						
Balance, January 1	0	4,252	880	944	1,537	**7,613**
Additions	88	108	0	47	6	**249**
Disposals	(0)	(575)	(270)	(142)	(47)	**(1,034)**
Balance, December 31	**88**	**3,785**	**610**	**849**	**1,496**	**6,828**
Accumulated depreciation						
Balance, January 1	(0)	(3,419)	(731)	(917)	(1,222)	**(6,289)**
Additions	(12)	(386)	(30)	(27)	(109)	**(564)**
Disposals	0	575	270	141	47	**1,033**
Balance, December 31	**(12)**	**(3,230)**	**(491)**	**(803)**	**(1,284)**	**(5,820)**
Net book value, December 31	**76**	**555**	**119**	**46**	**212**	**1,008**

						Total 2021
Cost						
Balance, January 1	46	4,252	886	1,036	1,628	**7,848**
Additions	0	0	0	2	0	**2**
Disposals	(46)	0	0	(82)	(91)	**(219)**
Currency translation effects	0	0	(6)	(12)	0	**(18)**
Balance, December 31	**0**	**4,252**	**880**	**944**	**1,537**	**7,613**
Accumulated depreciation						
Balance, 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**
Currency translation effects	0	4	6	12	0	**22**
Balance, December 31	**(0)**	**(3,419)**	**(731)**	**(917)**	**(1,222)**	**(6,289)**
Net book value, December 31	**0**	**833**	**149**	**27**	**315**	**1,324**

6. Intangible Assets

6.1 Vamorolone

In November 2018, Santhera entered into an agreement to acquire an option from Idorsia Ltd, a biopharmaceutical company headquartered in Allschwil, Switzerland (**Idorsia**), for an exclusive sublicense of vamorolone, a non-hormonal steroid modulator for the treatment of DMD. The option to the sublicense, which was valued at CHF 34.8 million, was initially recognized as capitalized development costs. In September 2020, Santhera exercised the option to obtain worldwide exclusive rights to vamorolone in DMD and all other indications, whereupon a further CHF 12.4 million was added to capitalized development costs in connection with the consideration paid in exchange for the revised license rights. During 2022, an additional CHF 3.9 million of advanced regulatory-based milestones payments have been capitalized. Given that vamorolone is still in development and regulatory approval is pending, the intangible asset is deemed not available for use and therefore has not been amortized to date.

6.2 Lonodelestat

In February 2018, Santhera entered into a license agreement with Polyphor Ltd, Allschwil, Switzerland (now Spexis Ltd, "**Spexis**"), under which lonodelestat was inlicensed on an exclusive world-wide basis in any indication. Lonodelestat (previously known as POL6014), a highly potent and selective peptide inhibitor of human neutrophil elastase (**hNE**), is in development for the treatment of cystic fibrosis (**CF**). As consideration for the acquisition of the license, an initial payment of CHF 6.2 million was paid in 238,924 Santhera Shares and initially recognized as capitalized development costs. Given that lonodelestat is has not yet been approved and is still in development, the intangible asset is deemed not available for use and therefore has not been amortized to date, however tested for impairment at least annually. Development has been paused and following an impairment assessment the intangible cost has been impaired (see notes 7.2 and 20.1),

6.3 Idebenone

Idebenone, the active substance in marketed product Raxone is authorized in the European Union, Norway, Iceland, Liechtenstein, Israel, South Korea and Serbia for the treatment of LHON. The idebenone intangible asset was deemed available for use in September 2015 upon obtaining marketing authorization approval in the European Union. The estimated useful life of the asset was determined to be 10 years (until 2025) and has been amortized on a straight-line basis. In 2019, Santhera outlicensed Raxone to Chiesi Farmaceutici S.p.A., Parma, Italy (**Chiesi**) for the treatment of LHON and any other potential ophthalmological indications for all territories worldwide except the U.S., Canada, and France.

In early 2023, management committed to the sale of the idebenone intangible asset and has initiated an active program to locate a buyer. The sale is expected to be completed before the end of 2023. The disposal is consistent with the Group's strategic realignment to focus its activities on the vamorolone development in order to advance operational preparations for a potential launch of vamorolone in the U.S. and/or the EU as early as Q4 2023, subject to obtaining FDA and EMA approvals. The proceeds of disposal are expected to exceed the carrying amount of the asset and accordingly no impairment losses have been recognized. See Note 7.3 for more information on the idebenone impairment assessment.

6.4 Movements in carrying value of intangible assets

In CHF thousands	Vamorolone	Lonodelestat	Idebenone	Software and patents	**Total 2022**
Cost					
Balance, January 1	47,145	6,210	30,387	813	**84,555**
Additions	3,903	0	0	0	**3,903**
Disposals	(0)	(0)	(0)	(219)	**(219)**
Balance, December 31	**51,048**	**6,210**	**30,387**	**594**	**88,239**
Accumulated amortization					
Balance, January 1	(0)	(0)	(19,246)	(713)	**(19,959)**
Additions	(0)	(0)	(3,040)	(43)	**(3,083)**
Disposals	0	0	0	219	**219**
Impairment	(0)	(6,210)	(0)	(0)	**(6,210)**
Balance, December 31	**(0)**	**(6,210)**	**(22,286)**	**(537)**	**(29,033)**
Net book value, December 31	**51,048**	**0**	**8,101**	**57**	**59,206**

					Total 2021
Cost					
Balance, January 1	47,145	6,210	30,387	800	**84,542**
Additions	0	0	0	13	**13**
Disposals	(0)	(0)	(0)	(0)	**(0)**
Balance, December 31	**47,145**	**6,210**	**30,387**	**813**	**84,555**
Accumulated amortization					
Balance, January 1	(0)	(0)	(16,206)	(663)	**(16,869)**
Additions	(0)	(0)	(3,040)	(50)	**(3,090)**
Disposals	0	0	0	0	**0**
Impairment	(0)	(0)	(0)	(0)	**(0)**
Balance, December 31	**(0)**	**(0)**	**(19,246)**	**(713)**	**(19,959)**
Net book value, December 31	**47,145**	**6,210**	**11,141**	**100**	**64,596**

7. Impairment Test of Intangible Assets

Indefinite-lived intangible assets or intangible assets that are not yet available for use and not yet amortized, are reviewed for impairment at least annually, or when facts and circumstances warrant. Intangible assets available for use with a finite useful life are evaluated for potential impairment whenever facts and circumstances indicate that the asset's carrying value may not be recoverable. The Group currently has no intangible assets with indefinite useful lives.

Management performs its annual impairment assessment of intangible assets not yet available for use in the fourth quarter of each year and at each interim reporting date, and performs an impairment assessment of its finite-lived intangible assets to determine whether there is any indication that the intangible assets may be impaired by comparing the asset carrying value with its recoverable value. If the carrying value of the asset exceeds the recoverable value, which is calculated using a discounted cash flow model, then an impairment loss equal to the difference is recognized in the consolidated income statement.

The use of discounted cash flow models requires significant judgment and estimates, which are inherently uncertain and thus, actual results may differ from those estimates. Sensitivity analyses are performed around certain of these assumptions in order to assess the reasonableness of the assumptions and the resulting estimated recoverable values. The following summarizes the results of management's impairment assessment for each of the intangible assets.

7.1 Vamorolone

Management used a risk-adjusted net present value (**rNPV**) discounted cash flow model, a commonly used valuation method that accounts for the success rate of a drug in clinical development, to determine the vamorolone asset's value in use. The rNPV model considers the development and use patent period of the products. No terminal value was calculated since it is probable that when the exclusivity period ends sales could decrease. Key assumptions used in the rNPV model are as follows:

	Dec 31, 2022	Dec 31, 2021
Discount rate	12%	10%
Tax rate	15%	15%

The discount rate used considers the Group's estimated weighted average cost of capital. Other key assumptions for the calculation of the rNPV are based on 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 the probability of reaching the market at 80% (2021: 25%), reflecting the uncertainty as to whether a final and successful market registrations can be achieved, and considering standard industry success factor measures. The increase in probability of success reflects the achieved progression of development through to regulatory submission for review.

Management also performed a sensitivity analysis considering reasonable changes in the assumptions used, such as the discount rate. The results of the sensitivity analysis demonstrated that changes in the key assumptions would not cause the carrying value to exceed the recoverable value at December 31, 2022. Hence, the impairment test of the vamorolone intangible asset, as of December 31, 2022, did not result in the requirement to recognize an impairment loss. For the year ended December 31, 2021, the impairment assessment did not result in the recognition of an impairment loss.

7.2 Lonodelestat

Owing to resource constraints, Santhera's focus for months to come will be on advancing vamorolone through the regulatory process towards approval and on preparations for market entry. Consequently, Santhera has put the development program for lonodelestat on hold. Preparations for a Phase 2 study in an acute pulmonary indication are far advanced, however, continuation of the program will be subject to additional funding being available. Due to the inherent uncertainties in the research and development processes, intangible assets not available for use are particularly at risk of impairment if the project is not expected to result in a commercialized product. As a result, an impairment loss of CHF 6.2 million has been recognized as part of development expenses in the consolidated income statement for the year ended December 31, 2022. This impairment loss may be reversed in a subsequent period if the requirements for the reversal of an impairment loss are met. For the year ended December 31, 2021, the impairment assessment did not result in the recognition of an impairment loss.

7.3 Idebenone

Management used the standard net present value (**NPV**) discounted cash flow model to determine the idebenone asset's recoverable value. No terminal value was calculated since the asset's useful life ends in mid-2025. Key assumptions used in the NPV model are as follows:

	December 31, 2022	**December 31, 2021**
Discount rate	12%	10%
Tax rate	15%	15%

The discount rate used considers the Group's estimated weighted average cost of capital. Other key assumptions for the calculation of the NPV are based on 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 also performed a sensitivity analysis considering reasonable changes in the assumptions used, such as the discount rate. The results of the sensitivity analysis demonstrated that changes in the key assumptions would not cause the carrying value to exceed the recoverable value at December 31, 2022. Hence, the impairment test of the idebenone intangible asset, as of December 31, 2022, did not result in the requirement to recognize an impairment loss. For the year ended December 31, 2021, the impairment assessment did not result in the recognition of an impairment loss.

As introduced in Note 6.3, subsequent to December 31, 2022, management committed to the sale of the idebenone intangible asset. It is highly probable that the sale will be completed before the end of 2023. Therefore, it is expected that the asset's carrying value will be recovered principally through a sale transaction rather than through continuing use. The proceeds of disposal are expected to exceed the carrying amount of the asset and accordingly no impairment losses have been recognized for the year ending December 31, 2022.

8. Deferred Tax Assets

In CHF thousands	Dec 31, 2022	Dec 31, 2021
Temporary differences on inventory	3	88
Deferred tax assets recognized	**3**	**88**
Temporary differences on intangible assets, net	959	1,318
Temporary differences on convertible bonds	13	57
Tax loss carryforwards	(972)	(1,375)
Deferred tax liabilities recognized	**0**	**0**
Tax loss carryforwards	298,066	252,071
Of which recorded	(7,225)	(10,223)
Of which unrecorded	**290,841**	**241,848**
Unrecorded tax loss carryforwards expiring in:		
1 year	41,918	2,514
2 years	41,237	41,999
3 years	27,734	41,237
4 years	1,455	27,734
5 years	46,035	1,455
More than 5 years	99,306	98,772
Without expiration	33,156	28,137
Total unrecorded tax loss carryforwards	**290,841**	**241,848**

Due to the uncertainty surrounding the future results of operations and the uncertainty as to whether Santhera can use the tax 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 (CHF 1.8 million at December 31, 2022 and CHF 4.8 million at December 31, 2021) and noncurrent warrant liabilities (CHF 5.1 million at December 31, 2022 and CHF 4.7 million at December 31, 2021).

9. Inventories

In CHF thousands	Dec 31, 2022	Dec 31, 2021
Semi-finished goods	0	0
Finished goods	108	428
Total inventories	**108**	**428**

In August 2021, Santhera began supplying Raxone free of charge to patients with LHON in France after the French authorities challenged the temporary pricing of Raxone and removed Raxone from the list of reimbursed drugs. Inventory for Raxone provided as free of charge to patients in France is drawn from inventory previously fully impaired. Starting in April 2023, Raxone is once again on the list of reimbursed products in France, and meanwhile Santhera has resumed generating sales. See Note 16 for more information about the France pricing reimbursement.

10. Trade and Other Receivables

In CHF thousands	**Dec 31, 2022**	**Dec 31, 2021**
Trade receivables, gross	557	1,121
Other receivables	653	974
General allowance for expected credit losses on trade receivables	(19)	(23)
Specific allowance for expected credit losses on trade and other receivables	(100)	(136)
Total trade and other receivables, net	**1,091**	**1,936**

Trade receivables arise from Raxone product sales. Other receivables consist mainly of value added tax amounts due from local tax jurisdictions. Trade and other receivables are due within 30 to 120 days and bear no interest.

The Group uses an allowance matrix to estimate the allowance for expected credit losses on trade receivables. The expected credit loss rate is based on the Group's historical experience and the Group's expectation of economic conditions over the period until the trade receivables are expected to be paid. Where there is no reasonable expectation of recovery, a specific allowance is established to fully write off trade receivables and other receivables. Indicators that there is no reasonable expectation of recovery include, amongst others, the failure of a debtor to engage in a repayment plan.

The allowance matrices below show the expected credit losses on the Group's trade receivables at December 31, 2022 and December 31, 2021:

In CHF thousands	Current	0-30 days	31-60 days	61-90 days	91-180 days	181-360 days	>360 days	**Dec 31, 2022**
Expected credit loss rate	0.3%	0.9%	2.1%	4.2%	7.7%	11.5%	13.0 to 25%	
Trade receivables	220	211	0	0	0	0	126	**557**
Expected credit loss	1	2	0	0	0	0	16	**19**

								Dec 31, 2021
Expected credit loss rate	0.3%	0.9%	2.1%	4.2%	7.7%	11.5%	13.0 to 25%	
Trade receivables	376	528	8	51	103	48	7	**1,121**
Expected credit loss	1	5	0	2	8	6	1	**23**

The table below summarizes the changes in the allowance for expected credit losses for the years ending December 31, 2022 and December 31, 2021:

In CHF thousands	**2022**	**2021**
Allowance for expected credit losses, January 1	159	66
Reversals	(43)	0
Increases	3	93
Allowance for expected credit losses, December 31	**119**	**159**

11. Cash and Cash Equivalents

In CHF thousands	**Dec 31, 2022**	**Dec 31, 2021**
Cash at banks and on hand:		
in CHF	1,096	20,301
in EUR	130	288
in GBP	6	61
in USD	48	468
in CAD	18	24
other currencies	55	66
Total cash and cash equivalents	**1,353**	**21,208**
Of which: Short-term time deposits with maturity of less than three months	0	341

12. Share Capital

12.1 Ordinary share capital

At the AGM held on June 30, 2022, the shareholders approved a reduction of the nominal value of the Shares from CHF 1.00 to CHF 0.01 per Share, which is contained within the capital reserves and share premium in these consolidated financial statements. The legal process for this change was concluded in September 2022.

At the Extraordinary General Meeting (**EGM**) held on November 29, 2022, the shareholders approved an increase of ordinary share capital by up to CHF 400,000.00 to up to CHF 1,137,213.74 by issuing up to 40,000,000 fully paid-in registered shares with a par value of CHF 0.01 each.

During the year ended December 31, 2022, a total of 18,600,000 new Shares were issued for financing transactions, share-based compensation, and for treasury shares.

As of December 31, 2022, issued share capital totals CHF 753,205.10, consisting of 75,320,510 Shares with a nominal value of CHF 0.01 each. As of December 31, 2021, issued share capital totaled CHF 54,607,810, consisting of 54,607,810 Shares with a nominal value of CHF 1 each.

12.2 Treasury shares

During the year ended December 31, 2022, a total of 18,600,000 new Shares were issued to be held as treasury shares intended to be used for financing transactions and share-based compensation, and of which 14,181,862 treasury shares were used for the same.

As of December 31, 2022, the Company holds 9,438,017 treasury shares with a nominal value of CHF 0.01 each for a total value of CHF 94,380. As of December 31, 2021, the Company held 5,019,879 treasury shares with a nominal value of CHF 1 each for a total value of CHF 5,019,879.

12.3 Authorized shares

At the EGM held on December 15, 2021, the shareholders approved an increase of authorized shares to 27,303,905 and in a second step, by an additional 10,000,000 within three months from December 15, 2021, the date of the EGM. At the AGM held on June 30, 2022, the shareholders approved an increase of an additional 2,656,782 authorized shares (and its extension until June 29, 2024). At the EGM held on November 29, 2022, the shareholders approved an increase to authorized shares by CHF 100,000.00 (and its extension until November 28, 2024).

During the year ended December 31, 2022, a total of 3,100,000 shares were issued out of the authorized capital for new Share issuances intended to be held as treasury shares.

As of December 31, 2022, authorized share capital totals CHF 368,606.87, consisting of 36,860,687 shares with a nominal value of CHF 0.01 each. As of December 31, 2021, authorized share capital totaled CHF 27,303,905, consisting of 27,303,905 shares with a nominal value of CHF 1 each.

12.4 Conditional shares

Pursuant to Article 3b and Article 3c of the Company's Articles of Incorporation, the Company has conditional shares. The conditional shares represent conditional capital authorized for issuance for share-based compensation, under the exclusion of shareholders' pre-emptive rights, and financing transactions, respectively.

Article 3b conditional shares

During the year ended December 31, 2022, a total of 381,094 shares were issued out of Article 3b conditional capital for new Share issuances for share-based compensation. As of December 31, 2022, Article 3b conditional capital totals CHF 50,345.83 consisting of 5,034,583 shares with a nominal value of CHF 0.01 each. As of December 31, 2021, the total was CHF 5,425,677, consisting of 5,425,677 shares with a nominal value of CHF 1 each.

Article 3c conditional shares

At the EGM held on December 15, 2021, the shareholders approved an increase of Article 3c conditional shares to 21,878,228 and in a second step, by an additional 10,000,000 within three months from December 15, 2021, the date of the EGM. At the EGM held on November 29, 2022, the shareholders approved a further increase by CHF 100,000.00.

