



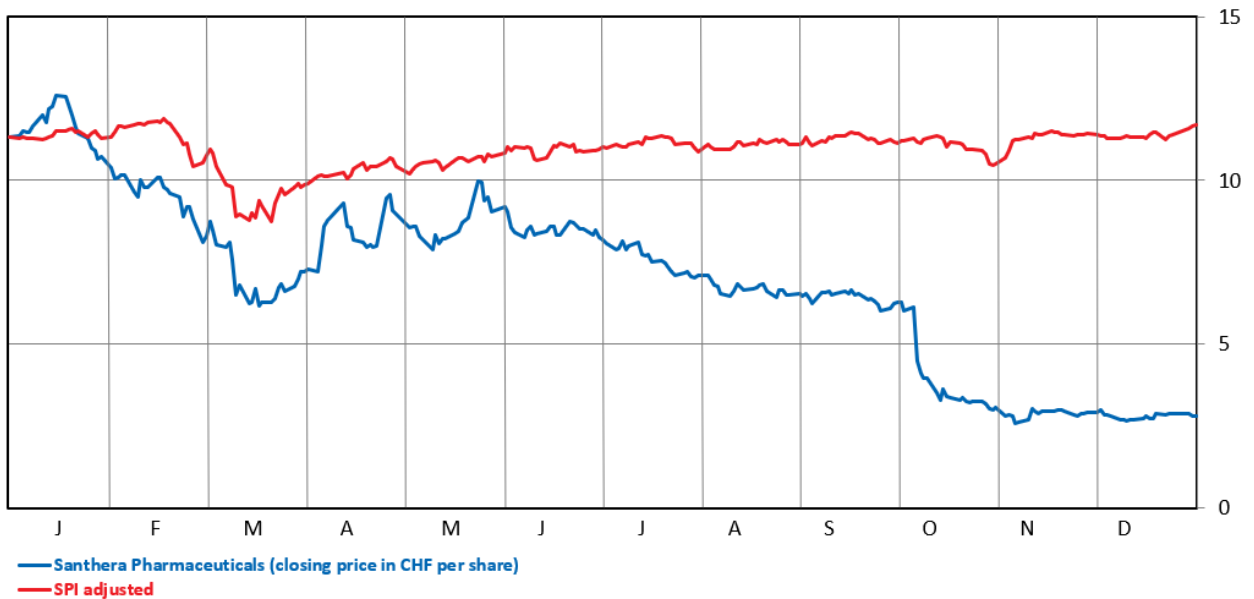
Annual Report 2020

Financial Key Figures

IFRS consolidated, in CHF thousands	2020	2019
Revenue from contracts with customers	15,008	75,376
Operating expenses	-58,347	-80,652
Operating result	-53,076	-10,442
Net result	-67,659	-18,973
Basic and diluted net result per share (in CHF)	-5.08	-1.73
Freely available liquid funds at December 31 *	12,411	31,358
Net change in cash and cash equivalents	-18,947	9,387

* Cash and cash equivalents

Share Price Development in 2020



High	CHF 12.58 (January 17, 2020)
Low	CHF 2.59 (November 5, 2020)
Share price performance in 2020	-75.3%
Share price at year-end	CHF 2.80
Market capitalization at year-end	CHF 54 million
Average trading volume	68,381 shares/day

(based on closing share prices)

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Letter to Our Shareholders

Dear Shareholders,

Having emerged from a challenging 2020, we are pleased to have started 2021 with the strong foundation of a refreshed clinical and operational strategy.

Our future strategy is now focused on vamorolone, which we believe can provide significant value to patients, caregivers, and ultimately shareholders. It represents the key foundation for the future of Santhera, which continues to focus on Duchenne muscular dystrophy (DMD) and other rare diseases.

Vamorolone is currently being developed jointly by ReveraGen and Santhera for early stage DMD patients requiring an anti-inflammatory, muscle strengthening treatment with a differentiated safety and favorable tolerability profile to make it suitable for longer term administration. Recent encouraging data leads us to conclude that vamorolone could emerge as a foundational therapy in DMD for all patients irrespective of gene mutation and as a promising alternative to existing corticosteroids, the current standard of care in children and adolescent patients with DMD. Based on the collective clinical experience with vamorolone, we look forward with optimism to the readout of the 6-month top-line data from the pivotal VISION-DMD study, the next value enhancing inflection point. Subject to a positive outcome in Q2-2021, we will push ahead with the filing of a New Drug Application (NDA) with the US FDA and will step up preparations for market entry.

In terms of pursuing a vamorolone-lead strategy, securing financing was of prime urgency in 2020 and will remain a key priority in 2021. Various financing alternatives have already been put in place and have provided sufficient liquidity up to the next development milestone in Q2-2021. Currently, the restructuring of our outstanding CHF 60 million 5% Convertible Bonds due 2022 is in progress, giving participating bondholders a choice of accepting the amendments proposed to the recent bondholders' meeting and/or the terms offered in the exchange offer which are economically the same, mutatis mutandis. We are very pleased and grateful to you as Santhera's shareholders for already having approved a substantial capital increase, a prerequisite for bond conversion or ex-change and fundraising post clinical readout, at the Extraordinary General Meeting held on March 18. Subject to positive results from the pivotal VISION-DMD study, we are confident in our ability to successfully raise additional funds to advance the pipeline, prepare for commercialization and fund our operations.

For lonodelestat, our second clinical development candidate, data from a Phase 1b study were shared in March, which confirmed elastase inhibition in patients with cystic fibrosis (CF) and established an effective dose and a favorable tolerability profile. On this basis, the design of the further clinical study program for lonodelestat in cystic fibrosis has started alongside an evaluation of its potential in other chronic inflammatory conditions of the lung.

On the business development side, the Company is pursuing a proactive portfolio management strategy through out-licensing agreements for both vamorolone (in non-DMD indications and geographies outside the US and Europe) and lonodelestat (in non-CF indications). A further diversification of these platform-type pipeline products may offer an additional source of non-dilutive income streams in the mid-term.

We are committed to pursuing clinical development programs that aim to provide differentiated therapies to patients suffering from rare and severe diseases with high unmet medical needs. Our ambition to deliver a promising new treatment to patients suffering from DMD was shattered following the disappointing interim analysis of the large Phase 3 SIDEROS trial, last October, and the resulting closure of our program for Puldysa® (idebenone) in DMD. Moreover, it forced us to embark on a painful restructuring in which we had to say goodbye to the majority of our colleagues but allowed us to cut costs and align our Company with a focus on our future ambitions, primarily surrounding vamorolone.

We want to take a moment to recognize the huge efforts of Santhera employees over the last year, in both good times as well as battling their way through difficult phases without ever losing sight of our goals and our passion for delivering therapies to patients in need. We particularly also want to acknowledge the ongoing support of patients and their caretakers, our scientific and clinical partners, advisors and shareholders, without whom we couldn't continue our important research.

In just a year, we have completely transformed Santhera. We have new management, a new pipeline, a smaller, restructured company with lower fixed costs, new shareholders as well as—and subject to completion of our convertible bond restructuring—a new and stronger balance sheet. Only very few stones have been left unturned. We have survived market downturns, loss of our lead program and the pandemic's disruption and now feel the new energy and are optimistic about our future. We understand the pain caused to shareholders and employees in 2020 but are also proud to have a future. We are ready to launch 'Santhera 2.0' on the back of positive topline results for vamorolone. We hope you also see the new potential that lies ahead of us—and hope that we can count on your support as a shareholder for many more years to come.

Sincerely,



Elmar Schnee
Chairman



Dario Eklund
Chief Executive Officer

REVIEW OF 2020

Last year's events—mapping out Santhera's future

In a year of global turmoil, 2020 saw Santhera undergo major changes in both its pipeline and structure, with vamorolone emerging as the Company's new lead asset. The pursuit of financing opportunities to overcome Santhera's tight liquidity situation was a priority throughout the year. The 2020 highlight was certainly the deal in which Santhera acquired an assignment for the global option rights of vamorolone from Idorsia and the concurrent exercise of the license rights with ReveraGen. A substantial setback were the disappointing SIDEROS interim analysis results and the resulting closure of the Puldysa® (idebenone) program in Duchenne muscular dystrophy (DMD). This entailed a painful restructuring in which Santhera had to bid farewell to the majority of colleagues in order cut costs and align the Company with a focus on its future ambitions, primarily surrounding vamorolone.

Securing financing to advance the pipeline and fund operations

One of the main priorities for Santhera during 2020 was securing financing to provide sufficient liquidity up to the next development milestone in Q2-2021. From early 2020, the management of Santhera initiated roadshows to introduce the new equity story as well as the new CEO and CFO to past, present and potential future investors. In parallel, the Company undertook a deep cost saving exercise and evaluated various financing alternatives in order to sufficiently extend its cash reach. The overall objective of the meetings with investors was to increase awareness about the investment opportunity Santhera offers and subsequently increase their interest in participating in an upcoming equity financing. The interest in Santhera was solid and hence the expectation was that a raise was going to be successful.

Unfortunately, the global fears about the spread of Covid-19 had started to take a toll and stock markets around the world tumbled by -20-40% from their peak only within weeks. Hence, the Company also focused on securing financial means through pursuing non-equity dilutive funding. In the absence of a larger raise, and in order to provide some short-term equity funding, the Company entered into a standby equity program with IRIS in order to provide CHF 12 million in the period to April 2021, with the option to extend a further 12 months to provide a further CHF 12 million. Later in the year, Santhera was pleased to undertake a number of agreements with Highbridge Capital (New York) of which the initial agreement was to provide up to CHF 20 million based around the achievement of certain milestones. In November 2020, the former financing with Highbridge was amended to provide up to CHF 18 million (CHF 6 million of which was previously committed) in senior secured notes exchangeable into shares at the option of Highbridge.

The Company's cash balances of CHF 12.4 million (as of December 31, 2020), together with the amended Highbridge facility, other financing and cost reduction initiatives, were expected to provide sufficient funding to Santhera to reach the next major value enhancing inflection point, namely the 6-month topline readout of the VISION-DMD study with vamorolone.

REVIEW OF 2020

Puldysa program and SIDEROS

Unfortunately, Santhera and the DMD community suffered a deep loss in October when the SIDEROS study with Puldysa® (idebenone) was discontinued following an interim analysis showing futility. SIDEROS was a large double-blind Phase 3 study designed to demonstrate that Puldysa reduces the rate of respiratory decline in patients with DMD and taking steroids, thereby confirming the results of the prior positive Phase 3 study DELOS without concomitant steroid medication. During May 2020, as the SIDEROS study approached full enrollment, a routinely performed statistical assessment showed a high study power and pointed to the usefulness of conducting an interim analysis. On this basis, Santhera completed enrollment into the SIDEROS trial and mandated the independent Data and Safety Monitoring Board (DSMB) to perform an interim analysis, testing for efficacy while preserving data integrity. The results of the interim analysis were to be used as supportive evidence towards a positive CHMP opinion in the application for conditional marketing authorization (CMA) for Puldysa which was pending with the European Medicines Agency (EMA). In contrast to all expectations, the outcome of the interim analysis revealed that the probability of reaching the primary endpoint at the end of the study was lower than 20% and therefore too small to merit the continuation of the study. Due to these disappointing results, Santhera terminated the program for idebenone in DMD. Out of respect and gratitude for participating patients and families, and for the sake of contributing to the research and treatment improvement in this devastating disease, Santhera is investigating the cause for the trial failure.

Restructuring to adapt the organization to the new reality and extend cash reach

As a consequence of the termination of the Puldysa program, for which Santhera committed significant resources in anticipation of a European launch early 2021, the Company initiated a restructuring process. Early November 2020, Santhera announced reducing its workforce by more than 50 positions to 47 full-time equivalent (FTE) employees and initiated closure of its European subsidiaries. The US operations remained untouched as the US is expected to be the first launch country for vamorolone in 2022. These steps were undertaken in order to align operations to focus on progressing vamorolone for DMD, Santhera's top development priority, and extend the Company's cash reach up to the next value enhancing inflection point, on the back of which raising additional financing would become possible. It was a painful process to undergo for all at Santhera, but it allowed the Company to focus on its future ambitions. The know-how of the core team in the development of DMD drug candidates and the commercialization of a rare disease product—with extensive regulatory experience with the FDA and EMA, strong relationships with key clinical experts and the patient community, and proven market access capabilities—will be leveraged in order to bring vamorolone to patients.

Vamorolone—Santhera's strategic near- and mid-term pipeline priority

Vamorolone, an anti-inflammatory, muscle strengthening treatment for early-stage DMD patients, is being developed jointly by ReveraGen and Santhera and became the Company's lead development asset. On September 2, 2020, Santhera announced the completion of a license assignment from Idorsia (SIX: IDIA) and the early exercise

REVIEW OF 2020

of a licensing option to vamorolone with ReveraGen BioPharma, Inc (US: private). In executing the Company's longer-term plans, it was originally anticipated that the Company would exercise its sub-license option for vamorolone in early 2021 which would have required USD 30 million as an exercise fee (together with obligations after that time) and successful financing activities in the meantime. However, following discussions with the parties ReveraGen and Idorsia, the Company pursued the early option exercise coupled with the granting of a full license to Santhera and amendments to the agreement. These steps achieved two goals: they fully secured the asset while at the same time reduced the near-term cash requirement for option exercise by CHF 18-24 million in the subsequent 18 months.

In 2020, the vamorolone development program made significant progress with core and extension studies generating a wealth of encouraging new clinical data, shedding light on the compound's novel mode of action, its efficacy, differentiated safety and favorable tolerability profile. The molecular distinctions of vamorolone compared to standard corticosteroids are thought to explain the unique properties of the drug candidate by dissociating efficacy from typical steroid safety-related concerns that limit their use and lead to high levels of treatment discontinuation. Recently published data from open-label studies (VBP15-003 and VBP15-LTE) evaluated the long-term safety, tolerability and efficacy of vamorolone in patients with DMD and showed improvements from baseline with vamorolone on all measured motor functions through the 18-month follow-up period. These improvements were comparable to those seen in historic corticosteroid-treated patients. Equally important, vamorolone did not show stunting of growth, as seen with deflazacort and prednisone, and also showed fewer physician-reported adverse events such as mood disturbance, excessive hair growth, and Cushingoid appearance. On this basis, Santhera believes that vamorolone could emerge as a foundational therapy in DMD for all patients irrespective of gene mutation and a promising alternative to existing corticosteroids, the current standard of care in children and adolescent patients with DMD. The next value enhancing inflection point is the readout of topline data from the pivotal VISION-DMD study, expected in Q2-2021. If positive, this would pave the way for a US NDA submission in Q1-2022 and in the EU, upon availability of positive 12-month data, in Q2-2022.

Lonodelestat—positive results in early phase cystic fibrosis trial

Likewise, lonodelestat, a potent and selective circular peptide inhibitor of human neutrophil elastase (hNE) in development to treat cystic fibrosis (CF), made good progress. Neutrophil elastase is an enzyme associated with tissue inflammation, leading to degradation of the lung tissue in CF and several other chronic inflammatory conditions of the lung where neutrophils play a prominent role in the disease process. In December 2020, Santhera completed a double-blind, placebo-controlled multiple ascending dose Phase 1b study in patients with CF which assessed the safety, tolerability, pharmacokinetics and pharmacodynamics of orally inhaled daily doses of lonodelestat for up to four weeks. The study established a safe dose regimen and provided promising data on the safety of lonodelestat. Furthermore, the study demonstrated that lonodelestat reaches its intended target in the lung and achieves the desired effect of complete inhibition of elastase without any drug/metabolite accumulation. On this basis, Santhera will now be optimizing the further clinical development program to advance lonodelestat for the treatment of CF and potentially for other inflammatory pulmonary conditions, whether acute or chronic.

REVIEW OF 2020

Partnering for platform-like molecules and early stage pipeline

Santhera has started the pursuit of partnering opportunities for vamorolone in additional indications outside DMD and in geographies outside the US and Europe which could result in significant future non-dilutive income streams. Preclinical data with vamorolone has 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 some of these diseases, the prescription of standard glucocorticoids is limited due to detrimental side-effects. In parallel, the Company is proactively pursuing collaborations with partners to assess and exploit the potential of londelestat in other pulmonary diseases beyond CF and for its undertakings in gene therapy.

Strengthening the capital structure

In early 2021, after year-end closing, Santhera proposed a restructuring of its existing CHF 60 million Senior Unsecured Convertible Bonds, which Highbridge Capital Management, LLC, as the largest bond investor with approx. 32% of the outstanding principal amount has agreed to support. A large majority of 89% of represented bondholders, equaling 58% of the total bonds outstanding, voted in favor of the resolutions proposed by the Company, however, the required threshold of 2/3 of all bonds outstanding to pass such resolutions to exchange all bonds was not met. On March 18, 2021, Santhera convened an Extraordinary General Meeting (EGM) where the Board proposed to shareholders the authorization and issuance of the shares required to implement the upsized financing from Highbridge and the intended restructuring of the existing convertible bonds. Santhera's shareholders supported all motions by the Board and approved an increase of the Company's capitals, thereby paving the way for the implementation of a new balance sheet structure and future fund raisings. Separately, the Company, on March 25, 2021, launched a bond exchange offer and on April 27, 2021 reported that 74.7% of bondholders had tendered under the Exchange Offer and, in parallel, seeking votes on the bondholders' resolution continued. The Company expects to announce the settlement date or a postponement of the settlement by May 3, 2021 at the latest. The Company views this strengthening of Santhera's capital structure as the best way to secure its operations past the 6-month VISION-DMD data readout, after which, if positive, it will seek additional financing to fuel its future growth plans and to prepare for a launch of vamorolone in early 2022.

Santhera's path forward

2020 was a year of unexpected obstacles for Santhera, but the Company has ended the year with its focus firmly on advancing its late-stage clinical drug candidate, vamorolone, and securing sufficient funding to support operations beyond Q2-2021. Upon a positive 6-month readout for vamorolone, Santhera is set to prepare for renewed growth from 2022 by transitioning from development to commercialization.

FINANCIAL HIGHLIGHTS

Financial Performance & Financing Activities

Santhera reported revenue of CHF 15.0 million and a net loss of CHF 67.7 million following a reduction in revenue due to the out-licensing of Raxone to Chiesi Group in 2019 and costs associated with Puldysa activities and termination in addition to other pipeline activities. Liquid funds (cash and cash equivalents) at year-end amounted to CHF 12.4 million.

2020 full-year net revenues in line with expectations

In 2020, Santhera reported net revenue from its product Raxone of CHF 15.0 million (2019: CHF 75.4 million including CHF 46.4 million out-licensing income). This predominantly reflects sales of Raxone for the treatment of Leber's hereditary optic neuropathy (LHON) in France where Santhera still markets the product following the out-licensing to Chiesi Group in August 2019 outside of North America (2019: 24 European countries, with the majority of sales reached in France and Germany). The reduction on prior year of CHF 60.4 million reflects the full year impact of territories out-licensed to Chiesi Group as well as the inclusion of the upfront milestone recognized in 2019.

Cost of goods sold

Cost of goods sold were CHF 10.4 million (2019: CHF 5.5 million). The increase was primarily due to a one-off impairment of CHF 6.0 million related to the discontinuation of Puldysa, partially offset by the full year impact of out-licensed Raxone activities.

Operating expenses

With CHF 58.3 million, total operating expenses were significantly lower year-on-year (2019: CHF 80.7 million). The decrease in development expenses to CHF 34.2 million (2019: CHF 41.2 million) was primarily related to the discontinuation of the Puldysa development in Q4-2020. Marketing and sales decreased to CHF 11.5 million (2019: CHF 20.1 million) primarily as a result of the full year impact of out-licensed Raxone activities and termination of the Puldysa program. General and administrative purposes decreased to CHF 12.4 million (2019: CHF 19.2 million) as support activities were reduced and the European subsidiaries were closed.

During the year, the Puldysa development program was terminated which necessitated an organizational restructuring. During 2020, cost of goods recorded an inventory impairment of CHF 6.0 million and operating expenses included Puldysa related costs of CHF 11.4 million which are both non-recurring. In addition, the organizational restructuring, resulting in a reduction of headcount by over 50%, is expected to reduce staff costs by approximately CHF 10.0 million in future periods. Together, these represent costs incurred in the year of CHF 27.4 million not expected to occur in future periods. Going forward, the Company continues to reduce cost in other areas, however, in the event of positive upcoming vamorolone results, the Company expects to increase certain costs to support approval and pre-commercialization activities. Other costs incurred to carry out post-marketing study obligations for Raxone which are expected to be completed during 2021 and support the ongoing development of lonodelestat, which announced positive Phase 1 results in March 2021.