During the year ending December 31, 2022, a total of 1,721,606 shares were issued out of the Article 3c conditional shares for new Share issuances for financing transactions. As of December 31, 2022, Article 3c conditional capital totals CHF 301,566.22, consisting of 30,156,622 shares with a nominal value of CHF 0.01 each. As of December 31, 2021, the total was CHF 21,878,228, consisting of 21,878,228 shares with a nominal value of CHF 1 each.

13. Financial Liabilities

13.1 Equity-linked financing arrangements

Exchangeable Notes – Highbridge Capital Management

In July 2020, the Company and its subsidiary Santhera Pharmaceuticals (Schweiz) AG (**Santhera Schweiz**), entered into a subscription agreement with a fund managed by Highbridge Capital Management LLC (any such entity, **Highbridge**), providing for the issuance of senior secured Exchangeable Notes (**Exchangeable Notes**), subject to certain conditions and available in tranches, and exchangeable for Shares. The Exchangeable Notes are guaranteed by the Company and certain of its subsidiaries and secured by a comprehensive security package, including security over all shares of Santhera Schweiz and other subsidiaries of the Company, as well as over the Group's material intellectual property and other assets. In both 2021 and 2022, amendments to the subscription agreement have been made to increase the commitment principal from the original total.

The Highbridge Exchangeable Notes are considered 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 Exchangeable Notes are recognized as financial liabilities measured at amortized cost using the effective interest method and the embedded derivatives are recognized as financial liabilities measured at fair value through profit or loss during the year and during 2021.

In June 2022, the Company and Highbridge agreed on an amendment to increase the commitment principal amount by CHF 40 million (the "June Amendment"). The June Amendment provides for a tranche of CHF 20 million, which is unconditional and available for immediate drawdown. The remaining balance of CHF 20 million is divided into two tranches, each amounting to CHF 10 million, and subject to Highbridge consent for drawdown. Such a facility allows for periodic drawdowns (based on meeting certain criteria, an assessment of liquidity and other sources of funds, and sufficient Shares for exchanges available at the time) and can be exchanged by Highbridge for Shares at a discount to the volume-weighted average price (**VWAP**), subject to a variable floor. The maturity of these new Exchangeable Notes is May 2024. These new Exchangeable Notes pay a fixed interest, which Santhera can pay in cash or in kind at a rate of between 12% and 16% per annum.

In September 2022, Santhera and Highbridge agreed to amend the June Amendment, to allow for the immediate drawdown of a CHF 10 million tranche and amend certain provisions (the "September Amendment"). The new Exchangeable Notes can be exchanged by Highbridge for Shares at a discount to VWAP, subject to a reduced floor price. As part of this new money financing and further commitments, Santhera agreed on a new conversion price of CHF 1.20 for the remaining outstanding private convertible bond issued to Highbridge in 2021 (see Note 13.2 "2021/24 Private Bonds" for more information) and a new exercise price of CHF 0.80 per Share for the existing warrants held by Highbridge (see "Warrants – Highbridge" below for more information). A further tranche of CHF 10 million available for drawdown is conditional on management achieving certain milestones and other conditions.

For the year ended December 31, 2022, net proceeds from Exchangeable Notes totals CHF 33 million. As of December 31, 2022, the carrying value of the Exchangeable Notes totals CHF 22.1 million and the fair value of the embedded derivatives totals CHF 5.4 million. For the year ended December 31, 2021, proceeds from Exchangeable Notes totaled CHF 22 million. As of December 31, 2021, the carrying value of the Exchangeable Notes totaled CHF 1.5 million and the fair value of the embedded derivatives totaled CHF 0.4 million. AS at December 31, 2022 CHF 5.0 million remained available under the "September Amendment".

Warrants – Highbridge

In connection with the Highbridge Exchangeable Notes amendments of 2021, warrants were granted in two tranches equal to 15% of the total aggregate amount of the remaining existing facility, and new money tranches. In May 2021, a total of 984,769 warrants with a fair value of CHF 1.58 per warrant were granted. Each of the May warrants is exercisable at any time from the date of grant until March 15, 2026, for one Share at an exercise price of CHF 2.74. In September 2021, an additional 1,000,000 warrants with a fair value of CHF 1.05 per warrant were granted. Each of the September warrants is exercisable at any time until September 22, 2026, for one Share at an exercise price of CHF 2.00. The warrants are initially and subsequently recognized at fair value through profit or loss and are classified as financial liabilities until exercised by the holder.

The combined fair value of the warrants granted in 2021 was initially recognized as prepaid financing transaction costs. Once the Exchangeable Notes are issued, the prepaid financing transaction cost is expensed on a pro rata basis. As of December 31, 2022, prepaid financing transaction costs totals CHF 0.3 million. As of December 31, 2021, prepaid financing transaction costs totaled CHF 0.8 million.

In connection with the Highbridge Exchangeable Notes amendments agreed to in September 2022 (described above), a new exercise price of CHF 0.80 per Share was agreed for all the existing warrants held by Highbridge as of the September Amendment date.

As of December 31, 2022, the May 2021 and September 2021 warrants granted to Highbridge have a combined fair value of CHF 1.8 million and nil have been exercised. As of December 31, 2021, the combined fair value of the warrants totaled CHF 1.2 million and nil had been exercised. Refer to Note 13.3 for a summary of warrants issued and outstanding.

Warrants – equity raise

In September 2021, an equity offering transaction totaling CHF 20 million was entered into wherein investors subscribed (based on different subscription agreements) to a total of 12,670,078 Shares. As part of the equity raise transaction, Santhera issued one warrant for every two shares, for a total of 6,335,039 warrants granted with a fair value of CHF 1.05 per warrant at the grant date and an exercise price of CHF 2.00. The warrants are initially and subsequently recognized at fair value through profit or loss and are classified as financial liabilities until exercised by the holder.

As of December 31, 2022, the warrants granted in the September 2021 equity raise have a combined fair value of CHF 4.3 million and nil have been exercised. As of December 31, 2021, the combined fair value of the warrants totaled CHF 4.2 million and nil had been exercised.

Exchangeable Notes – Idorsia

In September 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 with a maturity date of September 1, 2021, to Idorsia. These Exchangeable Notes entitled Santhera to varying redemption options including settling the nominal value 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. The Exchangeable Notes issued to Idorsia were considered 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.

In September 2021, Santhera repaid the Idorsia Exchangeable Notes in full by transferring cash in the amount of CHF 3.5 million and 3,594,759 Shares with a value of CHF 6.5 million.

The table below summarizes the changes in financial liabilities arising from equity-linked financing arrangements and their financial instruments during the years ending December 31, 2022, and December 31, 2021:

In CHF thousands	Exchangeable Notes Highbridge	Exchangeable Notes derivatives Highbridge	Exchangeable Notes warrants Highbridge	Warrants equity raise	Exchangeable Notes Idorsia
Balance, December 31, 2020	**642**	**125**	**0**	**0**	**9,953**
Cash flows:					
Net proceeds	22,000	0	0	0	0
Repayments	0	0	0	0	(3,500)
Non-cash changes:					
Initial recognition of financial instruments at fair value	(8,462)	6,786	2,606	6,651	0
Nominal value of exchangeable notes converted into shares	(20,750)	0	0	0	(6,500)
Derecognition of financial instruments on conversion of exchangeable notes into shares	0	(6,509)	0	0	0
Effective interest/amortized cost/fair value adjustments	8,058	0	(1,404)	(2,470)	47
Balance, December 31, 2021	**1,488**	**402**	**1,202**	**4,181**	**0**
Cash flows:					
Net proceeds	33,000	0	0	0	0
Non-cash changes:					
Initial recognition of financial instruments at fair value	(8,773)	8,773	0	0	0
Nominal value of exchangeable notes converted into Shares	(14,325)	0	0	0	0
Issuance of notes against non-cash settlement	7,000	0	0	0	0
Derecognition of financial instruments on conversion of exchangeable notes into Shares	0	(2,551)	0	0	0
Effective interest/amortized cost/fair value adjustments	3,737	(1,184)	564	114	0
Balance, December 31, 2022	**22,127**	**5,440**	**1,766**	**4,295**	**0**

Equity-linked financial instruments valuation and sensitivity analysis

The equity-linked financing arrangements' financial instruments includes the embedded derivatives and warrants. The financial instruments valuations are based on Level 3 unobservable input parameters applying a simulation-based approach. The implied volatility, a significant valuation input, is determined by reference to the annualized daily trading volatility of Santhera's Shares for a historical lookback period equal to the expected remaining life of

the conversion right as of the valuation date. By construction, the compound financial instrument issued to Highbridge is assumed will be exercised by conversion to shares before maturity. For valuation purposes, it is therefore assumed that the expected exercise date is between the investing date and the maturity date.

The table below shows the implied volatility as of the valuation date:

Financial instruments	**Dec 31, 2022**	**Dec 31, 2021**
Equity-linked financing arrangements – derivatives	104%	73%
Equity-linked financing arrangements – warrants:		
Granted in May 2021	76%	78%
Granted in September 2021	72%	81%

The table below shows the impact that a 5% increase/decrease in volatility has on the fair value for each category of financial instrument and its effect on result before taxes as of the valuation date.

In CHF thousands		**Dec 31, 2022**	**Dec 31, 2021**
Financial instruments	Increase/decrease in volatility assumption	Effect on result before taxes	Effect on result before taxes
Equity-linked financing arrangements – derivatives			
Change in volatility	+5%	86	(5)
	-5%	(83)	4
Equity-linked financing arrangements – warrants			
Change in volatility	+5%	(29)	(40)
	-5%	22	50

13.2 Financing arrangements – convertible bonds

2017/22 Bonds

On February 17, 2017, Santhera issued senior unsecured convertible bonds with a maturity date of February 17, 2022 in the nominal value of CHF 60 million (**2017/22 Bonds**). The bonds were listed on the SIX and had interest bearing (5%) with a maximum term of five years and were convertible into Shares 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 could call the 2017/22 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 was at least 160% of the conversion price.

On March 25, 2021, Santhera announced an exchange offer for the 2017/22 Bonds. The holders of the 2017/22 Bonds who accepted the exchange offer would receive for each of their 2017/22 Bonds, one new bond issued in 2021 with a maturity in 2024 and 26 Shares on exchange.

With effective date May 4, 2021, upon settlement of the 2017/22 Bonds' restructuring, the aggregate nominal value of the 2017/22 Bonds was reduced from the original CHF 60 million to CHF 15.2 million. As consideration for the exchange, new bonds with a nominal value of CHF 30.3 million were issued (see below the "2021/24 Bonds").

As of December 31, 2021, the 2017/22 Bonds had a remaining aggregate nominal value of CHF 13.9 million and a carrying value of CHF 13.9 million.

During the year ended December 31, 2022, the remaining 2017/22 Bonds outstanding were fully repaid with effective date February 17, 2022 and delisted from the SIX Swiss Exchange.

2021/24 Bonds

On May 4, 2021, Santhera issued senior unsecured convertible bonds with a maturity date of August 17, 2024 in the nominal value of CHF 30.3 million (**2021/24 Bonds**). The bonds, listed on the SIX, have interest bearing (7.5%) with a maximum term of 39 months, and are convertible into Shares with a nominal value of CHF 1 each. The initial conversion price is fixed at CHF 3.0029. In addition, Santhera could call the 2021/24 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 2021/24 Bonds were offered as consideration for the 2017/22 Bonds. Accordingly, Santhera did not receive any cash proceeds upon issuance of the 2021/24 Bonds.

During 2021, 2021/24 Bonds with a total aggregate nominal value of CHF 10.7 million were converted into Shares. As of December 31, 2021, the 2021/24 Bonds had a remaining aggregate nominal value of CHF 19.6 million and a carrying value of CHF 15.4 million and the fair value of the derivatives totaled CHF 1.1 million.

During the year ended December 31, 2022, in connection with the Highbridge Exchangeable Notes September Amendment (described in Note 13.1 “Exchangeable Notes – Highbridge Capital Management”), approximately CHF 5.2 million of the CHF 10 million drawdown was used to repurchase the remaining outstanding 20221/24 Public Bonds issued to Highbridge. We repurchased CHF 6.0 million of bonds at a discount which resulted in a realized gain of CHF 1.5 million. This repurchase is recognized in the consolidated income statement for the year ended December 31, 2022.

During the year ended December 31, 2022, nil 2021/24 Bonds were converted into Shares. As of December 31, 2022, the 2021/24 Bonds have a remaining aggregate nominal value of CHF 13.5 million and a carrying value of CHF 11.6 million and the fair value of the derivatives totals CHF 0.8 million.

2021/24 Private Bonds

On October 14, 2021, in a private offering, Santhera issued senior unsecured convertible bonds to Highbridge with an aggregate nominal value of CHF 15 million (**2021/24 Private Bonds**). The terms of the 2021/24 Private Bonds are substantially similar to those of the 2021/24 Bonds, except for the conversion price fixed at CHF 1.76 and the floor price for purposes of interest payments fixed at CHF 1.25.

The proceeds from issuance of the 2021/24 Private Bonds was used for the repayment of the outstanding 2017/22 Bonds due on February 17, 2022.

As consideration for its commitment to subscribe for the 2021/24 Private Bonds, Highbridge received 1.5 million warrants with a fair value of CHF 1.05 per warrant at the date of issuance. Each warrant is exercisable at any time until September 22, 2026, for one Share at an exercise price of CHF 2.00. The warrants are initially and subsequently recognized at fair value through profit or loss and are classified as financial liabilities until exercised by the holder.

During 2021, nil 2021/24 Private Bonds and warrants were converted to Shares. As of December 31, 2021, the 2021/24 Private Bonds had an aggregate nominal value of CHF 15 million and a carrying value of CHF 10.4 million. As of December 31, 2021, the fair value of the warrants totaled approx. CHF 1 million and the fair value of the derivatives totaled CHF 2.6 million.

During the year ended December 31, 2022, in connection with the Highbridge Exchangeable Notes September Amendment (described in Note 13.1 “Exchangeable Notes – Highbridge Capital Management”), as part of the new

money financing and further commitments, Santhera agreed on a new conversion price of CHF 1.20 for the remaining outstanding 2021/24 Private Bonds and a new exercise price of CHF 0.80 per Share for the existing warrants held by Highbridge.

During the year ended December 31, 2022, 2021/24 Private Bonds with a total aggregate nominal value of CHF 3 million were converted into Shares. Nil warrants were exercised and converted into Shares. As of December 31, 2022, the 2021/24 Private Bonds have an aggregate nominal value of CHF 12 million and a carrying value of CHF 9.5 million. As of December 31, 2022, the fair value of the derivatives totals CHF 3.5 million and the fair value of the warrants totals CHF 1.3 million.

The following table summarizes the nominal and carrying values of the convertible bonds as of December 31, 2022, and December 31, 2021:

In CHF thousands					**Dec 31, 2022**		**Dec 31, 2021**	
	Offering	Currency	Interest	Maturity	Nominal value	Carrying value	Nominal value	Carrying value
2017/22 Bonds (ISIN: CH0353955195)	Public	CHF	5%	2022	0	0	13,945	13,880
2021/24 Bonds (ISN: CH0563348744)	Public	CHF	7.5%	2024	13,547	11,613	19,568	15,387
2021/24 Private Bonds	Private	CHF	7.5%	2024	11,971	9,467	15,002	10,409
Total convertible bonds					**25,518**	**21,080**	**48,515**	**39,676**
Less current portion of convertible bonds with short-term maturities						0		(13,880)
Noncurrent portion of convertible bonds with long-term maturities						21,080		25,796

The table below summarizes the changes in financial liabilities arising from convertible bond issuances and their financial instruments during the years ending December 31, 2022, and December 31, 2021:

In CHF thousands	2017/22 Bonds	2021/24 Bonds	2021/24 Bonds derivatives	2021/24 Private Bonds	2021/24 Private Bonds derivatives	2021/24 Private Bonds warrants
Balance, December 31, 2020	**57,875**	**0**	**0**	**0**	**0**	**0**
Redemption on exchange	(44,845)	0	0	0	0	0
Issue on exchange	0	30,270	0	0	0	0
Proceeds from bond issuance	0	0	0	15,002	0	0
Repurchased bonds	(1,210)	0	0	0	0	0
Initial recognition of financial instruments at fair value	0	(7,693)	7,693	(4,849)	3,274	1,575
Nominal value of bonds converted into Shares	0	(10,709)	0	0	0	0
Derecognition of financial instruments on conversion of bonds into Shares	0	0	(2,720)	0	0	0
Effective interest/amortized cost/fair value adjustments	2,060	3,519	(3,847)	256	(717)	(585)
Balance, December 31, 2021	**13,880**	**15,387**	**1,126**	**10,409**	**2,557**	**990**

(continued)	2017/22 Bonds	2021/24 Bonds	2021/24 Bonds derivatives	2021/24 Private Bonds	2021/24 Private Bonds derivatives	2021/24 Private Bonds warrants
Repayment of bonds	(13,935)	0	0	0	0	0
Repurchase of bonds	0	(6,014)	(45)	0	0	0
Nominal value of bonds converted into Shares	(10)	0	0	(3,031)	0	0
Derecognition of financial instruments on conversion of bonds into Shares	0	0	0	0	(1,117)	0
Effective interest/amortized cost/fair value adjustments	65	2,240	(251)	2,089	2,065	345
Balance, December 31, 2022	**0**	**11,613**	**830**	**9,467**	**3,505**	**1,335**

Convertible bonds financial instruments valuation and sensitivity analysis

The convertible bonds conversion rights, reset mechanisms, and early redemption options are considered embedded financial derivatives and requires initial recognition and subsequent measurement at fair value through profit or loss. The valuation of the embedded derivatives is based on Level 3 unobservable input parameters applying a simulation-based valuation approach. The implied volatility is determined by reference to the annualized daily trading volatility of Santhera's shares for a historical lookback period equal to the expected remaining life of the conversion right as of the valuation date.

The embedded conversion rights and reset mechanisms are directly related and have the same risk exposure. Therefore, these two derivatives are accounted for as a single financial instrument (i.e., a compound derivative). Due to the reset mechanisms, the compound derivative is not settled for a fixed number of Shares and hence classifies as a financial liability. The convertible bonds are recognized as financial liabilities measured at amortized cost using the effective interest method and the embedded derivatives are recognized as financial liabilities measured at fair value through profit or loss.