FINANCIAL HIGHLIGHTS

Financial income and expenses

Net financial income and expenses were CHF 14.4 million (2019: CHF 8.0 million). The increase of CHF 6.4 million was primarily due to the cost of raising additional funding during the year as well as the effect of currency gains & losses and the effect of derivative accounting adjustments.

Net result

The net result was a loss of CHF 67.7 million (2019: CHF 19.0 million), an increase of CHF 48.7 million on the prior year. The widening of the loss was predominantly the result of lower revenue of CHF 60.4 million following the out-licensing of Raxone which was only partially offset by cost reductions and also reflected the costs of development and termination of Puldysa.

Cash flow and cash balance

Cash used in operating activities was CHF 43.5 million (2019: inflow CHF 2.6 million) an increase of CHF 40.9 million which was mainly due to the reduction in revenue of CHF 60.4 million following out-licensing of Raxone being offset by other reduction in expenses.

The cash and cash equivalents at December 31, 2020 were CHF 12.4 million (2019: CHF 31.4 million).

Financial outlook

Santhera is still commercializing Raxone for LHON in France in a transitional phase and, as previously communicated, sales of the product are declining. From August 2021 onwards, as Raxone is expected to no longer be on the list of reimbursed products in France, the Company will continue to supply medication in the interest of patients, but does not expect to generate further products sales. Over the coming months, post-authorization studies will be completed upon which Santhera will resume discussions on reimbursement with the French authorities. Subject to the achievement of certain commercial milestones for Raxone, Santhera is entitled to contingent variable near- to mid-term milestone payments from Chiesi Group of up to EUR 49 million.

Currently, the Company has a limited cash runway to the third quarter 2021 and thus material uncertainties remain as to the Company's ability to continue as a going concern until December 31, 2021. Ongoing development activities and increase in pre-commercialization activities relating to vamorolone will require substantial additional funding, particularly in the latter part of 2021. Executing the Company's strategy depends on further funding to ensure the continuation of its operations through December 31, 2021.

As reported in the 2019 annual report, released in March 2020, Santhera had sufficient funds to mid-2020. The Company entered into financing arrangements with IRIS and Highbridge Capital which provided additional funding. As a result of the termination of the Puldysa program in 2020, the Company ended 2020 with a limited cash runway

FINANCIAL HIGHLIGHTS

and the anticipation to raise additional finance in the event of positive vamorolone 6-month study results expected in the second quarter of 2021. Following the initiatives taken during the fourth quarter of 2020, cash flow from operating activities had been significantly reduced and in February 2021 an amendment to the agreement with Highbridge was entered into which provided additional funding and extended the cash runway further into the third quarter of 2021.

Given the overall liquidity position and the requirement to raise additional funding during 2021, the Company commenced a restructuring of the CHF 60 million convertible bond maturing in February 2022. The process for this is in the final stages and is expected to result in an exchange of approximately 75% to a new bond with an extended maturity to August 2024, thereby reducing the amount maturing in February 2022 to approximately CHF 15.2 million.

Cash and cash equivalents as at April 27, 2021 were CHF 11.7 million, in addition CHF 6 million, subject to certain drawdown conditions being met, is available for drawdown under the Highbridge agreements.

The company held an Extraordinary General Meeting on March 18, 2021, where the shareholders approved additional authorized and conditional share capital that would be required in the event of conversion of the convertible bond for the new terms as well as to allow for some additional financing.

Santhera is currently evaluating a number of different options to secure additional financing of the Company which besides equity-based funding also includes debt financing, royalty financing, standby equity distribution agreement as well as the monetization of receivables. Potential requirements and sources will be further evaluated following the outcome of the upcoming vamorolone 6-month results. At the forthcoming Annual General Meeting on June 22, 2021, the Board plans to make corresponding proposals

RARE DISEASE FOCUS

Our Pipeline

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

Indication	Molecule	Development Stage						Milestones	Remarks
		Preclinical	Ph 1	Ph 2	Pivotal	Filing	Market		
Duchenne muscular dystrophy	vamorolone (oral suspension)	VISION-DMD						Q2-2021: Top line data expected	Licensed from ReveraGen
Cystic fibrosis	lonodelestat (inhaled)							Q1-2021: Successfully completed Phase 1	Licensed from Polyphor
Congenital muscular dystrophy	Gene therapy							Animal PoC ongoing	Collab. Univ. Basel & Rutgers
Inflammatory diseases e.g. IBD, COPD, Asthma	vamorolone							Preclinical biomarker studies published	Rationale for multiple diseases
Diseases associated with high hNE activity	lonodelestat							Under evaluation	Rationale for multiple diseases

Vamorolone option rights assigned from Idorsia and license taken from ReveraGen in Sep 2020
 IBD: Inflammatory Bowel Disease; COPD: Chronic Obstructive Pulmonary Disease
 hNE: Human Neutrophil Elastase; Lonodelestat was formerly known as POL6014
 PoC: Proof of Concept

The most advanced product is vamorolone in development as treatment for Duchenne muscular dystrophy (**DMD**), currently in a pivotal Phase 2b trial for which 6-month topline results are expected in Q2-2021. On this basis, and subject to a positive outcome, Santhera plans to file a New Drug Application (**NDA**) for vamorolone in DMD in the US in Q1-2022 and a Marketing Authorization Application (**MAA**) in the EU in Q2-2022. The early clinical stage pipeline includes lonodelestat, an innovative new investigational drug to treat cystic fibrosis (**CF**) and other neutrophilic pulmonary diseases as well as a collaboration in an exploratory gene therapy approach targeting congenital muscular dystrophies (**CMD**).

Both vamorolone and lonodelestat represent platform type pipeline molecules, each with potential for out-licensing and/or development in a broad range of additional indications in collaboration with partners.

DUCHENNE MUSCULAR DYSTROPHY

Vamorolone Highlights

Santhera, together with its licensor ReveraGen, is currently studying vamorolone for early stage patients with Duchenne muscular dystrophy (DMD) requiring an anti-inflammatory, muscle strengthening treatment with a differentiated safety and favorable tolerability profile to make it suitable for longer term administration and improving quality of life. Subject to positive 6-month data from the ongoing pivotal Phase 2b VISION-DMD trial, the Company prepares for a first submission of a New Drug Application (NDA) in the USA, followed by a Marketing Authorization Application (MAA) in the EU. Santhera's strategy aims to capture a wide range of patients independent of mutation, alone or in combination with other therapies.

DMD is one of the most common and devastating types of muscular degeneration and results in progressive muscle weakness, starting at young age and affecting 30,000 - 35,000 patients in US and EU combined. A genetic disorder, DMD primarily affects boys and is characterized by loss of the protein dystrophin in muscle cells as a result of genetic mutations. The average age at which boys will start to show symptoms of DMD is 3 to 5 years, and they are commonly unable to walk by their teenage years due to progressive muscle weakness and loss of muscle tissue over time. The prime therapeutic goal in ambulant boys with DMD is the preservation of motor function and delaying the time to wheelchair dependence.

Glucocorticoids are effective anti-inflammatory agents and current standard of care in DMD. However, their chronic use is associated with a series of clinically relevant side effects (e.g. stunted growth, weight gain, diabetes, hormonal imbalance, immunosuppression and recurrent fractures of bone) that lead to high levels of therapy discontinuations and often limit their use.

Novel pharmacology of vamorolone drives differentiated clinical benefit with improved safety profile

Vamorolone, a dissociative steroid, is a first-in-class multi-functional anti-inflammatory drug candidate with novel pharmacological properties. The compound binds to the same receptor as corticosteroids but modifications to its structure modifies interactions with glucocorticoid receptors leading to favorable changes of its downstream activity. This novel mode of action is designed to retain anti-inflammatory steroid efficacy and importantly reduce steroid-associated side effects that lead to early treatment discontinuation in a large proportion of DMD patients. Moreover, unlike steroids, vamorolone has antagonist properties on mineralocorticoid receptor pathways with the potential for a cardiac benefit in DMD. Its inherent membrane stabilizing properties are believed to support fragile muscle cell integrity, potentially counteracting the disease-related waste of muscle tissue. The safety and tolerability profile as observed in existing clinical trials could make it suitable for longer use as chronic therapy.

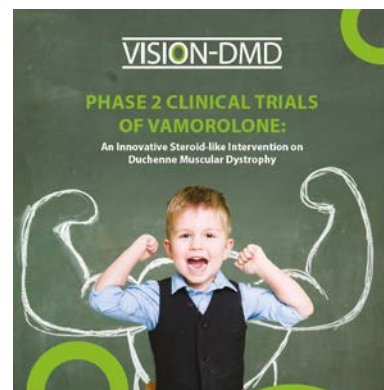
Vamorolone has been designed to offer the benefits of steroids for longer

In the currently completed studies, a total of 48 patients have received various doses of vamorolone; of which 41 patients have been treated and evaluated for a period of 2.5 years. Aggregate clinical data from these open label studies in DMD published to date showed sustained efficacy and clinical improvement with vamorolone across multiple endpoints coupled with a reduction of certain corticoid-specific side effects known to lead to treatment discontinuation. The Company believes vamorolone has the potential to become a foundational therapy in DMD for patients irrespective of the underlying gene mutation and a promising alternative to existing corticosteroids, the current standard of care in children and adolescent patients with DMD.

DUCHENNE MUSCULAR DYSTROPHY

In the pivotal Phase 2b VISION-DMD study (VBP15-004; [clinicaltrials.gov: NCT03439670](https://clinicaltrials.gov/ct2/show/study/NCT03439670)) in 121 boys the last patient has completed the last visit of the initial 6-month period. Study efficacy endpoints include timed function tests and measures of muscle strength and endurance. Safety endpoints include monitoring of weight gain, bone metabolism, cataracts, and biomarkers of metabolic disturbances. Top-line readout of the 6-month data is expected in Q2-2021.

Vamorolone has been granted Orphan Drug status in the US and in Europe, and has received Fast Track and Rare Pediatric Disease designations by the US FDA. In the UK, vamorolone in DMD has Promising Innovative Medicine designation, a status similar to a breakthrough therapy designation by the FDA.