A key input to determine the valuation of the financial instruments, the identified volatility, is calculated based on the historical returns of the Company's Shares over a period commensurate to the duration of the instrument.

The table below shows the implied volatility as of the valuation date:

Financial instruments	**Dec 31, 2022**	**Dec 31, 2021**
Derivatives:		
2017/22 Bonds	-	34%
2021/24 Bonds	88%	81%
2021/24 Private Bonds	88%	64%
Warrants:		
2021/24 Private Bonds	72%	81%

The table below shows the impact that a 5% increase/decrease in volatility has on the fair value for each category of financial instrument and its effect on result before taxes as of the valuation date:

In CHF thousands		**Dec 31, 2022**	**Dec 31, 2021**
Financial instruments	Increase/decrease in volatility assumption	Effect on result before taxes	Effect on result before taxes
2021/24 Bonds – derivatives			
Change in volatility	+5%	(45)	(56)
	-5%	67	219
2021/24 Private Bonds – derivatives			
Change in volatility	+5%	(7)	(132)
	-5%	2	107
2021/24 Private Bonds – warrants			
Change in volatility	+5%	(45)	(60)
	-5%	45	75

13.3 Summary of warrants issued and outstanding

The table below summarizes the changes in warrants granted and outstanding in connection with financing arrangements during the years ending December 31, 2022, and December 31, 2021:

Warrants granted	Expiry date	Exercise price (CHF)	**Outstanding Dec 31,2021**	Exercised	Expired/ Forfeited	**Outstanding Dec 31,2022**
984,769	Mar 15, 2026	0.80	984,769	0	0	984,769
4,250,000	Sep 22, 2026	0.80	4,250,000	0	0	4,250,000
4,585,039	Sep 22, 2026	2.00	4,585,039	0	0	4,585,039
9,819,808			**9,819,808**	**0**	**0**	**9,819,808**

14. Fair Value of Financial Liabilities Arising from Financing Activities

The table below summarizes the fair value hierarchy of financial liabilities measured at amortized cost and measured at fair value through profit or loss as of December 31, 2022, and December 31, 2021. During the year ended December 31, 2022, there have been no transfers between the different hierarchy levels.

In CHF thousands	**December 31, 2022**				
	Carrying	Fair Value Hierarchy			
	value	Level 1	Level 2	Level 3	Total
Exchangeable Notes	22,127	0	21,127	0	**21,127**
2021/24 Bonds	11,613	10,900	0	0	**10,900**
2021/24 Private Bonds	9,467	0	6,860	0	**6,860**
Total financial liabilities at amortized cost	**43,207**	**10,900**	**27,987**	**0**	**38,887**
Derivative financial instruments	9,775	0	0	9,775	**9,775**
Warrant financial instruments	7,396	0	0	7,396	**7,396**
Total financial liabilities at fair value through profit or loss	**17,171**	**0**	**0**	**17,171**	**17,171**

In CHF thousands	December 31, 2021				
	Carrying	Fair Value Hierarchy			
	value	Level 1	Level 2	Level 3	Total
Exchangeable Notes	1,488	0	1,488	0	**1,488**
2017/22 Bonds	13,880	14,000	0	0	**14,000**
2021/24 Bonds	15,387	14,300	0	0	**14,300**
2021/24 Private Bonds	10,409	0	10,209	0	**10,209**
Total financial liabilities at amortized cost	**41,164**	**28,300**	**11,697**	**0**	**39,997**
Derivative financial instruments	4,085	0	0	4,085	**4,085**
Warrant financial instruments	6,373	0	0	6,373	**6,373**
Total financial liabilities at fair value through profit or loss	**10,458**	**0**	**0**	**10,458**	**10,458**

The Group applies the following assumptions in estimating fair values of financial liabilities carried on an amortized cost basis:

- The carrying amounts of short-term debt and current maturities of long-term debt, excluding finance lease obligations, are deemed a reasonable approximation of fair values
- Long-term debt, excluding finance lease obligations: Fair values of the Company's publicly traded convertible bonds are determined using quoted market prices (Level 1 inputs). For convertible bonds and Exchangeable Notes without available quoted market prices, the fair values are determined by reference to the present value of future contractual cash flows discounted at observable market interest rates for instruments with similar characteristics to those held by the Company (Level 2 inputs)

15. Lease Liabilities

In CHF thousands	**2022**	**2021**
Balance, January 1	1,812	2,696
Additions	157	0
Disposals	(89)	(115)
Interest expense	42	63
Payments including interest expense	(688)	(802)
Currency translation effects	(4)	(30)
Balance, December 31	**1,230**	**1,812**
Less current portion of lease liabilities	(623)	(609)
Noncurrent portion of lease liabilities	607	1,203

For the years ended December 31, 2022 and December 31, 2021, nil and CHF 6 thousand, respectively, has been recognized as operating expense in the consolidated income statement for short-term lease obligations and leases of low value. Total cash outflow for lease payments amounts to CHF 0.7 million for the year ended December 31, 2022 and CHF 0.8 million for the year ended December 31, 2021.

16. Noncurrent Provisions

Provisions are recognized where a legal or constructive obligation has been incurred which will probably lead to an outflow of resources that can be reliably estimated. The table below summarizes the changes in noncurrent provisions for the year ended December 31, 2022 and December 31, 2021:

In CHF thousands	**2022**	**2021**
Balance, January 1	16,808	0
Additions	8,153	16,808
Utilizations	0	0
Reversals	0	0
Balance, December 31	**24,961**	**16,808**

Noncurrent provisions relate to the French Social Security pricing reimbursement for sales of Raxone for LOHN in France. Since obtaining the marketing authorization for Raxone in 2014, Raxone had 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).

In December 2019, as a result of a subsequent refusal of the French Ministry for Solidarity and Health to register Raxone on the lists of reimbursed products for patients and hospitals, 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 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.

In 2021, based on additional data from post approval studies in LHON, Santhera submitted an updated dossier to the Commission de la Transparence (**CdT**) to determine the medical value of Raxone. In January 2002, the CdT ruled inter alia that the service médical rendu (**SMR**) was "moderate" (and no longer "insufficient"). The amélioration du service medical rendu (**ASMR**) was determined to be IV (while earlier 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 would not only apply to future sales of Raxone, but also form the basis to calculate a refund for past sales. 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. 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. Given the difficulties in identifying a single drug as the comparator drug, Santhera 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.

While negotiations with the CEPS continued on the pricing reimbursement, as of December 31, 2021, based on the then most recent communications with the CEPS, Santhera estimated the provision for pricing reimbursement to be a total of CHF 16.8 million, of which CHF 10.7 million was recognized as a reduction in revenues (resulting in negative net sales in 2021) and of which CHF 6.1 million was recognized within marketing and sales expenses.

In 2022, based on further communications with the CEPS and discussions with external counsel, the pricing reimbursement provision was increased by an additional CHF 8.1 million. Of the CHF 8.1 million additionally accrued, CHF 6.0 million was recognized against net sales and CHF 2.1 million was recognized as marketing and sales expenses. As of December 31, 2022, the Company has recognized an aggregate of CHF 24.9 million in noncurrent provisions.

In February 2023, Santhera concluded the negotiations with the CEPS securing a final pricing reimbursement. The newly agreed price for Raxone in France is lower than the price applied under the temporary pricing scheme, leading to a settlement payment of approximately EUR 25.4 million (CHF 24.9 million), with 30% due in mid-2024 and the remainder one year later. In the event that sale of idebenone (referred to in note 6.3) is not completed the first payment is currently expected to be covered by the direct sales generated in France until mid-2024, while the majority of the second payment will be covered by direct sales beyond mid-2025. Outside of France and North America, Santhera has out-licensed Raxone to Chiesi Group.

When Raxone was officially taken off the list of reimbursed products, in August 2021 Santhera agreed with the French authorities to provide Raxone free of charge to existing and newly diagnosed LHON patients in France 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. After a settlement has been reached with the CEPS in February 2023, starting in April 2023, Raxone is on the list of reimbursed products in France and Santhera has resumed receive consideration for the sales.

17. Trade and Other Payables

Trade and other payables are due within 30 to 120 days and bear no interest.

In CHF thousands	**Dec 31, 2022**	**Dec 31, 2021**
Trade payables	3,895	2,412
Other payables (non-financial)	3,688	2,173
Total trade and other payables	**7,583**	**4,585**

18. Accrued Expenses

In CHF thousands	**Dec 31, 2022**	**Dec 31, 2021**
Development programs	3,160	4,029
Liabilities to employees (non-financial)	2,564	2,654
Accruals for pricing and reimbursements	0	333
Accruals for audit, consulting and other	2,380	1,539
Accruals for interest expense	2,747	1,155
Total accrued expenses	**10,852**	**9,710**

19. Current Provisions

Current provisions mainly consist of restructuring liabilities. In 2020, the Group initiated a restructuring plan in response to the discontinuation of Puldysa development and mainly represent employee-related costs. The changes in restructuring liabilities for the year ended December 31, 2022 and December 31, 2021 are as follows:

In CHF thousands	**2022**	**2021**
Balance, January 1	192	2,034
Additions	0	0
Utilizations	(114)	(1,253)
Reversals	(67)	(589)
Balance, December 31	**11**	**192**

20. Commitments and Contingent Liabilities

20.1 Commitments to future payments

License agreements with ReveraGen and Idorsia

In September 2020, Santhera exercised the option to obtain worldwide exclusive rights to vamorolone in DMD and all other indications from ReveraGen Biopharma, Inc., a clinical-stage drug development company headquartered in Rockville, MD, U.S. (**ReveraGen**). Under the terms of the agreement, 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 also required to pay ReveraGen and Idorsia 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 due to ReveraGen and Idorsia for three additional indications amount to up to USD 205 million in aggregate. Upon commercialization of vamorolone, Santhera has also committed to pay ReveraGen and Idorsia tiered royalties ranging from a single-digit percentage to low double-digit percentage in total on the annual net sales of vamorolone.

On June 2, 2022, Santhera announced an amendment to the agreement with ReveraGen, resulting in a reduction of the USD 40 million milestone payment due upon FDA approval (expected in the second half of 2023) 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).

License agreement with Spexis

In February 2018, Santhera entered into a license agreement with Spexis, under which lonodelestat was inlicensed on an exclusive world-wide basis in any indication. Lonodelestat (previously known as POL6014), a highly potent and selective peptide inhibitor of hNE, is in development for the treatment of 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. Consistent with existing licensing agreements, such contingent payments have not been capitalized. Spexis may terminate this Agreement for material breach in its entirety in the event that the Joint Steering Committee resolves on or before September 30, 2022 that the initiation of the first pivotal clinical trial will not be feasible for any reason at the latest by June 30, 2023, or that none of Santhera, its sublicensees, or its or their affiliates, initiates the first pivotal clinical trial with

lonodelestat on or before June 30, 2023. In case of such termination, the rights licensed to Santhera will revert to Spexis.

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 outlicensed to Chiesi Group.

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 the TLA, the companies also 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 was terminated as of March 1, 2022. No further commitments are due under this agreement.

License agreement with Novartis

On June 30, 2007, Santhera entered into an agreement with Novartis Pharma AG, Basel, Switzerland (**Novartis**), under which it inlicensed omigapil. Santhera developed omigapil for the treatment of congenital muscular dystrophy (**CMD**). The agreement was terminated as of December 31, 2021. No further commitments are due under this agreement.

Agreement with financial advisor

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 sufficient to enable the company to maintain a going concern.

Contracts for clinical development and other

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

Agreement with France authorities

The Company secured a final pricing reimbursement agreement with the French authorities related to the sales to date of Raxone for the treatment of LHON in February 2023 as referred to in note 31. If, during the performance of the present agreement, a circumstance or element arises which affects the defined price or discounts this may lead to a new negotiation of the price and the discounts. In the event of a new negotiation, the initial prices and revisions apply until a new

amendment to the agreement is signed. If negotiations fail, the price is set by unilateral decision of the Committee économique after re-examination and determination of the discount due under the French Social Security Code (in force prior to July 1, 2021).

20.2 Accrued liabilities and contingent liabilities

Management believes that accrued expenses are reasonably estimated based upon currently available information. However, given the inherent difficulties in estimating liabilities relating to clinical development, variable consideration, taxes, and possible litigation due to the uncertainty concerning both the amount and timing of future expenditures, additional costs may be incurred materially beyond the amounts accrued. The Company records a provision for its contingent obligations when it is probable that an outflow of resources will be required to settle the obligation and the amount can be reasonably estimated.

21. Equity Rights Plans

Santhera has established equity rights plans to align the long-term interests of the members of the Board, the Executive Management, its employees, and selected consultants who are eligible to participate. Rights granted under these plans are equity-settled and recognized as share-based compensation expense in the consolidated income statement. Pursuant to Article 3b of the Company's Articles of Incorporation, the Company has conditional shares. The conditional shares represent conditional capital authorized for issuance for share-based compensation, under the exclusion of shareholders' pre-emptive rights, and financing transactions, respectively.

Detailed remuneration disclosures for members of the Board and the Executive Management as required by Swiss law are provided in the Compensation Report included in the Annual Report 2022 on pages 108 to 121.

21.1 Employee long-term Incentive Plan (LTIP)

The objective of the Long-term Incentive Plan (**LTIP**) is to align variable long-term compensation with Santhera's strategy. The LTIP is designed to motivate participating employees 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 employees and the Company with those of shareholders beyond share price appreciation. In addition, the LTIP aims to strengthen executives' loyalty to Santhera, their identification with the Company and their motivation to stay with the Company. The LTIP consists of various plans in place as well as certain legacy plans under which no further grants will be made, each of which are described below.

Employee Stock Option Plan (ESOP)

In 2010, Santhera introduced the Employee Stock Option Plan (**ESOP**), and its subsequent renewals; ESOP 2010 and ESOP 2015 to provide incentives to the Executive Management, employees and consultants helping to ensure their commitment to Santhera over the long-term.

The ESOP contains 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 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 before maturity. Unvested stock options of employees leaving the Company are forfeited under all stock option plans.

Stock option grants were made periodically at the discretion of the Board or as contractually agreed with employees. Following the introduction of the new 2021 incentive compensation plans, no further grants are made under the ESOP. Refer to "ELTIP 2021" and "ELTIP 2022" further below for more information.

The table below summarizes the changes in the ESOP 2010, ESOP 2015, and the total number of stock options outstanding under the two plans for the years ended December 31, 2022 and December 31, 2021:

	2022		**2021**	
Number of stock options	**ESOP 2010**	**ESOP 2015**	**ESOP 2010**	**ESOP 2015**
Outstanding, January 1	25,301	218,285	25,301	218,285
Exercised	0	0	0	0
Granted	0	0	0	0
Forfeited	0	(4,440)	0	0
Expired	(2,750)	0	0	0
Outstanding, December 31	**22,551**	**213,845**	**25,301**	**218,285**

Employee Share Appreciation Rights Plans (ESARP)

In 2016, Santhera introduced the Employee Share Appreciation Rights Plan (**ESARP**), and its subsequent renewals; ESARP 2016, ESARP 2017, ESARP 2018, and ESARP 2019, for the Executive Management and employees. Share Appreciation Rights (**SARs**) grants are made periodically at the discretion of the Board or as contractually agreed with employees. The ESARP contains customary provisions in respect of the adjustment or cancellation of SARs upon termination of employment, retirement, death, disability and certain corporate transactions. The ESARP are administered under the responsibility of the Board.

In 2021, the Company amended the LTIP with regard to the share-based instruments and discontinued granting SARs, which were replaced with a forward-looking, time- and performance- based plan, providing for a combination of stock options and Performance Share Units (**PSUs**). The combination of stock options and PSUs is decided annually by the Compensation Committee when issuing the annual grant under the LTIP. Refer to "ELTIP 2021" and "ELTIP 2022" below for more information.

The tables below summarize the changes in the various ESARP and the total number of SARs outstanding under these plans for the years ended December 31, 2022 and December 31, 2021:

Number of SARs	**Outstanding Jan 1, 2022**	Exercised	Granted	Forfeited	Expired	**Outstanding Dec 31, 2022**
ESARP 2016	43,312	0	0	0	0	**43,312**
ESARP 2017	230,817	0	0	(2,737)	0	**228,080**
ESARP 2018	315,376	0	0	(4,262)	0	**311,114**
ESARP 2019	1,011,188	0	0	(8,599)	0	**1,002,589**
ESARP 2020	410,958	0	0	(28,283)	0	**382,675**
Total	**2,011,651**	**0**	**0**	**(43,881)**	**0**	**1,967,770**

Number of SARs	**Outstanding Jan 1, 2021**	Exercised	Granted	Forfeited	Expired	**Outstanding Dec 31, 2021**
ESARP 2016	43,312	0	0	0	0	**43,312**
ESARP 2017	546,193	0	0	0	0	**546,193**
ESARP 2018	0	0	0	0	0	**0**
ESARP 2019	1,757,746	0	0	(335,600)	0	**1,422,146**
Total	**2,347,251**	**0**	**0**	**(335,600)**	**0**	**2,011,651**

Employee Long-term Incentive Plan 2021, 2022 (ELTIP 2021, ELTIP 2022)

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 consisting of a combination of stock options and PSUs. The ELTIP 2021 was subsequently renewed in 2022 under the Employee Long-term Incentive Plan (**ELTIP 2022**).

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.

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 9.00 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; 6) first patient visit on new lonodelestat 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.

The tables below summarize the changes in the ELITP 2021, ELTIP 2022 and the total number of stock options and PSUs outstanding under these plans for the years ended December 31, 2022 and December 31, 2021:

Number of PSUs and stock options	**Outstanding Jan 1, 2022**	Exercised	Granted	Forfeited	Expired	**Outstanding Dec 31, 2022**
PSUs	2,195,975	0	71,250	(246,462)	0	**2,020,763**
Stock options	504,975	0	71,250	(49,462)	0	**526,763**
Total ELTIP 2021	**2,700,950**	**0**	**142,500**	**(295,924)**	**0**	**2,547,526**
PSUs	0	0	3,642,200	(105,350)	0	**3,536,850**
Stock options	0	0	1,647,790	(45,150)	0	**1,602,640**
Total ELTIP 2022	**0**	**0**	**5,289,990**	**(150,500)**	**0**	**5,139,490**

Number of PSUs and stock options	**Outstanding Jan 1, 2021**	Exercised	Granted	Forfeited	Expired	**Outstanding Dec 31, 2021**
PSUs	0	0	2,276,725	(80,750)	0	**2,195,975**
Stock options	0	0	513,725	(8,750)	0	**504,975**
Total ELTIP 2021	**0**	**0**	**2,790,450**	**(89,500)**	**0**	**2,700,950**

21.2 New management incentive plan (NMIP)

In November 2022, the Company introduced the New Management Incentive Plan (**NMIP**) for the members of the Executive Management. Under the NMIP, the members of the Executive Management were granted incentive awards in the aggregate net target amount of CHF 2,181,901 (applying a CHF-USD foreign exchange rate of 1:1.05), to be paid in cash or settled in Shares at the discretion of the Board. 65% of the target amount will be payable if marketing authorization for vamorolone in the U.S. is achieved by December 31, 2023. 35% of the target amount will be payable if a positive CHMP opinion with respect to vamorolone is obtained by December 31, 2023. Payment of any award is subject to (i) the recipient being in continued employment with the Group and not under notice, (ii) the employment agreement of the recipient having been terminated by reason of retirement or disability, or (iii) the employment agreement of the recipient having been terminated by the employer without cause; in the latter case the targets are deemed to be achieved at 100%.

21.3 Board equity rights plans

In 2015, the Company introduced the Board Stock Option Plan (**BSOP 2015**) to provide incentives to members of the Board. The BSOP 2015 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 2015.

In July 2016, Santhera replaced the BSOP 2015 with the Board Share Appreciation Rights Plans (**BSARP 2017**) and its subsequent renewals; BSARP 2018, BSARP 2019, BSARP 2020. Similar to the ESARP described above, the BSARP

contains customary provisions in respect of the adjustment or cancellation of SARs upon termination, retirement, death, disability and certain corporate transactions.

In June 2021, the Company adopted the Board Restricted Share Plan (**BRSP**) and its subsequent renewal; BRSP 2021, BRSP 2022. Under the BRSP, 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 Share Units (**RSUs**), valued at their fair market value based on the Share price at the grant date and other factors. Under the BRSP, annual RSU grants are made as of the day following the Company's annual general meeting of shareholders. In case of a termination of a participant's Board mandate, non-vested RSUs vest pro rata based upon the service period of the participant. If the participant has committed a severe breach of his/her duties or if he/she voluntarily resigns during the (one-year) term of his/her mandate, all of his/her RSUs are forfeited (unless the Board decides otherwise). In case of a termination by reason of disability, unvested RSUs continue to vest after termination of the mandate. In case of termination by reason of death, unvested RSUs vest immediately. Any existing period during which the transferability of the RSUs is limited will continue to run.

The tables below summarize the changes in the BSOP 2015, BSARP 2017, BSARP 2018, BRSP 2021, and the total number of stock options, SARs and RSUs, collectively outstanding for the years ended December 31, 2022 and December 31, 2021:

Number of stock option, SAR, RSU	**Outstanding Jan 1, 2022**	Exercised	Granted	Forfeited	Expired	**Outstanding Dec 31, 2022**
BSOP 2015	13,562	0	0	0	0	13,562
BSARP 2017	15,120	0	0	0	0	15,120
BSARP 2018	62,659	0	0	0	0	62,659
BSARP 2019	78,944	0	0	0	0	78,944
BSARP 2020	165,332	0	0	0	0	165,332
BRSP 2021	356,250	(222,918)	0	0	0	133,332
BRSP 2022	0	0	376,922	0	0	376,922
Total	**691,867**	**(222,918)**	**376,922**	**0**	**0**	**845,871**

Number of stock option, SAR, RSU	**Outstanding Jan 1, 2021**	Exercised	Granted	Forfeited	Expired	**Outstanding Dec 31, 2021**
BSOP 2015	13,562	0	0	0	0	13,562
BSARP 2017	322,055	0	0	0	0	322,055
BRSP 2021	0	0	356,250	0	0	356,250
Total	**335,617**	**0**	**356,250**	**0**	**0**	**691,867**

During the year ended December 31, 2022, a total of 222,918 RSUs under the BRSP 2021 equity rights plan were exercised with an CHF 0.51 weighted average share price at the date of exercise.

21.4 Terms of stock options outstanding

The table below summarizes the terms of the total number of stock options outstanding under all plans for the years ended December 31, 2022 and December 31, 2021:

	December 31, 2022			December 31, 2021		
Exercise price range (CHF)	Number of stock options outstanding	Number of stock options exercisable	Weighted average remaining contractual life (years)	Number of stock options outstanding	Number of stock options exercisable	Weighted average remaining contractual life (years)
0.84	4,881,570	3,278,930	9.00	0	0	0
1.35 to 2.73	526,763	199,221	8.08	504,975	0	9.72
3.89 to 4.53	18,001	18,001	1.00	20,751	20,751	1.85
22.25	4,550	4,550	1.00	4,550	4,550	2.53
69.30	12,650	12,650	3.00	12,650	12,650	4.31
82.10 to 114.50	214,757	214,757	2.66	219,197	219,197	3.77
Total	**5,658,291**	**3,728,109**	**7.29**	**762,123**	**257,148**	**7.76**

21.5 Terms of SARs, PSUs, RSUs outstanding

The table below summarizes the terms of the total number of SARs, PSUs, and RSUs collectively outstanding under all plans for the years ended December 31, 2022 and December 31, 2021:

	December 31, 2022			December 31, 2021		
Exercise price range (CHF)	Number of SARs, PSUs, RSUs outstanding	Number of SARs, PSUs, RSUs exercisable	Weighted average remaining contractual life (years)	Number of SARs, PSUs, RSUs outstanding	Number of SARs, PSUs, RSUs exercisable	Weighted average remaining contractual life (years)
N/A	6,067,867	0	0.0	2,552,225	0	2.36
6.61 to 18.90	1,695,113	1,405,027	6.52	1,731,995	1,072,653	7.94
36.70 to 38.70	341,457	341,457	4.99	345,719	345,719	6.06
51.75 to 54.85	225,983	225,983	3.97	228,720	228,720	5.07
76.50 to 77.80	27,272	27,272	3.70	27,272	27,272	5.18
Total	**8,357,692**	**1,999,739**	**5.60**	**4,885,931**	**1,674,364**	**4.74**

21.6 Fair value of equity rights

The fair value of the equity rights granted under all plans is measured on the grant date applying valuation models such as the Finnerty's average strike put option model for RSUs, Monte Carlo model for PSUs and the Black-Scholes model for stock options. The following are the parameters used at the valuation date:

	Dec 31, 2022	Dec 31, 2021
Market price of stock	CHF 0.84 to CHF 1.42	CHF 1.26 to CHF 4.95
Exercise price	CHF 0.00 to CHF 1.48	CHF 1.35 to CHF 2.73
Weighted average fair value at grant date	CHF 0.0.53to CHF 1.41	CHF 0.80 to CHF 1.33
Expected volatility (based on selected biotech companies)	50% to 79%	74% to 77%
Risk-free interest rate (spot rate, CHF)	-0.20% to 0.53% p.a.	-0.30% p.a.
Term	1 to 10 years	3 years
Expected dividend yield	0%	0%

All equity rights granted under all plans are equity-settled and recognized as non-cash share-based compensation expense in the consolidated income statement over the period Santhera receives services.

21.7 Share-based compensation

The table below summarizes the classification of share-based compensation expense recognized in the consolidated income statement for the year ended December 31, 2022 and December 31, 2021:

In CHF thousands	2022	2021
Development	1,302	420
Marketing and sales	696	128
General and administrative	3,454	1,917
Total share-based compensation	**5,452**	**2,465**

Share-based compensation for the year ended December 31, 2022, includes the 2021 cash bonus that was approved and paid out in the form of stock options totaling 3,422,430, with a fair value of CHF 1.8 million, excluding social security payments. The bonus accrual of CHF 1.9 million at December 31, 2021 has been released within employee expenses in 2022, refer to Note 25.1. These stock options are fully vested at the July 1, 2022 grant date. During the year ended December 31, 2022, a total of 43,500 of these stock options were exercised with an CHF 1.00 weighted average share price at the date of exercise.

22. Segment and Geographic Information

22.1 Revenue from contracts with customers

The following table presents the Company's revenues from contracts with customers disaggregated by region.

In CHF thousands	2022			2021		
	Europe	Asia	**Total**	Europe	Asia	**Total**
Net sales	(5,578)	0	**(5,578)**	(4,963)	0	**(4,963)**
Revenue from out-licensing transactions	0	11,190	**11,190**	1,126	0	**1,126**
Net sales to licensing partner	1,861	0	**1,861**	2,242	0	**2,242**
Total revenue from contracts with customers	**(3,717)**	**11,190**	**7,473**	**(1,595)**	**0**	**(1,595)**

The negative net sales in Europe in 2022 and 2021 are attributable to adjustments totaling CHF 6 million and CHF 10.8 million, respectively, relating to the Raxone for LHON pricing reimbursement negotiations in France. See Note 16 for more information on the refund liability included in provisions as at December 31, 2022. Excluding these adjustments, net sales total approx. CHF 0.4 million in 2022 and CHF 9.1 million in 2021.

Revenue from out-licensing transactions relates to the exclusive licensing agreement with Sperogenix Therapeutics Limited for the development and commercialization rights to vamorolone for the treatment of DMD and all other rare disease indications in Greater China. See Note 23 for more information.

Net sales to licensing partner relate to Raxone for LHON sales in Europe. In 2019, Santhera outlicensed Raxone to Chiesi Group for the treatment of LHON and any other potential ophthalmological indications for all territories worldwide except the U.S., Canada, and France. For the year ending December 31, 2022, Raxone direct sales are to Italy, France, and Switzerland, with the majority of sales reached in Italy. For the year ending December 31, 2021, Raxone was sold in five European countries, with the majority of sales reached in France and Germany.

22.2 Noncurrent assets (excluding financial instruments and deferred taxes)

The following table presents the Company's noncurrent assets (excluding financial instruments and deferred tax assets) disaggregated by country.

In CHF thousands	**Dec 31, 2022**	**Dec 31, 2021**
Switzerland	60,116	65,884
United States and Canada	55	36
Total noncurrent assets (excluding financial instruments and deferred taxes)	**60,171**	**65,920**

The Switzerland noncurrent assets reported at December 31, 2022 are net of an impairment loss of CHF 6.2 million relating to the lonodelestat intangible asset. As introduced in Note 7.2, Santhera has put the development program for lonodelestat on hold indefinitely owing to resource constraints. The impairment loss has been recognized as part of development expenses in the consolidated income statement for the year ended December 31, 2022.

23. Outlicensing Agreement with Sperogenix Therapeutics Limited

On January 4, 2022, Santhera entered into an exclusive licensing agreement with Sperogenix Therapeutics Limited (**Sperogenix**), a China-based company specializing in orphan diseases. Under the terms of the agreement, Santhera grants Sperogenix exclusive development and commercialization rights to vamorolone for the treatment of DMD and all other rare disease indications in Greater China (including mainland China, Hong Kong, Macau, and Taiwan). As consideration, Santhera;

- received a non-refundable initial payment of USD 12 million;
- is entitled to contingent regulatory-based milestone non-refundable payments of up to USD 22 million; and
- is entitled to contingent sales-based milestone non-refundable payments of up to USD 80 million, in addition double-digit royalties on net sales

Santhera assessed whether the performance obligation(s) promised in the agreement are distinct goods or services or represent a series of distinct goods or services to determine whether revenue is recognized at a point in time or when (or as) the performance obligation is satisfied. According to this assessment, Santhera identified one distinct performance obligation:

- Santhera grants a right to use license to Sperogenix for the development and commercialization of vamorolone in the agreed territory. This performance obligation is satisfied at the point in time when Sperogenix is granted the right of use license

The regulatory-based milestone payments are contingent upon Santhera obtaining regulatory approval. Therefore, revenue is recognized when the regulatory milestones are achieved. For the sales-based milestone payments, as well as the further double-digit royalties on net sales, these considerations are contingent on Sperogenix achieving sales milestones. As such, revenue for the sales-based milestone payments is recognized if and when the sales threshold is met, with the same exception as for the royalties.

During the year ended December 31, 2022, Santhera recognized the non-refundable initial payment of USD 12 million (CHF 11.2 million) as revenue from outlicensing transactions.

24. Operating Expenses by Nature

In CHF thousands	**2022**	**2021**
External development expenses	17,878	21,382
Patent and license expenses	745	518
Marketing and sales expenses	6,343	8,513
Employee expenses	12,221	12,961
Share-based compensation	5,452	2,761
General and administrative expenses	5,579	1,723
Depreciation and amortization	608	3,724
Impairment of intangible assets	6,210	0
Facility related and lease expenses	165	190
Other	915	100
Total operating expenses	**56,116**	**51,872**

25. Employee Expenses and Benefits

25.1 Employee expenses

In CHF thousands	**2022**	**2021**
Wages and salaries	9,449	10,285
Social security and other personnel-related expenses	2,668	2,169
Defined benefit pension plans change in employee benefit reserve	104	507
Share-based compensation	5,452	2,761
Total employee expenses	**17,673**	**15,722**

Average number of full-time equivalents throughout the year	46.5	47.1
Full-time equivalents at year-end	45.8	39.4
Total headcount at year-end	51.0	43.0

Employees with part-time and full-time permanent working contracts are considered full-time equivalents.

25.2 Pension plan

In accordance with the Swiss pension fund law "Federal Act on Occupational Old Age, Survivors' and Invalidity Pension Provision" (**OPA**), all employees of Santhera Pharmaceuticals Holding AG, and Santhera Pharmaceuticals (Schweiz) AG, both in Pratteln, 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 *Employee Benefits* 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 plan's funded status as measured under Swiss **OPA** rules.

The tables below present the respective calculations performed by an independent actuary as required by IAS 19:

Changes in defined benefit obligations

In CHF thousands	**2022**	**2021**
Present value of obligation, January 1	17,492	22,831
Current employer service cost	1,065	1,355
Interest cost	34	20
Employee contributions	589	569
Benefits paid / transfer payments	991	(5,687)
Insurance premiums	(139)	(136)
Remeasurements (refer to details below)	(2,503)	(1,460)
Present value of obligation, December 31	**17,529**	**17,492**
Remeasurements:		
Effect of changes in demographic assumptions	0	(814)
Actuarial (gain)/loss due to changes in financial assumptions	(3,751)	(237)
Actuarial (gain)/loss due to experience adjustments	1,248	(409)
Subtotal (gain)/loss	**(2,503)**	**(1,460)**
(Return)/loss on plan assets, excluding interest income	(656)	(424)
Total remeasurements in other comprehensive income (gain)/loss	**(3,159)**	**(1,883)**

In 2021, demographic assumptions changed due to increase in lump sum probabilities and reduction of disability probabilities.

Changes in plan assets

In CHF thousands	**2022**	**2021**
Fair value of plan assets, January 1	12,698	16,661
Interest income on assets	26	15
Employer contributions	863	853
Employee contributions	589	569
Benefits paid/transfer payments	991	(5,687)
Insurance premiums	(139)	(136)
Remeasurements (return/(loss) on plan assets, excluding interest income)	657	423
Fair value of plan assets, December 31	**15,685**	**12,698**

Net defined benefit asset/(obligation)

In CHF thousands	**Dec 31, 2022**	**Dec 31, 2021**
Present value of obligation	17,529	17,492
Fair value of plan assets	15,685	12,699
Net defined benefit asset/(obligation)	**(1,844)**	**(4,794)**

Plan asset allocation

In CHF thousands	**Dec 31, 2022**	**Dec 31, 2021**
Cash	267	140
Debt instruments	6,493	4,127
Equity instruments	5,395	4,203
Property	3,200	2,412
Others	330	1,816
Total fair value of plan assets	**15,685**	**12,698**

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

	2022	**2021**
Discount rate	2.0%	0.20%
Disability probabilities	80%	80%
Lump sum probabilities	30%	30%
Expected future salary increases	2.0%	1.5%

The table below shows the impact that changes to key assumptions have on the defined benefit obligation and the gross (net) service cost as of the pension plan valuation date:

In CHF thousands		**December 31, 2022**		**December 31, 2021**	
Sensitivity analysis	Increase/decrease in assumption	Defined benefit obligation	Gross (net) service cost	Defined benefit obligation	Gross (net) service cost
Discount rate	+0.25%	(422)	(15)	(566)	(64)
	-0.25%	443	17	605	68
Salary	+0.25%	88	(16)	105	16
Life expectancy	+1 year	247	15	352	27

Mortality rate

	2022	2021
Mortality assumptions are based on the BVG 2020 generation table life expectancy at age 65 (in years):		
Male	22.7	22.7
Female	24.5	24.5

Expected employer contributions, benefit obligations for the pensioners, duration of plan liabilities were as follows:

In CHF thousands (except duration of plan liabilities)	2022	2021
Expected employer contributions for the subsequent year	934	874
Benefit obligations for the pensioners	2,024	1,811
Duration of plan liabilities (in years)	14.3	16.6

26. Financial Income/(Expense)

26.1 Financial income

In CHF thousands	2022	2021
Interest income on cash and cash equivalents	0	1
Realized and unrealized foreign exchange gains, net	972	438
Change in fair value of financial instruments, net	2,891	9,023
Realized gain on Exchangeable Notes interest rate reset	617	0
Realized gain on exchange of 2017/22 Bonds	0	13,439
Realized gain on repurchase of 2021/24 Bonds	1,504	0
Total financial income	**5,984**	**22,901**

26.2 Financial expense

In CHF thousands	2022	2021
Interest and make-whole expenses	(20,147)	(16,368)
Interest expense on lease liabilities	(42)	(55)
Change in fair value of financial instruments, net	(3,088)	(367)
Financing transaction costs	(153)	(3,439)
Realized and unrealized foreign exchange losses, net	(1,194)	(501)
Total financial expense	**(24,624)**	**(20,730)**

27. Income Taxes

In CHF thousands	**2022**	**2021**
Current income tax expense	(375)	(62)
Deferred tax expense	(85)	(747)
Total income tax expense	**(460)**	**(809)**

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

In CHF thousands	**2022**	**2021**
Result before taxes	(70,616)	(55,526)
Tax expense at expected Group tax rate of 13.45% (2021: 13.45%)	9,498	7,468
Effect of tax rate difference Group versus local	1,047	81
Foreign withholding tax non-recoverable	(333)	0
Effect of nondeductible expenses	(84)	(691)
Utilization of previously unrecognized tax losses	38	13
Unrecognized deferred taxes	(10,626)	(7,680)
Effective income tax expense	**(460)**	**(809)**

According to currently applicable Swiss tax law, the period to offset tax loss carryforwards against taxable profit is limited to seven years.