Achievements

- Jun 2, 2020 – Completion of a long-term, open-label extension Phase 2a study of 24 months duration with vamorolone in patients with DMD. Including 6 months treatment in the preceding Phase 2a study, ReveraGen has now obtained safety and efficacy data with vamorolone over a period of 2.5 years in 41 boys with DMD.
- Sep 2, 2020 – Santhera has obtained an exclusive license from ReveraGen, the originator of vamorolone, for all indications worldwide. The agreements create further value for Santhera through the right to grant sub-licenses and a share in the expected Priority Review Voucher.
- Sep 11, 2020 – Partner ReveraGen Biopharma Inc. has completed enrollment into the pivotal VISION-DMD study with vamorolone in patients with DMD.
- Sep 14, 2020 – Publication of new data on the molecular mode of action of vamorolone compared to standard corticosteroids (prednisone and deflazacort) which are thought to explain the unique dissociative properties of vamorolone.
- Sep 22, 2020 – Publication of new open-label, long-term clinical data on the safety, tolerability and efficacy of vamorolone in patients with DMD. The data show a reduction of corticosteroid-specific side effects and sustained efficacy with vamorolone including clinical improvement through the 18-month follow-up period.
- Mar 3, 2021 – The last patient has completed the last visit for the first period of the placebo-controlled pivotal VISION-DMD study with vamorolone in patients with DMD.
- Apr 28, 2021 – Santhera and ReveraGen Announce New 2.5-year Treatment Data with Vamorolone in Duchenne Muscular Dystrophy.

Near-term targets

- 6-month top-line data from VISION-DMD study in Q2-2021.
- Subject to favorable VISION-DMD study data, filing of an NDA with the FDA planned for Q1-2022.

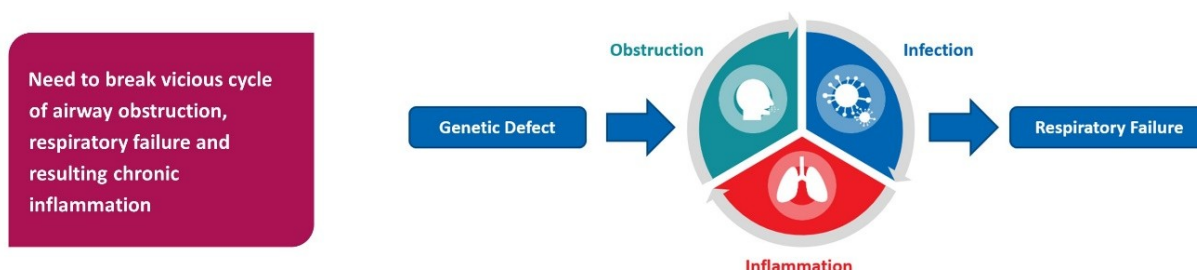
CYSTIC FIBROSIS

Lonodelestat Highlights

Lonodelestat, a selective inhibitor of an enzyme called human neutrophil elastase (NE), is in development to treat cystic fibrosis (CF). It is expected to provide a benefit for the patients in their mid- and long-term outcome by addressing the chronic inflammation which otherwise is destroying pulmonary tissue over time. Excessive neutrophil activity in a range of pulmonary inflammatory diseases provides a rationale for pipeline expansion and potential opportunities for lonodelestat beyond CF.

Cystic fibrosis (CF) is an inherited disease in which the body makes very thick, sticky mucus. The thick mucus causes problems in the lungs, pancreas, and other organs. People with cystic fibrosis suffer from chronic pulmonary infections and progressive loss of pulmonary function. CF is typically diagnosed in young children mostly within the first years of age. The cause are mutations in the so-called CF transmembrane conductance regulator (CFTR) gene.

The pulmonary symptoms are caused by accumulation of mucus, obstructing the airways and leading to persistent infection, influx of inflammatory cells like neutrophils with subsequent chronic inflammation. High levels of NE play a central role in the deterioration of pulmonary function associated with CF. Neutrophils produce NE, normally absent in the lung, which causes damage to structural, cellular and soluble components of the pulmonary tissues. Inhibition of NE is expected to stop or slow down the progression of pulmonary function loss, preserve pulmonary independence for longer and help to live longer with an improved overall quality of life for individuals with CF.



More than 80,000 patients in the US and Europe combined have been diagnosed with CF. While treatments have been approved to ameliorate airway obstruction and treat infections, currently no drug has been approved to directly target inflammation in this disease. There remains a need for treatments to effectively break the vicious cycle of obstruction, infection and inflammation.

Lonodelestat targets elastase, a protease responsible for pulmonary damage

Lonodelestat, licensed from Polyphor, is a highly potent, reversible and selective NE inhibitor. The compound effectively inhibits free and membrane-bound NE in very low (pico-molar) concentrations after inhaled and intranasal administration in various in vivo models of lung diseases.

CYSTIC FIBROSIS

Successful Phase 1 program paves way for further clinic development

Lonodelestat is designed to provide a benefit for the patients in their long-term outcome by addressing the chronic inflammation which otherwise is destroying pulmonary tissue over time. Available clinical data demonstrate that single doses of lonodelestat when administered by inhalation via an optimized eFlow® nebulizer (PARI Pharma GmbH) can achieve high drug concentrations in sputum and within the lung and result in complete inhibition of NE. The recently completed multiple ascending dose (MAD) study showed good tolerability and transient, near complete inhibition of elastase activity with daily inhalation of 40/80/160 mg QD and 80 mg BID over a period of 2-4 weeks. This Phase 1b study further confirmed the tolerability of lonodelestat after treatment of up to four weeks in patients with CF. No accumulation of lonodelestat or its metabolites was observed for any dose or frequency used during the Phase 1 program and no serious adverse events were reported. To date, the CF development program achieved key objectives by identifying a safe dose regimen, establishing the effect on the inflammatory biomarker and demonstrating high local targeting through inhalation.

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

Lonodelestat holds promise beyond CF

Chronic inflammation related to pathologically high elastase levels is associated with a number of additional indications which provides opportunities beyond CF for a very potent and selective elastase inhibitor directly delivered to the lung via inhalation such as lonodelestat. Lonodelestat may show therapeutic benefit for a range of neutrophilic pulmonary diseases with high medical need such as primary ciliary dyskinesia, alpha-1 antitrypsin deficiency, non-cystic fibrosis bronchiectasis, chronic obstructive pulmonary disease, lung cancer, acute respiratory distress syndrome (e.g. associated with Covid-19), pulmonary arterial hypertension and other disorders associated with excessive pulmonary NE levels.

Achievements

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

Near-term targets

- Following completion of the analyses of the positive MAD-trial, prepare for Phase 2 efficacy trial of lonodelestat in CF and potentially also other inflammatory pulmonary diseases.
- Advance partnering opportunities for additional indications of this platform-type compound.

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 team¹ with a vast background in the pharmaceuticals and biotech industry, from small and large companies.

Board of Directors



Elmar Schnee, Chairman



Martin Gertsch



Philipp Gutzwiller



Thomas Meier, Founder



Patrick Vink

Executive Committee



Dario Eklund, CEO



Andrew Smith, CFO
(from April 1, 2020)



Günther Metz, Head Business
Development



Oliver Strub, Group General Counsel

¹ The full profiles of the team members can be viewed in the Corporate Governance section in this annual report or by visiting <http://www.santhera.com/about-overview#board-of-directors>

Consolidated Financial Statements

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Consolidated Balance Sheet

	As of December 31, in CHF thousands	Notes	2020	2019
Assets				
Tangible assets		5	1,902	5,604
Intangible assets		6,7	67,673	58,479
Financial assets long-term			552	664
Deferred tax assets		13	837	1,049
Noncurrent assets			70,964	65,796
Prepaid expenses			344	637
Inventories		8	481	6,859
Trade and other receivables		9	4,487	8,901
Restricted cash short-term		10	0	1,500
Cash and cash equivalents		10	12,411	31,358
Current assets			17,723	49,255
Total assets			88,687	115,051
Equity and liabilities				
Share capital		11	19,430	11,165
Capital reserves and share premium			480,005	448,084
Retained earnings			-500,899	-433,240
Employee benefit reserve			-2,320	-3,160
Treasury shares		11	-1,580	-745
Translation differences			-990	-857
Total equity			-6,354	21,247
Convertible bonds		12	57,875	56,154
Noncurrent derivative financial instruments		12	0	617
Noncurrent contract liabilities		21	0	1,126
Noncurrent lease liabilities		12	1,927	2,827
Pension liabilities		23	6,170	9,116
Total noncurrent liabilities			65,972	69,840
Trade and other payables		14	5,715	9,532
Accrued expenses		15	8,645	11,427
Income tax payable			60	395
Current contract liabilities		21	1,126	1,597
Current lease liabilities		12	769	1,013
Current exchangeable notes (Idorsia & Highbridge)		12	10,595	0
Current derivative financial instruments		12	125	0
Current provisions		16	2,034	0
Total current liabilities			29,069	23,964
Total liabilities			95,041	93,804
Total equity and liabilities			88,687	115,051

Consolidated Income Statement

For the year ended December 31, in CHF thousands	Notes	2020	2019
Net sales	19	11,252	27,890
Revenue from out-licensing transactions	19,21	1,597	46,370
Net sales to licensing partner	19,21	2,159	1,116
Revenue from contracts with customers		15,008	75,376
<hr/>			
Cost of goods sold		-10,431	-5,450
<i>Of which amortization intangible assets</i>		-3,039	-3,039
Other operating income		694	284
Development	22	-34,228	-41,244
Marketing and sales	22	-11,474	-20,096
General and administrative	22	-12,440	-19,184
Other operating expenses	22	-205	-128
Operating expenses	22	-58,347	-80,652
Operating result		-53,076	-10,442
<hr/>			
Financial income	24	1,055	1,656
Financial expenses	24	-15,435	-9,608
Result before taxes		-67,456	-18,394
<hr/>			
Income taxes	25	-203	-579
Net result		-67,659	-18,973
<hr/>			
Basic and diluted earnings/loss per share (in CHF)	26	-5.08	-1.73

Consolidated Statement of Comprehensive Income

For the year ended December 31, in CHF thousands	Notes	2020	2019
Net result		-67,659	-18,973
<i>Items never to be reclassified to net income in subsequent periods:</i>			
Actuarial gains/losses on defined benefit plans	23	840	-485
<i>Items to be reclassified to net income in subsequent periods:</i>			
Currency translation differences		-133	-72
Other comprehensive result		707	-557
Total comprehensive result		-66,952	-19,530