28. 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.

In CHF thousands (except share and per share data)	**2022**	**2021**
Net result attributable to shareholders	(71,076)	(55,526)
Weighted average number of shares used in basic net result per share	60,927,311	34,169,858
Basic and diluted net result per share	**(1.17)**	**(1.62)**

Basic and diluted net result per share excludes Shares to be issued upon the future conversion of the Exchangeable Notes and convertible bonds, as they would be anti-dilutive. Any future conversions of the Exchangeable Notes and convertible bonds to Shares may have a dilutive effect on the basic net result per share in the future.

29. Transactions with Related Parties

29.1 Board and Executive Management compensation

The Company's related parties include members of the Board and Executive Management. The table below summarizes the Board and Executive Management compensation expense for the year ended December 31, 2022, and December 31, 2021:

In CHF thousands	**2022**	**2021**
Short-term employee benefits (wages, salaries, allowances)	2,381	1,783
Post-employment benefits (pension fund and defined benefit contributions)	954	513
Share-based compensation	5,494	2,391
Total Board and Executive Management compensation	**8,829**	**4,687**

Share-based compensation as disclosed in this note is based on fair values at the grant date of the equity right applying the parameters disclosed in Note 21.7.

29.2 Transactions with members of the Board and Executive Management

For the years ended December 31, 2022 and December 31, 2021 there are no loans outstanding or guarantee commitments granted to members of the Board and Executive Management.

30. Risk Management Objectives and Policies

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

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 U.S. 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.

30.1 Foreign currency exchange rate risk

Santhera holds cash and cash equivalents in two major currencies CHF and EUR 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.

In CHF thousands		**Dec 31, 2022**	**Dec 31, 2021**
	Increase/decrease in volatility assumption	Effect on result before taxes	Effect on result before taxes
Exposure to cash and cash equivalents denominated in EUR:			
Change in foreign currency rate	+5%	(7)	(12)
	-5%	7	12

30.2 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 meet its financial needs over time.

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

In CHF thousands		**Dec 31, 2022**	**Dec 31, 2021**
	Increase/decrease in volatility assumption	Effect on result before taxes	Effect on result before taxes
Exposure to cash and cash equivalents:			
Change in interest rate	+50 basis points	(7)	(106)
	-50 basis points	7	106

30.3 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 based on default probabilities and the ageing of outstanding invoices.

30.4 Liquidity risk

Prudent liquidity risk management implies maintaining sufficient cash and cash equivalents. Currently, the Company is financed through equity and debt financing as disclosed in Note 13. Santhera calculates on a rolling basis the needs for aligning the current expenses against the need for optimized financial investments.

30.5 Contractual undiscounted cash flows for financial liabilities

In CHF thousands	December 31, 2022					
	On demand	Less than 3 months	3 to 12 months	1 to 5 years	Total	Carrying value
Convertible bonds	0	0	0	25,518	25,518	21,080
Exchangeable Notes	0	27,675	0	0	27,675	22,127
Trade payables	0	3,895	0	0	3,895	3,895
Provisions	0	0	11	24,961	24,972	24,972
Accrued expenses	0	8,288	0	0	8,288	8,288
Lease liabilities	0	166	463	679	1,308	1,230
Total financial liabilities	**0**	**40,024**	**474**	**51,158**	**91,656**	**81,592**

In CHF thousands	December 31, 2021					
	On demand	Less than 3 months	3 to 12 months	1 to 5 years	Total	Carrying value
Convertible bonds	0	15,590	1,296	39,748	56,634	39,676
Exchangeable Notes	0	2,000	0	0	2,000	1,488
Trade payables	0	2,412	0	0	2,412	2,412
Noncurrent provisions	0	0	0	16,808	16,808	16,808
Accrued expenses	0	7,056	0	0	7,056	7,056
Lease liabilities	0	186	550	1,251	1,987	1,812
Total financial liabilities	**0**	**27,244**	**1,846**	**57,807**	**86,897**	**69,252**

Convertible bonds and Exchangeable Notes may be settled in Shares, subject to certain conditions. For settlement conditions see Note 13. 30% of the provision in the amount of CHF 24.9 million at December 31, 2022 is due in mid-2024 and the remainder one year later, see Note 16 for more information.

30.6 Categories of financial instruments

In CHF thousands	December 31, 2022			
	Carrying value	Financial assets at amortized cost	Financial liabilities at amortized cost	Financial liabilities at fair value through profit or loss
Financial assets				
Financial assets long-term	444	444	0	0
Trade receivables, net	438	438	0	0
Cash and cash equivalents	1,353	1,353	0	0
Total financial assets	**2,235**	**2,235**	**0**	**0**
Financial liabilities				
Convertible bonds	21,080	0	21,080	0
Exchangeable Notes	22,127	0	22,127	0
Derivative financial instruments	9,775	0	0	9,775
Warrant financial instruments	7,396	0	0	7,396
Noncurrent lease liabilities	607	0	607	0
Trade payables	7,583	0	7,583	0
Accrued expenses	8,288	0	8,288	0
Current lease liabilities	623	0	623	0
Total financial liabilities	**77,479**	**0**	**60,308**	**17,171**

	December 31, 2021			
	Carrying value	Financial assets at amortized cost	Financial liabilities at amortized cost	Financial liabilities at fair value through profit or loss
Financial assets				
Financial assets long-term	468	468	0	0
Trade receivables, net	962	962	0	0
Cash and cash equivalents	21,208	21,208	0	0
Total financial assets	**22,638**	**22,638**	**0**	**0**
Financial liabilities				
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 financial instruments	6,373	0	0	6,373
Noncurrent lease liabilities	1,203	0	1,203	0
Trade payables	2,412	0	2,412	0
Accrued expenses	7,056	0	7,056	0
Current lease liabilities	609	0	609	0
Total financial liabilities	**62,902**	**0**	**52,444**	**10,458**

30.7 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 2021, 2022, 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 Group) provided financing for the Group.

During the years ending December 31, 2022 and December 31, 2021, there were no changes in goals and policies of the treasury management.

31. Events after the Reporting Date

In January 2023, the FDA formally accepted the submission of the NDA for vamorolone in DMD for review and notified that it has set the target date for its decision on the NDA to October 26, 2023. Following the acceptance of NDA submission, the Company has received USD 2.0 million milestone payment in relation to China license.

In January 2023, the Company entered into a share exchange agreement with Idorsia, pursuant to which Idorsia transferred 346,500 of its registered shares to Santhera. As consideration, Santhera delivered 5,529,016 Shares, valued at CHF 0.9043 to Idorsia and issued 2,211,607 warrants to Idorsia, each of which is exercisable for one Share at an exercise price of CHF 0.9043 at any time until January 9, 2025. The purpose of such share exchange was to obtain short-term liquidity by selling the Idorsia Shares. As of the date of issuing these consolidated financial statements, all these Idorsia Shares have been sold generating net proceeds of CHF 5.6 million

In February 2023, the Company secured a final pricing reimbursement agreement with the French authorities related to Raxone for the treatment of LHON. The newly agreed price for Raxone in France is lower than the price applied under the temporary pricing scheme, leading to a settlement payment in the amount of approximately EUR 25.4 million, with 30% due around mid-2024 and the remainder one year later. The first payment is currently expected to be covered by sales generated until mid-2024, while the majority of the second payment will be covered by sales beyond mid-2025.

In February 2023, Santhera secured additional funding through a private placement of shares and an amendment of its existing financing arrangement with funds managed by Highbridge to provide up to CHF 22.2 million, subject to certain milestones and conditions. This is intended to cover the capital requirements of the Company through to the PDUFA date in October 2023, when an FDA decision on vamorolone is expected. Concomitant with this transaction, Santhera has formed Strategy Committee focusing on evaluating all strategic options for the Company and plans to nominate Bradley Meyer for election as a new member of its Board of Directors at the Company's upcoming AGM until when he will serve as a Board Observer. In addition, Santhera issued 40 million shares, 37 million of which were transferred to treasury, in the ordinary capital increase resolved by its s shareholders on November 29, 2022.

In March 2023, the Company announced that it has submitted a marketing authorization application (MAA) to the UK Medicines and Healthcare products Regulatory Agency (MHRA) for vamorolone for the treatment of DMD.

Building a better working world

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To the General Meeting of
Santhera Pharmaceuticals Holding Ltd, Pratteln

Basle, 31 May 2023

Report of the statutory auditor

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 2022, the consolidated statement of income, the consolidated statement of comprehensive income, the consolidated statement of changes in equity and the 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 27 to 84) give a true and fair view of the consolidated financial position of the Group as at 31 December 2022 and of 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 (ISA) and Swiss Standards on Auditing (SA-CH). 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, together with the requirements of the Swiss audit profession, as well as those of the International Ethics Standards Board for Accountants’ *International Code of Ethics for Professional Accountants (including International Independence Standards*) (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

The accompanying financial statements have been prepared assuming that the Group will continue as a going concern. As discussed in Note 2.3 to the consolidated financial statements, the Group depends on the external funds, has a net capital deficiency, and has stated that substantial doubt exists about the Company’s ability to continue as a going concern. Management's evaluation of the events and conditions and management’s plans regarding these matters are also described in Note 2.3 The financial statements do not include any adjustments that might result from the outcome of this uncertainty. Our opinion is not modified with respect to this matter.

Key audit matters

In addition to the matter 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. 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. 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 2022, under the financing agreement with Highbridge, the Group issued exchangeable notes in several tranches amounting to CHF 40.0 million in total, of which CHF 14.3 million was converted into equity as of 31 December 2022. The outstanding liability for exchangeable notes as of 31 December 2022 amounted to CHF 22.1 million and the value of the related derivative amounted to CHF 5.5 million.

In addition, the Group holds two bonds. In 2022, the Group repurchased CHF 6 million (nominal value) of the public bond and recorded a net gain of CHF 1.5 million in connection with this transaction. In September 2021, the Group issued a private convertible bond to Highbridge at a nominal value of CHF 15.0 million, of which CHF 3 million was converted into equity during 2022. As of 31 December 2022, the carrying amount of the private and the public bonds amounted to CHF 21.1 million and the value of the related derivatives amounted to CHF 4.3 million. Further, to cover the amendment and commitment fees for financing transactions, in 2021 the Group issued a total of 9'819'807 warrants valued at CHF 7.4 million as of 31 December 2022.

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".

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 2022.

Impairment assessment of intangible assets not yet available for use

Areas of focus	The Group has capitalized intangible assets not yet available for use in the amount of CHF 51.0 million. Based on the requirements of IAS 36, such intangible assets need to be tested for impairment at least annually. The Group recognized an impairment charge of CHF 6.2 million in 2022. 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 judgment 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".*
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. With respect to the impaired intangible asset, we evaluated management's assessment, including judgment applied to contractual terms and funding. 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 is required 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.

In January 2023, Santhera and CEPS closed the matter by signing an agreement which specifies the amount of the claw-back, timing of the claw-back settlement as well as the new reimbursement price. Based on the agreement, the Group has recorded a liability of CHF 25 million. as of 31 December 2022. We deem it a key audit matter due to the magnitude of the amount and the negative impact on the revenues.

Refer to note 3 "Critical Accounting Estimates, Assumptions and Judgments", and note 16 "Noncurrent Provisions".

Our audit response

We obtained a copy of the agreement between the Group and the CEPS and reviewed the terms and conditions. We obtained letters from both the internal and external legal counsel to confirm the settlement status. Additionally, we involved our internal specialist for their assessment and to confirm our understanding of the agreement clauses.

Further, we evaluated the Group's determination of the liability (presented within non-current provisions) and analyzed the underlying key assumptions behind the split between the adjustment to revenues and operating expenses.

Our audit procedures did not lead to any reservations regarding the accounting and disclosure of such liability as of 31 December 2022.

Other information

The Board of Directors is responsible for the other information. The other information comprises the information included in the annual report, but does not include the consolidated financial statements, the stand-alone financial statements, the tables marked “audited” on pages 114 and 116 to 119 of the compensation report and our auditor’s reports thereon.

Our opinion on the consolidated financial statements does not cover the other information 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 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.

Board of Directors’ responsibilities for the consolidated financial statements

The Board of Directors is responsible for the preparation of the consolidated financial statements, which 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, ISA and SA-CH 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 on EXPERTsuisse’s website at: https://www.expertsuisse.ch/en/audit-report. This description forms an integral part of our report.

Report on other legal and regulatory requirements

In accordance with Art. 728a para. 1 item 3 CO and PS-CH 890, we confirm that an internal control system exists, which has been designed for the preparation of the 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/ Martin Mattes	/s/ Diana Vejina
Licensed audit expert	ACCA
(Auditor in charge)	

Statutory Financial Statements of Santhera Pharmaceuticals Holding AG

Contents

Balance Sheet

In CHF thousands	Notes	December 31, 2022	December 31, 2021
Assets			
Cash and cash equivalents		653	6,441
Other receivables from third parties		117	77
Other receivables from shareholdings		203	214
Prepaid expenses and accrued income		33	8
Loans to shareholdings		0	8,936
Current assets		**1,006**	**15,676**
Loans to shareholdings[1]	3.1	162,147	161,904
Investments in shareholdings	3.2	401	404
Noncurrent assets		**162,548**	**162,308**
Total assets		**163,554**	**177,984**
Liabilities and equity			
Trade accounts payable to third parties		489	247
Other accounts payable to third parties		2,700	8
Payables to shareholdings		4,557	0
Other short-term liabilities		0	1,271
Accrued expenses		2,275	1,743
Senior unsecured convertible bonds[2]	2,3.3	0	13,945
Current liabilities		**10,021**	**17,214**
Senior unsecured convertible bonds[2]	2,3.3	25,518	34,564
Noncurrent liabilities		**25,518**	**34,564**
Total liabilities		**35,539**	**51,778**
Share capital	3.4	753	54,608
Statutory capital reserves:			
Reserves from capital contributions[3]		*58,683*	*19,188*
Other capital reserves		*2,573*	*2,850*
Total statutory capital reserves		61,256	22,038
Retained deficit:			
Results carried forward		*(41,414)*	*(39,801)*
Net result for the period		*(7,481)*	*(1,613)*
Total retained deficit		(48,895)	(41,414)
Other voluntary reserves (free reserves)		114,995	*95,995*
Voluntary accumulated result and other reserves		66,100	54,581
Treasury shares	3.5	(94)	(5,020)
Total equity		**128,015**	**126,206**
Total liabilities and equity		**163,554**	**177,984**

1 Non-interest bearing

2 Interest bearing

3 Value as per December 31, 2022, to be confirmed by Swiss Federal Tax Administration.

Income Statement

In CHF thousands	Notes	Year ended December 31,	
		2022	**2021**
General and administrative expenses	3.6	(3,494)	(6,184)
Employee expenses		0	(192)
Other operating expenses		0	(9)
Total operating expenses		**(3,494)**	**(6,385)**
Operating result		**(3,494)**	**(6,385)**
Financial income		1,523	14,727
Financial expenses		(5,510)	(9,956)
Financial result		**(3,987)**	**4,771**
Result before taxes		**(7,481)**	**(1,613)**
Direct taxes		0	0
Net result		**(7,481)**	**(1,613)**

Notes to the Statutory Financial Statements

1. Introduction

Santhera Pharmaceuticals Holding AG (the **Company**, together with its subsidiaries **Santhera** or **Group**) is the parent company of the Santhera Group. Group companies include all legal entities which are directly or indirectly owned and controlled by the Company. The Company, having the listing of its registered shares (**Shares**) on the SIX Swiss Exchange (SIX), is a Swiss stock corporation. Its purpose is to acquire, dispose and manage investments. The Company has its registered offices at Hohenrainstrasse 24, 4133 Pratteln, Switzerland.

2. Summary of Significant Accounting Policies

2.1 Basis of presentation

The statutory financial statements of the Company are prepared in accordance with the principles set out in the Swiss Code of Obligations (**CO**). Since Santhera prepares consolidated financial statements in accordance with the International Financial Reporting Standards (**IFRS**) of the International Accounting Standards Board (**IASB**), the Company has applied the exemption included in the CO article 961d, para. 1, thereby electing to forego presenting a statement of cash flows, the additional disclosures, and the management report otherwise required by the CO.

The presentation currency is Swiss francs (**CHF**). Amounts shown are rounded to the nearest CHF 1,000 unless otherwise indicated.

2.2 Material uncertainties and ability to continue operations

The financial statements have been prepared under the going concern assumption despite material uncertainties present as of December 31, 2022, that may be perceived to be contrary to this assumption. In order to support ongoing operating activities including preparation for the launch of vamorolone, the Group's lead pipeline candidate, the Group requires additional funds subsequent to the expected regulatory approvals in late 2023 of vamorolone in the U.S., the EU, and UK.

Cash at hand and additional funds available as of December 31, 2022, and as of the date of issuance of these financial statements are sufficient to allow the Group to reach the value inflection point of expected FDA approval on the PDUFA date of October 26, 2023. However, material uncertainties remain as to the Group's ability to continue as a going concern after the PDUFA date and until December 31, 2023. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

Executing the Group's strategy significantly depends on the following:

- Notification by the European Medicines Agency (EMA) on whether the Marketing Authorization Ap-plication (MAA) submission for vamorolone in Duchenne muscular dystrophy (DMD) is approved, which is expected in late Q3-2023
- Notification by the U.S. Food and Drug Administration (FDA) on whether the New Drug Application (NDA) submission for vamorolone in DMD is approved, which is expected in Q4-2023
- Notification by the UK Medicines and Healthcare products Regulatory Agency (MHRA) on whether the MAA submission for vamorolone in DMD is approved, potentially in Q4-2023
- Additional funding to ensure the continuation of operations through to December 31, 2023
- Ability to settle current debt obligations

In October 2022, the EMA validated the MAA for vamorolone for the treatment of DMD. Validation confirms that the submission is complete and that the review by the EMA's Committee for Medicinal Products for Human Use (CHMP) has begun. Santhera expects the CHMP to complete the review and issue an opinion regarding approval to EMA's European Commission (EC) in late Q3-2023. Subject to EC approval, vamorolone will receive marketing authorization in all member states of the European Union, as well as in Norway, Liechtenstein, and Iceland. Pending approval, Santhera plans to launch vamorolone in the EU in Q4-2023.