Consolidated Cash Flow Statement

For the year ended December 31, in CHF thousands	Notes	2020	2019
Result before taxes		-67,456	-18,393
Depreciation and impairment of tangible assets	5	3,960	1,653
Amortization and impairment of intangible assets	6,7	3,177	3,118
Expenses for equity rights plans	18, 23	3,029	6,255
Change in fair value of derivatives		-617	413
Change in pension liabilities	23	-2,106	648
Change in current provisions	16	2,034	0
Taxes paid		10	-343
Change in net working capital		3,245	5,776
Total financial result	24	14,380	7,952
Interest received		3	8
Interest paid		-3,169	-4,492
Cash flow from/(used) in operating activities		-43,510	2,595
Investments in tangible assets	5	-29	-98
Investments in intangible assets	6	-5	-131
Change in investments in other long-term financial assets		97	18
Change in restricted cash	10	1,500	3,000
Cash flow from in investing activities		1,563	2,789
Capital increase	11	0	7,125
Capital increases from options exercised	11	0	2
Proceeds from sale of treasury shares	11	901	1,830
Purchase of treasury shares	11	-922	-1,837
Proceeds from convertible notes (IRIS)		10,833	0
Proceeds from convertible notes (Highbridge)		13,726	0
Proceeds from current loan		0	4,732
Repayment of current loan		0	-4,732
Payment of principal portion of lease liabilities	12	-1,071	-1,055
Transaction cost (Idorsia)		-70	0
Cost of issuance share capital		-247	-1,936
Cash flow from financing activities		23,150	4,129
Effects of exchange rate changes on cash and cash equivalents		-150	-126
Net increase/decrease in cash and cash equivalents		-18,947	9,387
Cash and cash equivalents at January 1		31,358	21,971
Cash and cash equivalents at December 31		12,411	31,358

Consolidated Statement of Changes in Equity

In CHF thousands	Notes	Share capital	Capital reserves and share premium	Retained earnings	Employee benefit reserve	Treasury shares	Translation differences	Total
Balance at January 1, 2019		10,665	435,795	-414,267	-2,675	-904	-785	27,829
Net result		0	0	-18,973	0	0	0	-18,973
Other comprehensive result	23	0	0	0	-485	0	-72	-557
Total comprehensive result for the period		0	0	-18,973	-485	0	-72	-19,530
Transactions for equity rights plans	18, 23	0	6,255	0	0	0	0	6,255
Capital increase from options exercise		0	2	0	0	0	0	2
Capital increase		500	6,625	0	0	0	0	7,125
Cost of issuance share capital		0	-426	0	0	0	0	-426
Change in treasury shares		0	-167	0	0	159	0	-8
Balance at December 31, 2019		11,165	448,084	-433,240	-3,160	-745	-857	21,247
Balance at January 1, 2020		11,165	448,084	-433,240	-3,160	-745	-857	21,247
Net result		0	0	-67,659	0	0	0	-67,659
Other comprehensive result	23	0	0	0	840	0	-133	707
Total comprehensive result for the period		0	0	-67,659	840	0	-133	-67,659
Transactions for equity rights plans	18, 23	0	3,029	0	0	0	0	3,029
Capital increase for financing transactions	11	4,569	0	0	0	-4,569	0	0
Delivery of shares upon conversion of IRIS loans	11	0	11,909	0	0	2,079	0	13,988
Delivery of shares upon conversion of Highbridge loans	11	3,696	15,661	0	0	880	0	20,237
Capital increase Idorsia	6, 11	0	1,998	0	0	367	0	2,365
Cost of issuance share capital		0	-247	0	0	0	0	-247
Change in treasury shares	11	0	-429	0	0	408	0	-21
Balance at December 31, 2020		19,430	480,005	-500,899	-2,320	-1,580	-990	-6,354

Notes to the Consolidated Financial Statements

1 General Information

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

The Company, having its primary listing of its registered shares (**Shares**) on the SIX Swiss Exchange (**SIX**), is a Swiss stock corporation and the parent company of the Group. Its purpose is to acquire, dispose and manage investments. The Company has its registered offices at Hohenrainstrasse 24 in 4133 Pratteln, Switzerland.

The consolidated financial statements were approved for publication by the Board of Directors (**Board**) on April 28, 2021. They are subject to approval by the Annual General Meeting of Shareholders (**AGM**) on June 22, 2021.

2 Summary of Significant Accounting Policies

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

Basis of preparation

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

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

Material uncertainties and ability to continue operations

The consolidated financial statements of Santhera have been prepared under the going concern assumption despite several material uncertainties present that may be contrary to this assumption.

Following the announcement of the discontinuation of its Phase 3 SIDEROS study with Puldysa[®] (idebenone) in patients with Duchenne muscular dystrophy (DMD), in October 2020, the Company decided to implement a restructuring plan for the business with a focus on retaining key functions for bringing DMD drug candidate vamorolone to patients and execute on its other pipeline programs. The discontinuation of Puldysa[®] development also resulted in Santhera not being able to utilize fully the financing facility entered into with Highbridge or to enter into an equity financing anticipated on a successful study outcome. The Company required additional funds in order to reach the next inflection point, the topline results of the pivotal Phase 2b study in DMD of vamorolone then anticipated in the first quarter of 2021.

In November 2020, the Company provided an update on the organizational restructuring resulting in a 50% reduction in workforce, initiated further measures to reduce operational costs and announced an amendment to its financing facilities to provide up to CHF 15 million which together with other initiatives were anticipated to provide funding into early 2021 and to the 6-month vamorolone readout to an updated timeline of the second quarter 2021.

The series of events through 2020 continued the existence of a limited short term cash runway through the year resulting in cash and cash equivalents amounted to CHF 12.4 million as of December 31, 2020. However, because the current funds are insufficient to allow the Company to reach the value inflection points after the vamorolone readout, material uncertainties remain as to the Company's ability to continue as a going concern until December 31, 2021. Executing the Company's strategy significantly depends on the following

- the vamorolone pivotal study 6-month topline readout expected in the second quarter 2021,
- Further funding to ensure the continuation of its operations through December 31, 2021 in any scenario (i.e. also in vamorolone pivotal study 6-month topline results are positive).
- Continued revenue from Raxone, as well as no material adverse events as it relates the reimbursement status of Raxone in France (see note 17 Commitments and Contingent Liabilities)
- Ability to settle current debt obligations

The outcome of the pivotal Phase 2b study with vamorolone in ambulant patients with DMD, being conducted by ReveraGen, expected during the second quarter of 2021 is uncertain. In the event of positive results, the Management and Board of Directors plan to raise additional funds through a capital increase in the second half of 2021 in order to finance further development to support an NDA submission and pre-commercialization activities. In the event that results are inconclusive, the Management and the Board of Directors still plan to raise additional funds in order to reach the completion of the 12-month treatment period expected during the fourth quarter of 2021, the results of which will then be further assessed during the fourth quarter of 2021. As of the date of these financial statements no additional financing has yet been committed under any scenario. Further if in the second quarter 2021 the results of the vamorolone 6-month topline readout results are negative, it is probable that the vamorolone development in DMD would be discontinued. If vamorolone in DMD is discontinued at either the 6-month or 12-month timepoints, the Company would initiate further organizational restructuring measures and likely cessation of all business activities and monetization of the assets (e.g. milestones receivable from out-licensing Raxone, lonodelestat or vamorolone in non-DMD indications) that may incur termination cost.

The early clinical program for vamorolone to date has established a wide therapeutic safety margin with early Phase 1 data demonstrating no dose limiting toxicity across a twenty-fold dose range. Furthermore, the first phase of the multiple ascending Phase 2a study program in DMD patients aged 4 to less than 7 years old, demonstrating a clear dose relationship to pharmacodynamic markers of disease, after which patients entered into an extension phase with the aim to explore the efficacy, safety and tolerability of vamorolone over 2.5 years on well-established clinical outcome measures. The Phase 2a program demonstrated a dose dependent and clinical improvement across all timed function clinical outcomes compared to baseline for up to 18 months but importantly showed no growth stunting and a much-reduced incidence of behavioral changes, Cushingoid appearance with weight gain only occurring in a minority of patients at the higher dose that were down titrated but continued treatment. Comparison to external natural history data in treated and untreated cohorts, indicates that vamorolone offers similar anti-inflammatory benefits of current glucocorticoids but has a clear and well differentiated safety profile meeting market, physician and patient needs in avoiding many of the adverse effects that lead to early discontinuation of treatment that will lead to avoidance of many of the costly chronic adverse conditions currently burdening healthcare systems. The Phase 2a long term extension study 30-month (2.5 year) data is currently being analyzed but early analyses have indicated a consistent profile that was previously published. In summary the Phase 2a

program has demonstrated a clinically important improvement or disease stabilization across several well-established clinical outcome measures whilst importantly delivering data supporting a safety profile consistent with an improved tolerability profile enabling longer term use. The pivotal Phase 2b VISION-DMD study is in the same target population, utilizing the 2 higher doses and same clinical outcome measures as explored in the Phase 2a study. The study successfully completed recruitment in September 2020 with last patient last visit in March 2021, however, uncertainty remains over the upcoming results expected within the second quarter of 2021.

During February 2021 the Company increased its financing facility, by CHF 12 million with Highbridge to increase the runway beyond the next inflection point and allow for increased time to raise additional finance after the vamorolone results. The availability of funds from this facility is subject to certain conditions being met. In order to achieve an equity financing during 2021, Management and the Board of Directors also decided it was necessary to wholly or partially restructure Santhera's CHF 60 million Convertible Bond maturing in February 2022. Actions are currently ongoing to restructure this debt. As announced on April 27, 2021 74.7% of bonds held had been tendered for exchange and in parallel a consent solicitation process is continuing in order to seek a two third majority of all bondholders in order to restructure 100% of the convertible bond to the new terms offered. In any event a minimum amount of 74.7% of the convertible bond will be exchanged providing a new maturity date of August 2024 and a reduction in the nominal value, such that the CHF 60 million previously maturing in February 2022 would become CHF 15.2 million with the remaining revised nominal value and CHF 44.8 million maturing in August 2024. In addition to assist with short term liquidity the interest due on the exchanged bond at the Company's election may be paid in shares rather than cash.

Shareholders should note that whilst the Management and Board of Directors consistently continue to apply best efforts to evaluate and execute available options, there is no guarantee that the development studies will be successful, and any transaction can be realized or that such transaction would generate sufficient funds to finance operations through December 31, 2021. This material uncertainty may cast significant doubts about the going concern of the Company. If going concern cannot be supported, consolidated financial statements would have to be prepared using liquidation values.