In January 2023, the FDA formally accepted the NDA for vamorolone for the treatment of DMD for filing. The FDA has set October 26, 2023, as the Prescription Drug User Fee Act (PDUFA) target action date. The PDUFA date is the target date for the FDA to complete its review of the NDA. Furthermore, the FDA stated that it does not currently plan to hold an advisory committee meeting to discuss the application. Subject to approval, Santhera plans to launch vamorolone in the U.S. in Q4-2023.

In the event of approval, management and the Board plan to raise additional funds to finance ongoing development and may consider partnering to support commercialization activities in the U.S. and the EU. Should sufficient further funding not be available, the Group may review further organizational restructuring measures and reduction in business activities as well as consider the monetization of assets.

However, to ensure the execution of the Group's operating plan through to December 31, 2023, and beyond, additional funding will be needed. If the Group is unable to obtain the required funding to run its operations and to develop and commercialize its product candidates, the Group could be forced to delay, reduce or stop some or all of its research and development programs with the objective to ensure it remains solvent. The Group may seek additional funding through public or private financings or licensing agreements. The sale of additional equity may dilute existing shareholders.

Shareholders should note that whilst management and the Board 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, and that any transaction can be realized or that such transaction would generate sufficient funds to finance operations through to December 31, 2023. These material uncertainties may cast significant doubt about the ability of the Group to continue as a going concern.

However, management and the Board are of the view that it is more likely than not that the Group will continue to secure the additional funds needed in order to operate its business as planned with the objective to meet all of its obligations until December 31, 2023. Therefore, the financial statements have been prepared on a going concern basis.

2.3 Cash

Cash balances held primarily in Swiss francs include cash deposits in demand bank accounts, money market investment accounts and other liquid investments, and any interest earned on such cash balances.

2.4 Financial assets, short-term

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

2.5 Current assets and liabilities

Current assets are recorded at historical cost less adjustments for impairment of value. Current liabilities are recorded at historical cost.

2.6 Loans to shareholdings

Loans to shareholdings are valued at their acquisition cost adjusted for any impairment losses.

2.7 Investments in shareholdings

Investments in shareholdings are recorded at acquisition cost less adjustments for impairment of value. Investments in shareholdings are evaluated for impairment annually and any impairment loss is recorded when the carrying amount of such assets exceeds the fair value. Fair value estimates of investments in shareholdings are predominantly based on the income approach.

2.8 Convertible bonds

Convertible bonds are presented at nominal value.

2.9 Exchangeable notes

Exchangeable notes are presented at nominal value.

2.10 Treasury shares

Treasury shares are recognized at acquisition cost and deducted from shareholders' equity at the time of acquisition. Treasury shares held are intended to be used for financing transactions and share-based compensation. Santhera may also hold treasury shares for market making, for which is managed by an external bank. The gains or losses from market making are recognized in the income statement as financial income or financial expense.

2.11 Related parties

In the meaning of the CO, related parties are only considered to be shareholders, 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. Until the end of 2015, the loans to shareholdings consisted of fully impaired and subordinated loans to Santhera Pharmaceuticals (Schweiz) AG. To finance the activities in development and the commercialization of Raxone for Leber's hereditary optic neuropathy (**LHON**), in 2016 the loan granted to Santhera Pharmaceuticals (Schweiz) AG was increased (with the additional loans also being subordinated). As of December 31, 2022, loans to shareholdings total CHF 334.6 million. As of December 31, 2021, loans to shareholdings totaled CHF 334.2 million. All loans to shareholdings during 2022 and 2021 have been subordinated.

As part of the annual impairment reassessment as of December 31, 2022, the Executive Management concluded that approximately 48% of the total balance of loans to shareholdings is recoverable considering a positive outlook, in terms of market success for vamorolone for DMD.

3.2 Investments in shareholdings

The following companies are direct subsidiaries of Santhera Pharmaceuticals Holding AG, with 100% ownership and 100% voting rights:

Share capital nominal value			**Dec 31, 2022**	**Dec 31, 2021**
Direct subsidiary of Santhera Pharmaceuticals Holding AG:		Currency		
Santhera Pharmaceuticals (Schweiz) AG Pratteln, Switzerland	Active	CHF	125,000	125,000
Santhera Pharmaceuticals (Deutschland) GmbH Lörrach, Germany	Active	EUR	25,000	25,000
Santhera Pharmaceuticals (USA), Inc. Burlington, Massachusetts, USA	Active	USD	1,000	1,000
Santhera Pharmaceuticals (Canada), Inc. Montréal, Canada	Dormant	CAD	1,000	1,000
Oy Santhera Pharmaceuticals (Finland) Ltd Helsinki, Finland	In voluntary liquidation	EUR	2,500	2,500

Santhera Pharmaceuticals (Schweiz) AG is the primary operational entity while Santhera Pharmaceuticals (Deutschland) GmbH holds the market authorizations for the European Union. Oy Santhera Pharmaceuticals (Finland) Ltd, which is not employing any personnel, is in voluntary liquidation with the dissolution expected to be finalized in 2023. The investments in Santhera Pharmaceuticals (Canada), Inc. and Oy Santhera Pharmaceuticals (Finland) Ltd have been impaired during the year ending December 31, 2022.

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

Share capital nominal value			**Dec 31, 2022**	**Dec 31, 2021**
Direct subsidiary of Santhera Pharmaceuticals (Schweiz) AG:		Currency		
Santhera Pharmaceuticals (Liechtenstein) AG Ruggell, Fürstentum Liechtenstein	Active	CHF	50,000	50,000
Santhera (Italy) S.r.l. Milano, Italy	In voluntary liquidation	EUR	50,000	50,000
Santhera (Germany) GmbH München, Germany	Dormant	EUR	50,000	50,000
Santhera (Netherlands) B.V. Nieuwegein, The Netherlands	Dormant	EUR	50,000	50,000
Santhera (UK) Limited London, United Kingdom	Dormant	GBP	50,000	50,000
Santhera Pharmaceuticals (Spain), S.L.U Irun, Spain	Dormant	EUR	50,000	50,000

Santhera (Italy) S.r.l., which is not employing any personnel, is in voluntary liquidation with the dissolution expected to be finalized in 2023.

3.3 Convertible bonds

The following table summarizes the nominal values of the convertible bonds outstanding as of December 31, 2022, and December 31, 2021:

In CHF thousands					**Dec 31, 2022**	**Dec 31, 2021**
	Offering	Currency	Interest	Maturity	Nominal value	Nominal value
2017/22 Bonds (ISIN: CH0353955195)	Public	CHF	5%	2022	0	13,945
2021/24 Bonds (ISN: CH0563348744)	Public	CHF	7.5%	2024	13,547	19,562
2021/24 Private Bonds	Private	CHF	7.5%	2024	11,971	15,002
Total convertible bonds					**25,518**	**48,509**
Less current portion of convertible bonds with short-term maturities					0	(13,945)
Noncurrent portion of convertible bonds with long-term maturities					25,518	34,564

3.4 Share capital

At the Annual General Meeting (**AGM**) held on June 30, 2022, the shareholders approved a reduction of the nominal value of the shares from CHF 1.00 to CHF 0.01 per share, with allocation of the amount by which the Company's share capital has been reduced to the reserves from capital contribution. The legal process for this change was concluded in September 2022.

As of December 31, 2022, issued share capital totals CHF 753,205.10, consisting of 75,320,510 Shares with a nominal value of CHF 0.01 each. As of December 31, 2021, issued share capital totaled CHF 54,607,810, consisting of 54,607,810 Shares with a nominal value of CHF 1 each.

As of December 31, 2022, authorized share capital totals CHF 368,606.78, consisting of 36,860,687 shares with a nominal value of CHF 0.01 each. As of December 31, 2021, authorized share capital totaled CHF 27,303,905, consisting of 27,303,905 shares with a nominal value of CHF 1 each.

Pursuant to Article 3b and Article 3c of the Company's Articles of Incorporation, the Company has conditional shares. The conditional shares represent conditional capital authorized for issuance for share-based compensation, under the exclusion of shareholders' pre-emptive rights, and financing transactions, respectively. As of December 31, 2022, Article 3b conditional capital totals CHF 50,345.83 consisting of 5,034,583 shares with a nominal value of CHF 0.01 each. As of December 31, 2021, the total was CHF 5,425,677, consisting of 5,425,677 shares with a nominal value of CHF 1 each. As of December 31, 2022, Article 3c authorized conditional share capital totals CHF 301,566.22, consisting of 30,156,622 shares with a nominal value of CHF 0.01 each. As of December 31, 2021, the total was CHF 21,878,228, consisting of 21,878,228 shares with a nominal value of CHF 1 each.

3.5 Treasury shares

The table below summarizes the changes in treasury shares held during the years ending December 31, 2022, and December 31, 2021: (As referred to in note3.4 the nominal value per share was reduced from CHF 1.00 to CHF 0.01 during the year)

In CHF thousands (except share data)	**2022**		**2021**	
	No. of shares	Nominal value (CHF 0.01)	No. of shares	Nominal value (CHF 1.00)
Balance, January 1	5,019,879	50	1,301,075	1,580
Shares created for financing purposes	20,321,606	203	17,135,083	17,135
Shares used for financing purposes	(15,903,468)	(159)	(13,695,267)	(13,695)
Balance, December 31	**9,438,017**	**94**	**4,740,891**	**5,020**

3.6 General and administrative expenses

In CHF thousands	**2022**	**2021**
Administrative expenses	1,810	1,557
Consulting expenses	1,684	4,627
Total general and administrative expenses	**3,494**	**6,184**

4. Other Information

4.1 Full-time equivalents

The number of full-time equivalents at period end was not above 10 in 2022 and 2021.

4.2 Registered shares and 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 shareholder(s) held 5% or more of the Company's share capital at December 31, 2022: 75,320,510 Shares and December 31, 2021: 54,607,810 Shares, respectively:

	Dec 31, 2022		**Dec 31, 2021**	
	No. of shares	% of share capital	No. of shares	% of share capital
Idorsia Pharmaceuticals Ltd., Allschwil, Switzerland	7,482,259	10.15%	7,482,259	13.7%

4.3 Shareholdings of the members of the Board and the Executive Management

Number of shares	**Dec 31, 2022**	**Dec 31, 2021**
Members of the Board:		
Philipp Gutzwiller	44,458	7,100
Thomas Meier	140,319	84,222
Patrick Vink	107,229	1,000
Elmar Schnee (until June 30, 2022)	0	6,000
Total shares held by members of the Board	**292,006**	**98,322**
Executive Management:		
Stephanie Brown	0	0
Dario Eklund	25,000	0
Shabir Hasham (from May 1, 2022)	26,466	0
Günther Metz	10,000	10,000
Andrew Smith	0	0
Oliver Strub	0	0
Total shares held by the Executive Management	**61,466**	**10,000**

4.4 Equity rights granted to members of the Board

The tables below summarize the equity rights granted under all equity rights plans to the members of the Board that remain outstanding and that are vested and unvested at December 31, 2022 and December 31, 2021:

December 31, 2022

Members of the Board	**No. of Stock Options**		**No. of SARs** [(a)]		**No. of RSUs** [(b)]	
	Vested	**Unvested**	**Vested**	**Unvested**	**Vested**	**Unvested**
Philipp Gutzwiller	0	0	56,963	4,846	52,917	144,871
Thomas Meier	14,875	0	109,622	5,106	50,416	187,179
Patrick Vink	0	0	61,234	5,358	52,917	251,100
Total	**14,875**	**0**	**227,819**	**15,310**	**156,250**	**583,150**

December 31, 2021

Members of the Board	**No. of Stock Options**		**No. of SARs** [(a)]		**No. of RSUs** [(b)]	
	Vested	**Unvested**	**Vested**	**Unvested**	**Vested**	**Unvested**
Elmar Schnee *(until Jun 30, 2022)*	0	0	63,264	24,569	0	100,000
Philipp Gutzwiller	0	0	44,522	17,287	0	86,250
Thomas Meier	14,875	0	92,223	22,505	0	83,750
Patrick Vink	0	0	50,420	18,965	0	86,250
Total	**14,875**	**0**	**250,429**	**83,326**	**0**	**356,250**

4.5 Equity rights granted to Executive Management

The tables below summarize the equity rights granted under all equity rights plans to Executive Management that remain outstanding and that are vested and unvested at December 31, 2022 and December 31, 2021:

December 31, 2022

Executive Management	**No. of Stock Options**		**No. of SARs** [(a)]		**No. of PSUs** [(c)]	
	Vested	**Unvested**	**Vested**	**Unvested**	**Vested**	**Unvested**
Stephanie Brown	354,190	251,930	0	0	82,250	498,260
Dario Eklund	921,250	269,650	184,248	0	16,500	938,120
Shabir Hasham *(from May 1, 2022)*	176,885	155,320	52,350	23,820	5,610	388,940
Günther Metz	349,500	161,790	88,246	6,382	9,900	422,870
Andrew Smith	502,970	174,600	0	162,138	11,550	596,430
Oliver Strub	318,881	161,790	89,870	6,382	9,900	422,870
Total	**2,623,676**	**1,175,080**	**414,714**	**198,722**	**135,710**	**3,267,490**

December 31, 2021

Executive Management	**No. of Stock Options**		**No. of SARs** [(a)]		**No. of PSUs** [(c)]	
	Vested	**Unvested**	**Vested**	**Unvested**	**Vested**	**Unvested**
Stephanie Brown	0	117,500	0	0	0	117,500
Dario Eklund	0	50,000	0	184,248	0	450,000
Günther Metz	19,120	30,000	70,503	24,125	0	130,000
Andrew Smith	0	35,000	0	162,138	0	285,000
Oliver Strub	11,241	30,000	71,968	24,284	0	130,000
Total	**30,361**	**262,500**	**142,471**	**394,795**	**0**	**1,112,500**

(a) Share Appreciation Rights (**SARs**)

(b) Restricted Share Units (**RSUs**)

(c) Performance Share Units (**PSUs**)

4.6 Fair value of equity rights granted to members of the Board and employees

The table below presents the total equity rights granted under all equity rights plans during the years ended December 31, 2022 and December 31, 2021 and the respective fair value at the grant date summarized by grants made to the members of the Board and employees:

	2022		**2021**	
	Equity Rights Granted	**Fair Value**	**Equity Rights Granted**	**Fair Value**
	(Quantity)	(CHF 1,000s)	(Quantity)	(CHF 1,000s)
Board of Directors	376,922	241	356,250	409
Employees:				
Executive Management	5,522,320	3,378	1,375,000	560
Other employees	3,167,100	1,921	1,415,450	677
Total	**9,066,342**	**5,540**	**3,146,700**	**1,646**

The fair values presented are theoretical values and do not reflect income tax values. For information about the underlying equity rights plans, see Note 21 "Equity Rights Plans" of the consolidated financial statements included in the Annual Report 2022 on pages 66 to 72. Detailed remuneration disclosures for members of the Board and the Executive Management as required by Swiss law are provided in the Compensation Report included in the Annual Report 2022 on pages 108 to 121. For information about the Company's compensation system, see the Corporate Governance Report included in the Annual Report 2022 on pages 124 to 140.

4.7 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.

5. Events after the Reporting Date

In January 2023, the FDA formally accepted the submission of the NDA for vamorolone in DMD for review and notified that it has set the target date for its decision on the NDA to October 26, 2023. Following the acceptance of NDA submission, the Company has received USD 2.0 million milestone payment in relation to China license.

In January 2023, the Company entered into a share exchange agreement with Idorsia, pursuant to which Idorsia transferred 346,500 of its registered shares to Santhera. As consideration, Santhera delivered 5,529,016 Shares, valued at CHF 0.9043 to Idorsia and issued 2,211,607 warrants to Idorsia, each of which is exercisable for one Share at an exercise price of CHF 0.9043 at any time until January 9, 2025. The purpose of such share exchange was to

obtain short-term liquidity by selling the Idorsia Shares. As of the date of issuing these consolidated financial statements, all these Idorsia Shares have been sold generating net proceeds of CHF 5.6 million

In February 2023, the Company secured a final pricing reimbursement agreement with the French authorities related to Raxone for the treatment of LHON. The newly agreed price for Raxone in France is lower than the price applied under the temporary pricing scheme, leading to a settlement payment in the amount of approximately EUR 25.4 million, with 30% due around mid-2024 and the remainder one year later. The first payment is currently expected to be covered by sales generated until mid-2024, while the majority of the second payment will be covered by sales beyond mid-2025.

In February 2023, Santhera secured additional funding through a private placement of shares and an amendment of its existing financing arrangement with funds managed by Highbridge to provide up to CHF 22.2 million, subject to certain milestones and conditions. This is intended to cover the capital requirements of the Company through to the PDUFA date in October 2023, when an FDA decision on vamorolone is expected. Concomitant with this transaction, Santhera has formed Strategy Committee focusing on evaluating all strategic options for the Company and plans to nominate Bradley Meyer for election as a new member of its Board of Directors at the Company's upcoming AGM until when he will serve as a Board Observer. In addition, Santhera issued 40 million shares, 37 million of which were transferred to treasury, in the ordinary capital increase resolved by its s shareholders on November 29, 2022.

In March 2023, the Company announced that it has submitted a marketing authorization application (MAA) to the UK Medicines and Healthcare products Regulatory Agency (MHRA) for vamorolone for the treatment of DMD.