However, the Management and the Board of Directors of the Company are prepared to secure additional funds needed in order to operate its business as planned with the objective to meet all of its obligations until December 31, 2021. Hence, the consolidated financial statements have been prepared on a going concern basis.

Consolidation

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

The consolidated financial statements of Santhera include the accounts of Santhera Pharmaceuticals Holding AG, Pratteln, Switzerland, and its wholly owned subsidiaries Santhera Pharmaceuticals (Schweiz) AG, Pratteln, Switzerland; Santhera Pharmaceuticals (USA), Inc., Burlington, US; Santhera Pharmaceuticals (Canada), Inc., Montréal, Canada; Santhera Pharmaceuticals (Deutschland) GmbH, Lörrach, Germany; and Oy Santhera Pharmaceuticals (Finland) Ltd, Helsinki, Finland. The accounts further include the wholly owned subsidiaries of Santhera Pharmaceuticals (Schweiz) AG: Santhera Pharmaceuticals (Liechtenstein) AG, Ruggell, Fürstentum Liechtenstein; Santhera (Italy) S.r.l., Milano, Italy (in liquidation); Santhera (Germany) GmbH, München, Germany; Santhera (Netherlands) B.V., Nieuwegein, The Netherlands; Santhera (UK) Limited, London, United Kingdom; and Santhera Pharmaceuticals (Spain), S.L.U, Irun, Spain.

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

Changes in accounting policies

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

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

The following new, revised or amended standards became effective January 1, 2020, but did not have an impact on these Consolidated Financial Statements.

- Amendments to IFRS 3: Definition of a Business (effective January 1, 2020)
- Amendments to IAS 1 and IAS 8: Definition of Material (effective January 1, 2020)
- Various Amendments to References to Conceptual Framework in IFRS Standards (effective January 1, 2020)
- Amendments to IFRS 9, IAS 39 and IFRS 7: Interest Rate Benchmark Reform – Phase 1 (effective January 1, 2020)

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

- IFRS 17 Insurance Contracts (effective January 1, 2021)
- Amendments to IAS 1: Amendments to the classification of liabilities as current or non-current (effective January 1, 2022)

Segment reporting

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

Foreign currency translations

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

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

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

Intangible assets

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

IT software

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

Tangible assets

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

	Useful life
Equipment	4 to 10 years
IT hardware	2 to 5 years
Right-of-use assets (lease liabilities)	2 to 6 years
Leasehold improvements	2 to 10 years

Impairment of assets

Assets include intangible assets not yet available for use, intangible assets with finite useful lives and tangible assets (including right-of-use assets). In general, and in accordance with the terms of IFRS, assets not in use are capitalized at cost in the balance sheet and reviewed for impairment at least annually. The Impairment testing is performed at the same time every year or whenever there is an indication that the asset may be impaired. Once an intangible asset starts to be used, amortization starts. Testing for indicators of impairment for intangible assets with definite useful lives and for tangible assets is done at the end of each reporting period.

Trade and other receivables

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

Inventories

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

Financial assets

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

Financial assets subsequently measured at amortized cost

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

Financial assets at fair value through profit or loss

Santhera classifies all other financial assets at fair value through profit or loss. Principally, these are instruments held for trading. Assets in this category are classified as current assets if they are either held for trading or are expected to be realized within 12 months of the reporting date. Valuation is at fair value through profit or loss. Realized and unrealized gains and losses arising from changes in the fair value are included in the income statement in the period in which they arise.

Interest income

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

Leases

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

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

Right-of-use assets

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

Lease liabilities

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

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

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

Short-term leases and leases of low-value assets

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

Cash and cash equivalents

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

Restricted cash

Cash set aside in escrow and not available to finance Santhera's day-to-day operations is shown under this category. Maturities of less than 12 months are considered short-term; those of more than 12 months are long-term.

Share capital

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

Treasury shares

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

Financial liabilities

Santhera classifies its financial liabilities into two categories:

Financial liabilities at fair value through profit or loss

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

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

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

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

Other liabilities measured at amortized costs

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

Income taxes

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

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

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

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

Earnings/loss per share

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

Employee benefits

Post-retirement benefits

Santhera operates both defined benefit and defined contribution pension schemes.

- **Defined benefit scheme:**

Santhera's pension plan in Switzerland is classified as a defined benefit plan. Payments under this scheme are made directly to the pension fund for the account of each insured person. Typically, on retirement, an employee will receive an amount of the accumulated defined benefit obligation depending on several factors such

as the total individual amount paid in, age and implied life expectancy. The compensation will be in the form of a lifelong pension or a lump sum payment. The scheme also covers disability as a consequence of illness and death-in-service.

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

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

- **Defined contribution schemes:**

Defined contribution schemes are also funded through direct payments for the account of each insured person. Upon retirement, an employee will receive an amount of the accumulated contributions in the form of a 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 stock option and share appreciation rights (**SAR**) 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. Under all plans, options and share appreciation rights are equity-settled. The fair value of options and SAR is determined at the grant date and recognized as personnel expense over the period Santhera receives services for each award. Where stock option awards are modified as a minimum, the expenses are recognized as if no terms had been modified; modifications which increase the fair value of options are expensed additionally. Unless determined otherwise by the Board, terminations of employment by the employer are treated as forfeiture and any previously accumulated share-based payment expenses for unvested awards are reversed.

Provisions

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

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

Revenue recognition

Revenue from contracts with customers is recognized at an amount that reflects the consideration to which Santhera expects to be entitled in exchange for transferring goods or services to a customer.

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

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

Revenue from out-licensing, incl. revenue from royalties

Out-licensing agreements are concluded, where the counterparty has to pay license fees which are usually in the form of upfront and milestone payments as well as royalty payments. Santhera determines its performance obligations under such arrangements and in case of multiple deliverables allocates the transaction price to each distinct performance obligation on a relative stand-alone selling price basis. Typically, these arrangements include obligations such as maintenance of patents, research and development support and services, memberships in joint steering committees and other involvement in the arrangement, in which case the upfront and milestone payments may represent advance payments for future services and/or the right to access the underlying intellectual property of the Group. Revenue from such agreements is recognized upon transfer of control of the license or services rendered.

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

Revenue associated with upfront payments or performance milestones

Such revenue is recognized in accordance with respective agreements.

Development / intangible assets

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

3 Critical Accounting Estimates, Assumptions and Judgments

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

- Assessment of the Group's ability to continue as a going concern.
- Measurement and impairment testing of intangible assets not yet available for use, see note 7 "Impairment Test for Intangible Assets".
- Measurement and testing for net realizable value of inventory, see note 8 "Inventories".
- Valuation of derivative financial instruments in connection with financial liabilities, see note 12 "Financial Liabilities".
- Personnel expenses from share-based payments in accordance with IFRS 2, i.e. estimates regarding the valuation of equity rights plans when granted, see note 18 "Equity Rights Plans".
- Actuarial valuations in the context of defined benefit pension plans where various assumptions on e.g. discount rates, salary increase rates and mortality rates, etc. bear significant uncertainties due to the long-term nature of the plans, see note 23 "Employee Expenses and Benefits".

4 Exchange Rates of Principal Currencies

	Income statement in CHF		Balance sheet in CHF	
	average rates		year-end rates	
	2020	2019	2020	2019
1 Euro (EUR)	1.0702	1.1128	1.0822	1.0858
1 US dollar (USD)	0.9390	0.9937	0.8812	0.9683
1 British pound (GBP)	1.2045	1.2690	1.2036	1.2739
1 Canadian dollar (CAD)	0.7003	0.7489	0.6911	0.7430

5 Tangible Assets

	Right-of- use assets vehicles	Right-of- use assets offices	Equip- ment	IT hard- ware	Leasehold improve- ments	2020
In CHF thousands						
Cost						
At January 1	737	4,112	902	1,109	1,614	8,474
Additions ¹	26	173	15	14	15	243
Disposals	-776	0	-26	-81	0	-883
Remeasurements	69	0	0	0	0	69
Exchange differences	-10	-33	-5	-6	-1	-55
At December 31	46	4,252	886	1,036	1,628	7,848
Accumulated depreciation and impairment losses						
At January 1	269	787	412	871	531	2,870
Additions	248	741	92	137	207	1,425
Impairment ²	300	1,530	222	29	468	2,549
Disposals	-768	0	-26	-81	0	-875
Exchange differences	-3	-12	-2	-5	-1	-23
At December 31	46	3,046	698	951	1,205	5,946
Net book value ³	0	1,206	188	85	423	1,902
2019						
	Right-of- use assets vehicles	Right-of- use assets offices	Equip- ment	IT hard- ware	Leasehold improve- ments	2019
In CHF thousands						
Cost						
At January 1	612	3,765	879	1,060	1,615	7,931
Additions	228	0	29	69	0	326
Disposals	-76	0	0	-16	0	-92
Remeasurements	0	371	0	0	0	371
Exchange differences	-27	-24	-6	-4	-1	-62
At December 31	737	4,112	902	1,109	1,614	8,474
Accumulated depreciation						
At January 1	0	0	300	682	303	1,285
Additions	311	791	115	208	228	1,653
Disposals	-35	0	0	-16	0	-51
Exchange differences	-7	-4	-3	-3	0	-17
At December 31	269	787	412	871	531	2,870
Net book value ¹	468	3,325	490	238	1,083	5,604

¹ Including non-cash items (e.g. right of use assets)

² Refer to note 20 "Restructuring / Reorganization"

³ Net book value of right-of-use assets amounts to TCHF 1,206 and the value of owned tangible assets amounts to TCHF 696 in 2020. In 2019 the net book value of right-of-use assets amounts to TCHF 3,793 and the value of owned tangible assets amounts to TCHF 1,811. See note 12 "Financial Liabilities" for further information on leases.

6 Intangible Assets

		vamorolone (in process R&D)	lonodeles- tat (in pro- cess R&D)	Idebenone	fipamezole	IT soft- ware/ patents	2020
	In CHF thousands						
Cost							
At January 1		34,780	6,210	30,387	0	796	72,173
Additions ¹		12,365	0	0	0	5	12,370
Disposals		0	0	0	0	0	0
Exchange differences		0	0	0	0	-1	-1
At December 31		47,145	6,210	30,387	0	800	84,542
Accumulated amortiza- tion							
At January 1		0	0	13,168	0	526	13,694
Additions		0	0	3,038	0	120	3,158
Impairment		0	0	0	0	18	18
Disposals		0	0	0	0	0	0
Exchange differences		0	0	0	0	-1	-1
At December 31		0	0	16,206	0	663	16,869
Net book value		47,145	6,210	14,181	0	137	67,673
2019							
	In CHF thousands	Option to vamorolone sub-license (in process R&D)	lonodeles- tat (in pro- cess R&D)	Idebenone	fipamezole	IT soft- ware/ patents	
Cost							
At January 1		34,780	6,210	30,387	3,918	666	75,961
Additions		0	0	0	0	131	131
Disposals		0	0	0	-3,918	0	-3,918
Exchange differences		0	0	0	0	-1	-1
At December 31		34,780	6,210	30,387	0	796	72,173
Accumulated amortiza- tion							
At January 1		0	0	10,130	3,918	446	14,494
Additions		0	0	3,038	0	79	3,117
Disposals		0	0	0	-3,918	0	-3,918
Exchange differences		0	0	0	0	1	1
At December 31		0	0	13,168	0	526	13,694
Net book value		34,780	6,210	17,219	0	270	58,479

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

During 2020 there was a trigger for impairment of intangible assets in use (see to note 7 "Impairment Test for Intangible Assets").

7 Impairment Test for Intangible Assets

Idebenone

“Idebenone” represents the intangible asset of Santhera which has become available for use in September 2015 and has an estimated useful life of 10 years. On August 2, 2019, Santhera closed a licensing transaction with Chiesi Farmaceutici S.P.A., Parma, Italy (Chiesi). On October 6, 2020, Santhera announced the discontinuation of developing Puldysa (idebenone) for patients with DMD which constituted a triggering event for an impairment assessment. The result of the test in respect of idebenone showed that the carrying amount of the intangible asset continues to be supported by ongoing and expected revenues from Raxone (idebenone) received from Chiesi and the market in France in respect of the approved treatment for LHON.

Vamorolone and Ionodelestat

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

Management used a risk-adjusted Net Present Value (**rNPV**) model which contains several assumptions in order to verify the recoverable amount. This is a customary way for the valuation of pharmaceutical intangibles. The rNPV model considers mainly the period over the net cash flows of the development and use patent period of the products; hence the models contain data for the periods from 2021 through 2032 for vamorolone and 2037 for ionodelestat. No terminal value was calculated since it is probable that after the exclusivity period the sales could decrease. For the purpose of estimating these cash flows as per December 31, 2020, Santhera made general estimates for:

	2020	2019
WACC	12.0%	10.4%
Tax rate	17.97%	13.45%

Considering the markets and respective risk-profile for both assets, Santhera used the same WACC and tax rate assumptions for the impairment testing of vamorolone and ionodelestat. Other input elements for the calculation of the rNPV are based on the individual agreements with Polyphor, Idorsia or ReveraGen together with management estimates, such as the expected revenues based on estimated market size and patient numbers, expected market penetration rates, product pricing and project- or product-related costs taking into account externally available data where relevant. Management estimates probability of reaching the market lies between 25% (2019: 20%) for ionodelestat and 45% (2019: 27%) for vamorolone, reflecting the uncertainty as to whether a final and successful market registrations can be achieved, and considering standard industry success factor measures

The impairment test of the recoverable amount of the intangible assets performed, as of December 31, 2020 and 2019, did not result in the requirement to recognize an impairment. Santhera performed a sensitivity analysis considering reasonable changes in the assumptions used, such as changes in number of patients on drug, sales price and probability of reaching the market. The sensitivity analysis for 2020 did not reveal any indicators of impairment as at the reporting date.

8 Inventories

	In CHF thousands	2020	2019
Raw material (active pharmaceutical ingredients)		0	5,632
Semi-finished goods		85	694
Finished goods		396	533
Total at December 31		481	6,859

In October 2020, Santhera announced that due to the futility of the terminated SIDEROS study the global development program of Puldysa will be ended. Based on this Santhera wrote down related inventories (raw material CHF 5.0 million, semi-finished goods CHF 1.0 million). In 2019, Santhera wrote-down some of its inventories. Due to changed regulatory requirements raw material in the amount of CHF 1.15 million had to be written-down. Semi-finished and finished goods were written-down due to limited shelf life in the amount of CHF 0.65 million.

9 Trade and Other Receivables

	In CHF thousands	2020	2019
Trade receivables (gross)		2,389	5,359
Other receivables		2,164	3,688
Allowance for expected credit losses		-66	-146
Total at December 31		4,487	8,901

Trade receivables in 2020 result from product sales, see note 19 "Segment and Geographic Information". Other receivables consist mainly of amounts due from the government for tax reimbursements (e.g. VAT). They are due within 30 to 120 days and bear no interest.

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

	Current	0-30 days	31-60 days	61-90 days	91-180 days	181-360 days	>360 days	As of Dec. 31, 2020
Expected credit loss rate (in %)	0.3%	0.9%	2.1%	4.2%	7.7%	11.5%	13.0 to 25%	
Estimated total gross carrying amount at default (in TCHF)	1,653	280	76	64	105	73	168	2,389
Expected credit loss (in TCHF)	5	2	2	3	8	9	37	66
	Current	0-30 days	31-60 days	61-90 days	91-180 days	181-360 days	>360 days	As of Dec. 31, 2019
Expected credit loss rate (in %)	0.3%	0.9%	2.1%	4.2%	7.7%	11.5%	13.0%	
Estimated total gross carrying amount at default (in TCHF)	2,833	565	479	250	484	573	175	5,359
Expected credit loss (in TCHF)	8	5	10	10	34	59	20	146

As of December 31, 2020, an allowance for expected credit losses (ECL) of TCHF 66 was recognized on the trade receivables (as of December 31, 2019: TCHF 146).

	In CHF thousands	2020	2019
Expected credit losses January 1		-146	-77
Allowance for doubtful debts		0	0
Reversal of allowance for ECL		146	0
Increase in allowance ECL		-66	-69
Outstanding at December 31		-66	-146

10 Cash and Cash Equivalents and Restricted Cash

10.1 Cash and cash equivalents

	In CHF thousands	2020	2019
Cash at banks and on hand			
In CHF		11,183	19,285
In EUR		913	7,875
In GBP		74	1,243
In USD		130	2,769
In CAD		48	112
Other currencies		63	74
Total at December 31		12,411	31,358
Of which: Short-term deposits			
In CHF		0	127

10.2 Restricted cash

	in CHF thousands	Dec. 31, 2020	Dec. 31, 2019
Short-term		0	1,500
Total at period end		0	1,500

Restricted cash was designated for interest payments due related to the convertible bonds during the first 3 years (starting 2017). These funds were kept in an escrow account with the bond agent.

11 Share Capital

Ordinary share capital

In April 2019, 500,000 Shares were issued out of the authorized share capital in connection with a private placement. During 2019, 500 Shares were issued from conditional capital upon the exercise of stock options. As a result, as of December 31, 2019, the share capital amounted to CHF 11,165,063, divided into 11,165,063 Shares at a nominal value of CHF 1 each.

During 2020, the total amount of 4,569,291 Shares was issued out of the authorized share capital for financing arrangements in connection with IRIS, Paris, France, and Highbridge Capital Management, LLC, USA (**Highbridge**) (see note 12 "Financial Liabilities"). In the second half of 2020, the total amount of 3,695,342 Shares was issued out of the conditional share capital for financing arrangements in connection with Highbridge. As a result, as of December 31, 2020, the share capital amounted to CHF 19,429,696, divided into 19,429,696 Shares at a nominal value of CHF 1 each.

Treasury shares

In the second half of 2016, Santhera entered into an agreement for market making with a well-known bank. Independently, the bank buys and sells Shares on the market on behalf of the Company. On December 31, 2020, Santhera held 57,991 treasury Shares (2019: 54,892 treasury Shares).

Starting in the first half 2020 Santhera created treasury Shares from its authorized capital in order to use them for financing arrangements of the Group (exchangeable notes) and as payment in the connection of the transaction with Idorsia Ltd, Allschwil, Switzerland (**Idorsia**). On December 31, 2020, Santhera held 1,243,084 treasury Shares for financing arrangements (2019: no such treasury Shares were held).

Authorized share capital

In several increases during 2020, the aggregate amount of 4,569,291 Shares were issued out of the authorized share capital in connection financing arrangements. On the occasion of the AGM on April 22, 2020, the shareholders approved the increase of the authorized share capital. The Board is authorized to increase the share capital at any time until April 21, 2022, through the issuance of up to 2,080,709 Shares with a nominal value of CHF 1 each.

Conditional share capital

At the AGM on April 22, 2020, the shareholders approved the increase of the conditional share capital by an aggregate amount of CHF 4,800,000 through the issuance of a maximum of 4,800,000 Shares.

As of December 31, 2020, the Company had a conditional share capital, pursuant to which the share capital may be increased by

- a maximum amount of CHF 687,052 (2019: CHF 687,552) through the issuance of up to 687,052 (2019: 687,552) Shares, under the exclusion of shareholders' pre-emptive rights, for equity rights being exercised under the Company's equity rights plans, see note 18 "Equity Rights Plans", and
- a maximum amount of CHF 1,104,658 (2019: CHF 2,500,000) by issuing up to 1,104,658 (2019: 2,500,000) Shares, through the exercise of warrants/options and/or notes granted in connection with bonds or similar debt instruments linked with option and/or conversion rights granted by the Company.

12 Financial Liabilities

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

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

12.1 Financial liabilities- Equity linked instruments

During 2020, Santhera has established different equity-linked financing programs in order to receive additional liquidity in support of the Company's ongoing regulatory and development programs.

Highbridge

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

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

The embedded financial derivatives, are valued by an independent consultant at period end at fair value, applying a simulation-based valuation approach. They are classifying as Level 3 financial instruments in the fair value hierarchy. Some input parameters may not be observable in the market and may be derived from market prices or rates or estimated based on assumptions. One of the significant unobservable inputs is the volatility, which is derived from Santhera's historical share price. The period of volatility data used is measured according to the remaining life of the exchangeable note. The observed volatility as of December 31, 2020, amounts to 64.7%. There are also assumptions made based on the expected remaining lifetime and in connection with the expected exercise date which is June 26, 2021. By construction, the compound financial instrument issued to Highbridge will be exercised early, before maturity. For valuation purposes, it was therefore assumed that the expected exercise date is between the investing date and the maturity date.