Mandatory offset of accumulated result pursuant to art, 674 CO:

In CHF thousands	**Dec 31, 2022**	**Dec 31, 2021**
Other voluntary reserves (free reserves)	114,995	95,995
Mandatory offset of accumulated losses	(48,895)	0
Other voluntary reserves (free reserves) to be carried forward	**66,100**	**95,995**

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To the General Meeting of
Santhera Pharmaceuticals Holding Ltd, Pratteln

Basle, 31 May 2023

Report of the statutory auditor

Report on the audit of the financial statements

Opinion

We have audited the financial statements of Santhera Pharmaceuticals Holding Ltd, which comprise the balance sheet as at 31 December 2022, the income statement for the year then ended, and notes to the financial statements, including a summary of significant accounting policies.

In our opinion, the financial statements (pages 92 to 103) comply with Swiss law and the Company's articles of incorporation.

Basis for opinion

We conducted our audit in accordance with Swiss law and Swiss Standards on Auditing (SA-CH). Our responsibilities under those provisions and standards are further described in the "Auditor's responsibilities for the audit of the financial statements" section of our report. We are independent of the Company in accordance with the provisions of Swiss law and the requirements of the Swiss audit profession, 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.

Emphasis of matter

We draw attention to Note 2.2 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. Our opinion is not modified in respect of this matter.

Key audit matters

In addition to the matter 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. 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. 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 responsibilities for the audit of the 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 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

Area of focus	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 judgment 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. *Refer to note 3.1 and 3.2 related to the investment in and the long-term receivables from shareholdings.*
Our audit response	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.

Other information

The Board of Directors is responsible for the other information. The other information comprises the information included in the annual report, but does not include the consolidated financial statements, the stand-alone financial statements, the tables marked “audited” on pages 114 and 116 to 119 of the compensation report and our auditor’s reports thereon.

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

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the 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.

Board of Directors' responsibilities for the financial statements

The Board of Directors is responsible for the preparation of the financial statements in accordance with the provisions of Swiss law and the Company's articles of incorporation, and for such internal control as the Board of Directors determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the Board of Directors is responsible for assessing the Company'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 Company or to cease operations, or has no realistic alternative but to do so.

Auditor's responsibility

Our objectives are to obtain reasonable assurance about whether the 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 and SA-CH 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 financial statements.

A further description of our responsibilities for the audit of the financial statements is located on EXPERTsuisse's website at: https://www.expertsuisse.ch/en/audit-report. This description forms an integral part of our report.

Report on other legal and regulatory requirements

In accordance with Art. 728a para. 1 item 3 CO and PS-CH 890, we confirm that an internal control system exists, which has been designed for the preparation of the 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/ Martin Mattes
Licensed audit expert
(Auditor in charge)

/s/ Diana Vejina
ACCA

Compensation Report

Contents

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 the calendar year 2022, the compensation to the Board paid/payable compared to the approval by shareholders at the Annual General Meeting (**AGM**) of June 30, 2022 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 Thomas Meier 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 (**AoI**) 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 AoI 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 approves:

- Executive employment agreements;
- Salary increases, bonus payments and equity grant pools 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 2022.

Compensation periods and approvals by shareholders

For the Board, the compensation period starts after the 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.

At the AGM of the Company, the shareholders shall vote on:

- the compensation for the Board for the election period from the current year AGM to the AGM of the subsequent year
- the fixed compensation for Executive Management for the subsequent calendar year of the AGM (prospective
- the variable cash compensation for Executive Management for the prior calendar year of the AGM (retrospective), and
- the variable compensation for Executive Management for the Long-Term Incentive for the current year.

	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 2023

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

1. Consultative vote on the Compensation Report 2022.
2. Board

   The maximum total amount of the compensation for the period between the AGM 2023 and the AGM 2024.
3. Executive Management

   3.1. The maximum total amount of the fixed compensation for the period from January 1, 2024 to December 31, 2024.

   3.2. The maximum total amount of the variable compensation for the cash bonus for the period from January 1, 2022 to December 31, 2022.

3.3. The maximum total amount of the variable compensation under the Long-Term Incentive Plan for the period from January 1, 2023 to December 31, 2023.

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. In 2022, the Company benchmarked the remuneration of EM members compared to remuneration of executive management in peer companies. The Company decided to target the 50th percentile (fixed and variable compensation) of comparable pre-commercial companies of similar size.

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 (**RSUs**)**;** 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 (i) the annual cash fees and (ii) the share value at the vesting date of the RSU, when shares are granted for such RSUs. 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 RSUs, 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 RSU Plans, see Note 21 *"*Equity Rights Plans*"* in the audited consolidated financial statements for the year ended December 31, 2022.

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 for each EM member is determined at the discretion of the Compensation Committee, which considers (i) the financial situation of the Company, (ii) the achievement of corporate objectives in the past year and (iii) the individual performance of the EM member when making such determination.

Long-term incentive plan

Under the LTI, members of the EM receive a combination of options and Performance Share Units (**PSUs**). The combination of options and PSUs is decided annually by the Compensation Committee when issuing the annual grant under the LTI.

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 Share Appreciation Rights (**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 forward-looking and 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 Executive 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).

New management incentive plan (NMIP)

In November 2022, the Company introduced a New Management Incentive Plan (**NMIP**). The NMIP is a non-recurring performance and time-based incentive designed to promote retention and alignment with company goals.

For more information about the Long-Term Incentive or New Management Incentive Plans, see Note 21 *"Equity Rights Plans"* in the audited consolidated financial statements for the year ended December 31, 2022.

Compensation awarded to the Board of Directors in 2022

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

At the AGM 2022, the shareholders approved the compensation awarded to the Board of Directors in 2022 for the period from the AGM 2022 to the AGM 2023 of in total CHF 625,000 (excl. social security contributions) which is granted 50% in cash and 50% in RSUs. The compensation paid or payable is lower than the approved amount due to the BoD consisting only of three members and the BoD waiving the committee fees for the Scientific Committee as this is not intended to take place during this election period.

Annual cash fees

At the AGM 2022, the shareholders approved a total cash compensation for the entire Board of a maximum of CHF 312,500 for the period between the AGM 2022 and the AGM 2023, excluding social security contributions.

Restricted share units (RSUs)

At the AGM 2022, the shareholders approved a total maximum amount of CHF 312,500 to be granted in RSUs for the period until the AGM 2023. In accordance with the 2022 Board Restricted Shares Plan (**BRSP 2022**), RSUs were granted to the Board members as of July 1, 2022, based upon a fair market value of the instrument of CHF 0.65 per RSU.

The table below represents the approved maximum compensation for the Board, the actual amounts paid in 2022 and those still payable until AGM 2023.

	Approved AGM 2022 – AGM 2023[2]	**Paid/payable AGM 2022 – AGM 2023**[2]
Total Board fees (CHF) cash or foreseen	**312,500**	**240,000**
RSU (CHF)	**312,500**	**240,000**
Total compensation (CHF)	**625,000**	**480,000**
RSU (number)[1]		376,922

1 The shareholders approved a fix amount in CHF which was converted into a number of RSUs based on the fair market value of such RSU (CHF 0.65) on the first trading day immediately following the AGM 2022 excluding assumed social security contributions.
2 Excluding social security contributions.

Disclosure of compensation of members of the Board for the financial years 2022 and 2021 (audited)

In CHF	Annual cash fees	RSU[1]	Total compensation[2]	Number of RSU granted[4]
2022				
Elmar Schnee[3]	0	50,000	100,000	153,846
Philipp Gutzwiller	72,500	72,500	145,000	111,538
Thomas Meier	83,750	83,750	167,500	128,846
Patrick Vink	36,667	72,500	142,500	162,821
Total	**192,917**	**278,750**	**555,000**	**557,051**

In CHF	Annual cash fees	RSU[1]	Total compensation[2]	Number of RSU granted
2021				
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
Total	**241,205**	**712,500**	**953,705**	**356,250**

[1] Reflects value of share-based payments in accordance with IFRS 2 at grant, i.e. the value of unvested stock options attributable at grant. 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.

[2] The Total compensation does not include mandatory employer social security contributions on the annual cash fees and the shares delivered (2022: CHF 18,467; 2021: CHF 26,794). For all SARs held by Board members as of December 31, 2022, 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 2022 is CHF 0.

[3] Member of the BoD until June 30, 2022 (AGM 2022).

[4] Includes CHF 83,333 of cash compensation exchanged for RSUs (128,205).

Changes in the Board of Directors in 2022

At the AGM 2022, shareholders elected Thomas Meier, PhD, as Chairman of the Board of Directors. Elmar Schnee, Chairman of the Board and member of the Compensation Committee of Santhera since 2017, did not stand for re-election.

Compensation awarded to the Members of the Executive Management in 2022

The compensation awarded to the members of the Executive Management in 2022 consisted of (i) fixed compensation as per the limit approved at the AGM 2021 and (ii) variable compensation as per the limit approved at the AGM 2022.

Comparison of the approved and paid EM fixed compensation

At the AGM 2021, shareholders approved a maximum total compensation for the EM for 2022 as follows: CHF 4,100,000 for the fixed compensation in cash.

In CHF	Approved 2022	Paid 2022
Fixed Compensation	4,100,000	2,747,723 [1]

1 Includes a sign-on bonus CHF 143,840 for Stephanie Brown, President North America reported as fixed compensation.

Comparison of the approved and paid EM variable compensation

The AGM in June 2022approved a maximum total amount of variable cash compensation of the members of the Executive Management for the period from January 1, 2021, to December 31, 2021, of CHF 1,200,000, which was settled in the form of Stock Options given the difficult financial situation with an exercise price of CHF 0.842 per option. The EM members did not receive a cash bonus in three consecutive years. The AGM 2022 also approved a variable compensation for the financial year 2022 as an annual grant under the LTI program for the members of Executive Management in the maximum total amount of CHF 2,400,000 (incl. employer contributions to social security).

The Extraordinary General Meeting (**EGM**) in November 2022 approved an additional one-time maximum variable compensation of CHF 2,500,000 for the members of the Executive Management (incl. employer contributions to social security) to retain Executive Management, so it can continue its efforts to bring the Company to the next value inflection points, while pursuing strategic options including but not limited to non-dilutive funding in the form of outlicensing agreements and/or the monetization of assets and, in parallel, is also evaluating debt financing, royalty financing or, depending on the market conditions, equity based funding.

The variable compensation granted on December 1, 2022 is performance and time based; and will be paid out after the retention period of December 31, 2023 only if and when performance criteria, set by the Board, are met. The Board will, at its discretion, pay such compensation intended to retain Executive Management, depending on the financial condition of Santhera and the availability of shares (e.g., from authorized or conditional capital or treasury shares) (i) in cash, (ii) in equity instruments, such as options or performance share units, or (iii) a mix of cash and equity instruments.

In CHF	Approved 2022	Paid 2022
Maximum amount Variable Compensation	6,100,000	3,557,387 [1]
Thereof		
Variable Compensation 2021 [2]	1,200,000	1,181,996
- Number of Stock Options		2,038,052
Variable Compensation 2022	4,900,000	2,375,391
- Number of Stock Options		1,031,290
- Number of PSUs		2,203,700
-Equity instruments or cash to be determined		2,348,399

1 Included in the amounts are assumed social security payments on the fair market value of allocated PSU and Options.

2 The Variable Cash Compensation 2021 was paid out in the form of options.

Disclosure of compensation of members of the Executive Management for the years 2022 and 2021 (audited)

In CHF	Base salary	Allowances	Cash bonus[3]	Fair value of PSU/ stock Options[1]	Social security and pension[2]	Total compen-sation	Number of PSU/Stock options granted
2022							
Dario Eklund	505,008	43,272	0	1,615,205	266,536	2,430,021	1,645,520
Other 5 members of EM[4)]	1,567,775	72,100	0	3,879,113	687,956	6,206,944	3,876,800
Total	**2,072,783**	**115,372**	**0**	**5,494,318**	**954,492**	**8,636,965**	**5,522,320**

In CHF	Base salary	Allowances	Cash bonus[3]	PSU/ Options[1]	Social security and pension[2]	Total compen-sation	Number of PSU/ options granted
2021							
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
Total	**1,455,641**	**86,532**	**0**	**1,678,715**	**512,632**	**3,733,520**	**1,375,000**
2021							

[1] Reflects the fair 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 instruments (i.e., SARs, Stock Options or PSUs) is CHF 0 until when the SAR or Options are exercised respectively when PSUs are converted into shares of the Company. Includes the 2021 Cash bonus, which was paid out in the form of Stock Options and the EGM 2022 grant that may be settled in equity instruments or cash to be determined.

[2] Included in the amounts are assumed social security payments on the fair market value of allocated PSU/Stock Options.

[3] 2021 Cash bonus was approved and paid out in the form of Stock Options and is included in the PSU/Option information.

[4] Including Chief Medical Officer as of May 1, 2022.

Changes in the Executive Management in 2022

Chief Medical Officer (CMO): Shabir Hasham, MD was appointed Chief Medical Officer of the Company effective May 1, 2022.

Executive Contracts

The employment contracts with the EM members are compliant with the OaEC and the Company's Articles of Incorporation and no EM member has a notice period of longer than 12 months. 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 that 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 2022, 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 (2021: CHF 0) for such payments in 2022.

Disclosure of compensation of former Board members for the years 2022 and 2021 (audited)

In CHF	Total payment
2022	
n/a	–
Total	**0**
2021	
n/a	–
Total	**0**

Disclosure of compensation of former EM members for the years 2022 and 2021 (audited)

In CHF	Total payment
2022	
n/a	-
Total	0
2021	**160,922**
Kristina Sjöblom Nygren[1)]	160,922

[1] 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.

Shareholdings of Members of the Board and Executive Management

Disclosure of shareholdings in the Company of Board members as of December 31, 2022 and December 31, 2021 (audited)

December 31, 2022	Number of shares	Number of stock options (vested)	Number of stock options (unvested)	Number of SAR (vested)	Number of SAR (unvested)	Number of RSU (vested)	Number of RSU (unvested)
Philipp Gutzwiller	44,458	0	0	56,963	4,846	52,917	144,871
Thomas Meier	140,319	14,875	0	109,622	5,106	50,416	187,179
Patrick Vink	107,229	0	0	61,234	5,358	52,917	251,100
Total	**292,006**	**14,875**	**0**	**227,819**	**15,310**	**156,250**	**583,150**

December 31, 2021	Number of shares	Number of stock options (vested)	Number of stock options (unvested)	Number of SAR (vested)	Number of SAR (unvested)	Number of RSU (vested)	Number of RSU (unvested)
Elmar Schnee[1]	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
Total	**98,322**	**14,875**	**0**	**250,429**	**83,326**	**0**	**356,250**

[1] Member of the BoD until June 30, 2022 (AGM 2022)

Disclosure of shareholdings in the Company of Executive Management members as of December 31, 2022[1] and December 31, 2021 (audited)

December 31, 2022	Number of shares	Number of Stock Options (vested) [1]	Number of Stock Options (unvested)	Number of SAR (vested) [1]	Number of SAR (unvested)	Number of PSU (vested)	Number of PSU (unvested)
Stephanie Brown	0	354,190	251,930	0	0	82,250	498,260
Dario Eklund	25,000	921,250	269,650	184,248	0	16,500	938,120
Shabir Hasham[2]	26,466	176,885	155,320	52,350	23,820	5,610	388,940
Günther Metz	10,000	349,500	161,790	88,246	6,382	9,900	422,870
Andrew Smith	0	502,970	174,600	0	162,138	11,550	596,430
Oliver Strub	0	318,881	161,790	89,870	6,382	9,900	422,870
Total	**61,466**	**2,623,676**	**1,175,080**	**414,714**	**198,722**	**135,710**	**3,267,490**

December 31, 2021	Number of shares	Number of Stock Options (vested)	Number of Stock Options (unvested)	Number of SAR (vested)	Number of SAR (unvested)	Number of PSU (vested)	Number of PSU (unvested)
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
Total	**10,000**	**30,361**	**262,500**	**142,471**	**394,795**	**0**	**1,112,500**

1 The exercise price of vested and unvested options ranges from CHF 0.84 to CHF 89.45.

2 Shabir Hasham appointed Chief Medical Officer as of May 1, 2022.

Outlook

Outlook for Board compensation

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

Function	Compensation (CHF)	Number	Total (CHF)[1)]
Chairman of the Board (**COB**)	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	20,000	1	20,000
Member of the CC	10,000	1	10,000
Total			**710,000**

[1] Excluding employer contributions to AHV/IV/ALV that does not form part of remuneration

At minimum, 50% of the total compensation is made in the form of restricted shares. The Board of Directors proposes that the AGM 2023 approves Board remuneration totaling not more than CHF 1,100,000 (excluding legally required employer's contributions to AHV/IV/ALV) for the period ending at the AGM 2024. The amount includes an amount for 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 2022 has already approved the fixed compensation (which includes base salary, allowances, social security contributions and payments to the pension fund) for 2023 in the amount of CHF 2,950,000.

For the fixed compensation for 2024, the Board will propose an amount of CHF 3,300,000 to the AGM 2023 which is based on six Executives.

Outlook for variable compensation

The Variable compensation of the members of the EM consists of an annual cash bonus and an annual grant under the companies' LTI program. Following three successive years of no cash bonus payments and materially reduced LTI grants relative to the amounts approved by the shareholders, the BoD plans to propose a total maximum variable compensation to the members of the EM of CHF 3,200,000.

In CHF	For approval in 2023	2022	2021
Maximum amount Variable Compensation	**3,200,000**	**6,100,000**	**554,219**
Thereof:			
Cash Bonus	800,000	1,200,000[1]	0
Stock Options / PSUs	2,400,000	4,900,000[2]	554,219

[1)] The Variable Cash Compensation 2021 was paid out in the form of options in 2022.

[2)] The amount includes CHF 2,500,000 approved at November 2022 EGM.

Annual cash bonus

The annual cash bonus for 2022 is based on the achievement of Company and individual goals. The Company goals included the submission of the applications for vamorolone in Duchenne muscular dystrophy (**DMD**) to the U.S. Food and Drug Administration (**FDA**) and the European Medicines Agency (**EMA**), as well as the successful completion of financing.

Overall, Company targets were partially achieved. The Company completed the New Drug Application (**NDA**) submission to the FDA (with delay) as well as submitted the Marketing Authorization Application (**MAA**) to the EMA (on time) for vamorolone in DMD. The Company completed a capital increase of 60 million shares for financing and restructured milestone payments by USD 20 million. However, financing until approval was not achieved due to difficult market conditions and the delay of the US FDA filing.

The Company plans to propose to the shareholders at the AGM 2023 a cash bonus payment of maximum CHF 800,000 (incl. social security contributions) below the cash bonus at target. The cash bonus can be paid out in the form of equity and timing of such payout will be financing dependent.

Long-term incentive plan – annual grant

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 2023 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, which reflects the annual targeted quantum for the Executive Management Team.

Building a better working world

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To the General Meeting of
Santhera Pharmaceuticals Holding Ltd, Pratteln

Basle, 31 May 2023

Report of the statutory auditor on the compensation report

Opinion

We have audited the compensation report of Santhera Pharmaceuticals Holding Ltd for the year ended 31 December 2022. The audit was limited to the information on compensation, loans and advances pursuant to Art. 14-16 of the Ordinance against Excessive Compensation in Listed Companies Limited by Shares (Verordnung gegen übermässige Vergütungen bei börsenkotierten Aktiengesellschaften, VegüV) in the tables marked “audited” on pages 114 and 116 to 119 of the compensation report.

In our opinion, the information on compensation, loans and advances in the compensation report complies with Swiss law and Art. 14-16 VegüV.

Basis for opinion

We conducted our audit in accordance with Swiss law and Swiss Standards on Auditing (SA-CH). Our responsibilities under those provisions and standards are further described in the “Auditor’s responsibilities for the audit of the compensation report” section of our report. We are independent of the Company in accordance with the provisions of Swiss law and the requirements of the Swiss audit profession, 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.

Board of Directors’ responsibilities for the compensation report

The Board of Directors is responsible for the preparation of a compensation report in accordance with the provisions of Swiss law and the Company's articles of incorporation, and for such internal control as the Board of Directors determines is necessary to enable the preparation of a compensation report that is free from material misstatement, whether due to fraud or error. The Board of Directors is also responsible for designing the compensation system and defining individual compensation packages.

Auditor’s responsibilities for the audit of the compensation report

Our objectives are to obtain reasonable assurance about whether the information on compensation, loans and advances pursuant to Art. 14-16 VegüV is 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 and SA-CH 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 this compensation report.

As part of an audit in accordance with Swiss law and SA-CH, we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement in the compensation report, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit 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 Company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made.

We communicate with the Board of Directors or its relevant committee regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide the Board of Directors or its relevant committee with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, actions taken to eliminate threats or safeguards applied.

Ernst & Young Ltd

/s/ Martin Mattes	/s/ Diana Vejina
Licensed audit expert	ACCA
(Auditor in charge)	

Corporate Governance Report

Contents

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 provides more detailed information.

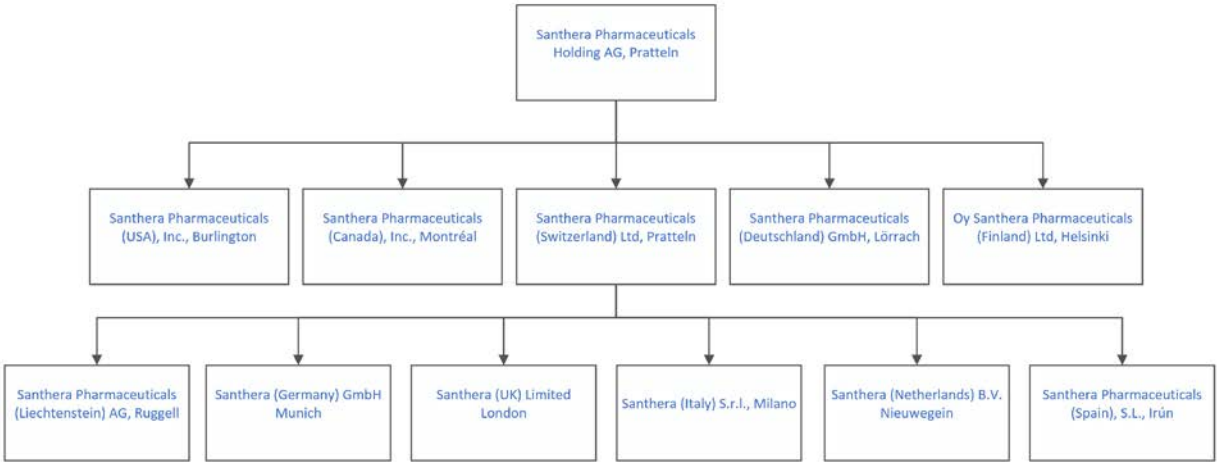
Group Structure and Shareholders (DCG 1)

Group structure (DCG 1.1)

Listed company

Name	Santhera Pharmaceuticals Holding AG (**Company**, together with its affiliates, **Santhera**)
Legal domicile	Hohenrainstrasse 24, 4133 Pratteln, Switzerland
Register number	CHE-105.388.338
Listing	SIX Swiss Exchange
Symbol	SANN
Security ID	2714864
ISIN	CH0027148649
Market capitalization	CHF 104 million (December 31, 2022) SIX was closed on Dec 31; that's why I put in 30
Website	www.santhera.com
Duration of Company	Not limited
Subsidiaries	See following section as well as note 3.2 *"Investments in shareholdings"* 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	Dormant
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	In voluntary liquidation

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 0.01 each (**Shares**). As of December 31, 2022, it had the following ordinary, authorized and conditional share capital:

Type of capital	Capital as per commercial register		Effectively outstanding capital			
	Amount in CHF	As % of ordinary capital	Amount in CHF	As % of ordinary capital	Expiry	Section in Articles
Ordinary capital	737,213.74	100.0	753,205.10	100.0		3
Authorized capital	368,606.87	50.0	368,606.87	48.9	December 14, 2023	3a
Conditional capital for warrants/option rights granted in connection with debt instruments	313,746.64	42.6	301,566.22	40.0	For conversion rights: 10 years from issue date. For options: 7 years from issue date.	3c
Conditional capital for ESOP/BSOP/EIP	54,156.77	7.3	50,345.83	6.7		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 21 "Equity Rights Plans" to the consolidated financial statements.

Changes in share capital (DCG 2.3)

For changes in capital that occurred in 2020 and 2021, see the Company's Annual Reports for 2020 and 2021, which can be downloaded at http://www.santhera.com/assets/files/financial_reports/2020-Santhera-Annual-Report_final.pdf and https://www.santhera.com/assets/files/financial_reports/2021-Santhera-Annual-Report-10.06.22-Final-for-publication-2x.pdf. For changes that took place in 2022, 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, 2022, the Company had one single class of registered Shares with a nominal value of CHF 0.01 each. All Shares were fully paid in and are nonassessable. The Company has not issued any participation certificates or any profit-sharing certificates.

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)

For an overview of convertible bonds, see note 13.2 *"Financing arrangements – convertible bonds"*.

Options, warrants

See the statutory financial statements of the Company, note 13.1 *"Equity-linked financing arrangements"*, *note 13.2 "Financing arrangements – convertible bonds" and* note 21 "*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
Thomas Meier[1, 2]	1962	DE	2017	⭘	○	○	⭘
Philipp Gutzwiller[1]	1968	CH	2017	○	⭘		
Patrick Vink[1, 3]	1963	NL	2017	○		⭘	○
Elmar Schnee[4]	1959	CH	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. He was elected as Chairman at the 2022 AGM on June 30, 2022.

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

4 Elmar Schnee did not stand for re-election at the 2022 AGM. After the AGM, Thomas Meier became Chairman of the Board of Directors and a Member in both the AC and CC, replacing Elmar Schnee.

Thomas Meier

Thomas Meier, born 1962, German citizen, became a Member of Santhera's Board in 2017 and was elected Chairman of the Board at the 2022 AGM. 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 and is member of both the Audit Committee and the Compensation 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) as well as chairman of the privately held SEAL Therapeutics AG (Switzerland). Previously, he acted as chairman of the privately held company Pharmabiome AG (Switzerland) until 2021.

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 Gutzwiller is a Managing Director at Mizuho Bank, leading the European coverage effort for large Consumer and Healthcare clients. From 2014 to 2020, he successively held different managerial roles in healthcare at Lloyds Banking Group plc, where he eventually served as Digital Product Lead, Corporate and Institutional Clients. Prior to these roles, he advised corporations and private equity investors on corporate finance transactions at UBS Investment Bank and DC Advisory. Before his 20-year experience in banking, Philipp spent several years at Roche as financial controller, deputy Finance Director of an operating subsidiary as well as in the corporate M&A team.

He has no other activities and vested interests.

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, he served as chairman of the listed company Acacia Pharma Group plc (UK). Previously, he served as chairman (2017-2020) of the listed company Targovax ASA (Norway), as member of the board (2017-2019) of the listed company Arch BioPartners Inc. (Canada), and as chairman (2015-2022) of the privately held company NMD Pharma A/S (Denmark). He is chairman of privately held F2G Ltd. (UK), chairman of privately held Essential Pharma (UK) and is a member of the Board of Directors of Armyt Pharma plc (UK), Spero Therapeutics (US), SQZ Biotech (US) and board member of several privately held life science companies as well as an advisor to private equity and venture capital funds.

Elmar Schnee

Elmar Schnee, born 1959, Swiss citizen, was Santhera's Chairman of the Board and Member of the Compensation Committee from 2017 until the 2022 AGM. He was both a non-executive and an independent Board Member.

Elmar Schnee has a master's 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).

At the time of his resignation, he served as Chairman of the Board and a member of the audit committee and the compensation committee and had several board memberships outside Santhera.

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

See note 29 "*Transactions with Related Parties*" 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.

Number of permitted activities (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 Thomas Meier (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 by the Board.

The Audit Committee consists of two Board members, Philipp Gutzwiller (Chairman) and Thomas Meier (member). 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, an M&A or a 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).

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). In very few instances, e.g., due to the urgency of a situation, the Board has approved a transaction in principle and authorized CEO, CFO, GC and EVP Business Development to negotiate details as long as they remained substantially the same as those presented to it.

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. 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 inlicensing or partnering opportunities and monitor compliance with the Company's standards of scientific integrity. The Scientific Committee holds at least two meetings per year and additional meetings as needed or requested by any of its members. However, due to the reduced size of the Board, the Scientific Committee did not hold any further meetings in 2022 and will not do so until the Board decides otherwise.

Meetings in 2022

Corporate Body	In person meetings	Tele- and video-conferences	Circular resolutions	Average duration in hrs
Board of Directors	2	12	11	Ca. 1½
Audit Committee	1	0	0	Ca. 2
Compensation Committee	1	5	0	Almost 1½
Scientific Committee	0	0	0	0

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, legal or other advisors to its meetings. In the reporting period, the Board did so on one occasion, when it invited three M&A advisers to discuss potential transactions with them.

In the year under review, the Board discussed the Company's strategy, major projects and risks. It evaluated potential M&A, outlicensing transactions, equity based and non-dilutive funding with about 40 parties.

Among the key risks identified at the beginning of 2022 were the financial situation of the Company, the regulatory risk in the U.S. with respect to vamorolone, the discussions with the French authorities about a claw-back, a 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 were put in place.

Extraordinary transactions and issues must be reported by the CEO to the Board immediately. CEO, CFO and GC are 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. In the year under review, the Company has continuously improved certain of its financial processes.

Gender guidelines (DCG 3.8 and 4.5)

The Company has not implemented any gender guidelines, but plans to do so in due course of time.

Executive Management (DCG 4 and 3.6)

In 2021, the Executive Management consisted of five Executives[1].

Executive	Function	Nationality	Year of Birth
Dario Eklund	Chief Executive Officer (**CEO**)	AT/FI	1968
Andrew Smith	Chief Financial Officer (**CFO**)	GB	1962
Stephanie Brown	President North America	CA	1960
Shabir Hasham[1]	Chief Medical Officer (**CMO**)	GB	1970
Günther Metz	Head Business Development, EVP	DE	1958
Oliver Strub	Group General Counsel & Secretary to the Board, EVP	CH	1963

[1] As of May 1, 2022

Members of the Executive Management are appointed by the Board upon proposal by the CEO with the exception of the CEO 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 People & Culture, the Head Investor Relations & Communications, the Head Global Marketing & Partner Management, the Head of Development, the Head Technical Development & Operations and the Head European Affiliates & EU Market Access - 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, people & culture, taxes, legal and compliance.

Dario Eklund

Dario Eklund, born 1968, Finnish and Austrian citizen, is Santhera's CEO since December 1, 2019.

Dario 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. He was a member of Vifor's Corporate Executive Committee and a member of the Board of Directors of the joint venture with Fresenius Medical

Care (Vifor Fresenius Medical Care Renal Pharma Ltd.). From 2005 to 2014, he served as Vice President and 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, he was 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.

Andrew Smith

Andrew Smith, born 1962, British citizen, joined Santhera as Chief Financial Officer (**CFO**) on April 1, 2020, and is also responsible for IT.

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, he was CFO and COO at Allecra Therapeutics GmbH, a clinical-stage biopharmaceutical company developing novel therapies to combat antibiotic resistance (2017-2020). Previously, Andrew was CFO (2015-2017) and VP Finance (2011-2014) of NASDAQ-listed Sucampo Pharmaceuticals Inc., based in the US, and Finance Director (2009-2010) Sucampo UK. Earlier, he served as Director (2006-2009) for Retroscreen Virology Ltd., a contract virology company assisting in development of influenza vaccines, and 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.

Andrew Smith is a non-executive board member of Arix Bioscience plc, United Kingdom.

Stephanie Brown

Stephanie Brown, born 1960, Canadian citizen, joined Santhera as President North America and a member of the Executive Management in December 2021.

Stephanie earned a B.S. in Chemistry with Biology from Mount Allison University, Canada, and an MBA from Heriot-Watt University, Scotland.

Before joining Santhera, she was Senior Vice President and Head of the Rare Diseases Franchise, North America (2019-2021) at Ipsen Pharmaceuticals (France). Prior to Ipsen, Stephanie Brown was Vice President and Head of Novartis' U.S. Neuroscience Franchise (2017-2019). Earlier in her career, Stephanie Brown served at Takeda Pharmaceuticals USA as Senior Vice President, US Head Specialty business Unit (2016-2017), at Biogen as Vice president, Global Rare & Specialty Therapeutics (2014-2016) and Head of Global Marketing, Interferon Franchise (2013-2014), at Genentech as Franchise Head, US Sales & Marketing, Cystic Fibrosis (2011-2013) and Director, US Virology Marketing (2010-2011) and held various roles at Merck (2005-2010).

Stephanie Brown is a board member of the listed company ObsEva SA, Switzerland.

Shabir Hasham

Shabir Hasham, born 1970, British citizen, joined Santhera in 2015. Shabir has been appointed as Chief Medical Officer (**CMO**) 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.

At Santhera, before becoming CMO, he served as Global Development Program Lead & Global Head Medical Affairs (2019-2022) and Head of Medical Affairs EU & RoW (2015-2019). Before joining Santhera in 2015, Shabir held various positions at Novartis (2007-2015) including EU Medical Director (2013-2015) and Global Associate Brand Director (2009-2013) for the Neuroscience franchise at Novartis Pharma, and Senior Medical Manager (2007-2010) 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 (2006-2007) and Pfizer's cardiovascular business (2003-2006).

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.

Oliver Strub

Oliver Strub, born 1963, Swiss citizen, joined Santhera in 2006 as Group General Counsel & Secretary to the Board.

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.

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)

Body	Maximum of mandates on board of listed companies	Maximum of mandates on board of privately held companies
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 Rights (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).

Quorums required by the Articles of Association (DCG 6.2)

There are no statutory quorums which differ from the applicable legal provisions. Changes – if required by the amended corporate law - will be implemented in due course of time.

Convocation of the general meeting of shareholders (DCG 6.3)

Currently, the Articles of Incorporation require 10% of the share capital to call an extraordinary general meeting. The amended corporate law provides that 5% are sufficient to do so. The Company will propose a respective amendment to the Articles of Incorporation in due course of time.

Inclusion of items on the agenda (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. The amended corporate law

provides that 0.5% of the share capital is sufficient to demand that agenda items be included. The Company will propose a respective amendment to the Articles of Incorporation in due course of time.

Entries 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. As soon as RSU vest, the restriction period is waived. As soon as PSU vest, all performance criteria are deemed to be fulfilled. As soon as another instrument vests, all conditions are deemed fulfilled and any restriction is waived.

Other than that, as of December 31, 2022, 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 Martin Mattes. He assumed his responsibility in 2022 (DCG 8.1.2).

Auditing fees and additional fees (DCG 8.2/8.3)

The following fees were charged in the 12-month period ended December 31 for professional services rendered by Ernst & Young(audit-related fees have been incurred in connection with capital increases and related comfort letters and review procedures):

In CHF thousands	2022	2021
Audit services	829	698
Audit-related services	180	84

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.

Information instruments pertaining to the external audit (DCG 8.4)

The Board performs its supervisory and control functions towards the external auditors. In particular, the Board or the Audit Committees 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. All Board and Board Committee minutes, together with any pre-reads, are shared with the auditors. Material contracts are also shared, together with internal memos that are relevant for the auditors. In addition, the auditors have access to certain finance applications, receive legal letters from law firms and documents that contain representations of Board and Executive Management.

Information Policy (DCG 9)

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

The most important information tools are news releases, the AGMs, the Annual Report, the Interim Report and the website 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/news-subscriptions.

For contact details, see www.santhera.com/contact.

Corporate events 2023

The 2023 Annual General Meeting will be held on June 27, 2023 in Pratteln. See also www.santhera.com/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 (e.g. 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 2022 Annual Report, the quiet period has started on April 13, 2023 and will end on June 1, 2023, at close of business. As of the date of this report, no decision has been made on subsequent reporting dates; therefore, 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. The Company 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 Duchenne muscular dystrophy (DMD) as an alternative to standard corticosteroids. For vamorolone in the treatment of DMD, Santhera has a new drug application (NDA) under review by the U.S. FDA, a marketing authorization application (MAA) under review by the European Medicines Agency (EMA) and an MAA submitted to the UK Medicines and Healthcare products Regulatory Agency (MHRA). The clinical stage pipeline also includes lonodelestat to treat cystic fibrosis (CF) and other neutrophilic pulmonary diseases. Santhera outlicensed 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.

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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