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

Sensitivity analysis:

	December 31, 2020	
	Increase/decrease in volatility assumption	Effect on result before taxes in CHF thousands
Change in volatility	+5%	-2
	-5%	3

Idorsia

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

The exchangeable notes issued to Idorsia represent compound financial instruments, including a host contract which classifies as a financial liability and different embedded derivatives that have been valued as one compound derivative. The financial liability is initially recognized under current exchangeable notes with an amount of TCHF 9'930 net of transaction costs and amortized to the nominal amount using the effective interest method. The carrying amount of the liability at the balance sheet date is TCHF 10,000. The value of the embedded derivatives is solely based on entity specific information and is insignificant.

IRIS

On April 8, 2020, Santhera entered into an agreement with IRIS, for the issuance of and subscription to warrants in the initial gross amount of CHF 12.0 million, giving access to notes which are convertible into shares over a period of 12 months. Santhera has the option to extend the financing in the aggregate gross amount of up to additional CHF 12 million over a further period of up to 12 months after the initial period, under similar terms and conditions.

Warrants totaling CHF 12 million, or CHF 10.8 million net of transaction costs were issued between April 14, 2020 and November 13, 2020 and were wholly converted to shares during the year to December 31, 2020.

As a result of the implementation of the contractual agreements Santhera issued for free 4,800 warrants in favor of IRIS. These warrants entitle IRIS to subscribe to convertible notes under certain conditions. One convertible note's principal amount is CHF 2,500 and the note does not bear interest. The subscription price for a convertible note for IRIS is 97% of the principal amount. Each note is convertible at the discretion of its holder into a number of shares of Santhera. The shares used for conversion are taken from Santhera's treasury shares and shall immediately bear the same rights of all other existing shares and can be traded at the SIX.

The warrants issued under the agreement are measured at fair value through profit or loss considering the 3% discount on exercise as well as the discount and terms of the conversion feature of the convertible notes to which the warrants give right to. As of December 31, 2020, all of the 4,800 warrants issued were exercised and the respective notes are converted into equity. Further, the extend option to issue additional warrants for up to CHF 12 million has not yet been exercised. There was no outstanding liability at the balance sheet date.

The convertible notes were classified as hybrid contracts containing a host that is a financial liability and embedded derivatives separated from the host and measured at fair value with all changes in fair value recognized in profit or loss.

Changes in liabilities arising from equity-linked instruments

In CHF thousands	Converti- ble notes Highbridge	Current derivative financial instru- ments Highbridge	Converti- ble notes Idorsia	Converti- ble notes IRIS	Current derivative notes IRIS
December 31, 2019	0	0	0	0	0
Proceeds from convertible notes	13,726	0	0	10,833	0
Cash flows in 2020	13,726	0	0	10,833	0
Non-cash changes					
Recognition of financial instruments	0	3,416	9,930	0	2,348
Derecognition of derivative financial instruments on warrants exercise	0	0	0	360	-360
Nominal value of convertible notes converted into shares	-13,844	-3,583	0	-12,000	0
Effective interest method/transaction cost/fair value adjustments	760	613	23	807	0
Derecognition of derivative financial instruments on conversion of notes	0	-321	0	0	-1,988
December 31, 2020	642	125	9,953	0	0

12.2 Financial liabilities- Convertible bonds

On February 17, 2017, Santhera issued senior unsecured convertible bonds in the nominal amount of CHF 60 million. The bonds, listed on the SIX, are interest bearing (5% per annum) with a maximum term of 5 years and are convertible into registered Shares of Santhera with a nominal value of CHF 1 each. The initial conversion price was fixed at CHF 86.4006 and was reset in accordance with the terms of the bond in February 2018 to CHF 64.80. In addition, Santhera may call the convertible bonds at any time on or after the second anniversary of the issue date at par, plus accrued interest, if any, if the VWAP of the Shares is at least 160% of the conversion price. The convertible bonds are measured at amortized costs applying the effective interest method. The fair value of the bond (Level 1) at December 31, 2020, amounts to CHF 18 million (2019: CHF 39.5 million).

The embedded financial derivatives (conversion right, reset mechanism and early redemption option) are valued by an independent consultant initially and at period end at fair value, applying a simulation-based valuation approach. The valuation of the embedded derivatives is based on input parameters, classified as Level 3. The simulation is mainly based on the historical volatility of Santhera shares. The period of volatility data used is measured according to the remaining life of the convertible bonds. The volatility used as per December 31, 2020, was 61% (December 31, 2019: 86%).

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

The value of the derivative liability, initially amounted to CHF 5.3 million (February 17, 2017). At December 31, 2019, the value was CHF 0.6 million and at December 31, 2020 CHF 0 million. The change in the fair value was recognized in the financial result and amounted in 2020 to TCHF -617 (2018: TCHF -413).

Sensitivity analysis:

	December 31, 2020		December 31, 2019	
	Increase/decrease in volatility assumption	Effect on result before taxes in CHF thousands	Increase/decrease in volatility assumption	Effect on result before taxes in CHF thousands
Change in volatility	+5%	0	+5%	-77
	-5%	0	-5%	63

Changes in liabilities arising from convertible bonds and current loan

	In CHF thousands	Convertible bonds	Derivative financial instruments	Current loan
December 31, 2018		54,569	204	0
Proceeds from current loan		0	0	4,732
Change in fair value of derivative financial instruments		0	413	0
Effective interest/amortized cost calculation		1,585	0	0
Repayment of current loan		0	0	-4,732
December 31, 2019		56,154	617	0
Change in fair value of derivative financial instruments		0	-617	0
Effective interest/amortized cost calculation		1,721	0	0
December 31, 2020		57,875	0	0

Lease liabilities

	In CHF thousands	2020	2019
Cost			
At January 1		3,840	4,377
Additions		199	228
Disposals		-259	-41
Remeasurements		12	343
Interest expense		95	111
Payments		-1,166	-1,166
Exchange differences		-25	-12
At December 31		2,696	3,840
Thereof noncurrent		1,927	2,827
Thereof current		769	1,013

Expenses relating to short-term leases amounting to TCHF 16 were recognized in the consolidated income statement in 2020 (2019: TCHF 16). The total cash outflow for leases amounts to TCHF 1,182 in 2020 (2019: TCHF 1,182).

13 Deferred Taxes

Net deferred taxes recorded

	In CHF thousands	2020	2019
Temporary differences on inventory		837	1,049
Deferred tax assets recognized		837	1,049
Temporary differences on intangible assets, net		1,677	2,037
Temporary differences on convertible bonds		290	434
Tax loss carryforwards		-1,967	-2,471
Deferred tax liabilities recognized		0	0
Tax loss carryforwards		194,878	155,477
Of which recorded		-14,626	-18,373
Of which unrecorded		180,252	137,104
Expiring in			
1 year		1,090	10,804
2 years		2,964	1,090
3 years		41,999	2,964
4 years		41,237	41,999
5 years		27,734	41,237
More than 5 years		37,086	10,815
Without expiration		28,142	28,195
Total unrecorded tax loss carryforwards		180,252	137,104

Due to the uncertainty surrounding the future results of operations and the uncertainty as to whether Santhera can use the loss carryforwards for tax purposes, deferred tax assets on tax loss carryforwards were only considered to the extent that they offset taxable temporary differences within the same taxable entity. As there are no temporary differences associated with investments in subsidiaries, no deferred tax liability has to be recognized. No deferred tax assets are recognized on temporary differences related to pension obligations from IAS 19 (TCHF 6,170 at December 31, 2019, and TCHF 9,116 at December 31, 2019, respectively).

14 Trade and Other Payables

	In CHF thousands	2020	2019
Trade payables		3,803	6,832
Other payables (nonfinancial)		1,912	2,700
Total at December 31		5,715	9,532

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

15 Accrued Expenses

	In CHF thousands	2020	2019
Development programs		5,153	3,743
Liabilities to employees		671	4,458
Accruals for pricing and reimbursement		475	510
Accrued marketing and sales expenses		376	305
Accruals for audit, consulting and other		862	1,303
Accruals for interest expenses		1,108	1,108
Total at December 31		8,645	11,427

16 Current Provisions

	In CHF thousands	2020
January 1, 2020		0
Additions		3,782
Utilized		-1,748
Total at December 31		2,034

Amounts added in 2020 result from the organization restructuring of the Group following discontinuation of Puldysa development. The amount primarily relates to amounts due to costs of terminating personnel employment agreements and is expected to be utilized within the first half of 2021.

17 Commitments and Contingent Liabilities

Commitments

Commitments for leases (noncancellable)

	In CHF thousands	2020	2019
Within 1 year		10	10
After 1 year through to 5 years		0	0
After 5 years		0	0
Total at December 31		10	10

Commitments to future payments under license agreements

Vamorolone license agreements with Idorsia and ReveraGen

On September 2, 2020, Santhera announced that it had exercised its license option and acquired rights for the additional territories of Japan and South Korea for all indications. Santhera's obligations are a payment of up to USD 7 million, payable in monthly instalments of up to USD 500,000 to ReveraGen, to fund development including the Phase 2b VISION-DMD study and USD 5 million to ReveraGen at the time when FDA supports an NDA filing with Phase 2b 6-month data. Santhera will pay to Idorsia and ReveraGen regulatory and commercial milestone payments of up to USD 90 million in the DMD indication and four one-time sales milestone payments of up to USD 135 million in aggregate. Regulatory milestone payments by Santhera to Idorsia and ReveraGen for three additional indications amount to up to USD 205 million in aggregate. Upon commercialization of vamorolone, Santhera has committed to pay tiered royalties ranging from a single-digit percentage to low double-digit percentage in total on the annual net sales of vamorolone to Idorsia and ReveraGen.

License agreement with Polyphor

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

Collaboration and license agreement with Takeda

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

Agreement with the University of Leuven

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

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

License agreement with Novartis

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

Agreement with the National Institutes of Health

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

Contracts for clinical development and other

As part of its ordinary course of business, Santhera has entered into several contracts for e.g. clinical and technical development services. Commitments are within current market prices and can be terminated at the Company's discretion. In connection with its clinical studies, Santhera entered into commitments for the purchase of material in the amount of up to CHF 2.4 million (to be delivered in 2021).

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

Contingent liabilities

Santhera believes that the accruals (see note 15 "Accrued Expenses") are adequately based upon currently available information. However, given the inherent difficulties in estimating liabilities relating to clinical development, regulatory, tax, possible litigation and certain other matters due to uncertainty concerning both the amount and timing of future expenditures, additional costs may be incurred materially beyond the amounts accrued.

French social security - Reimbursement Status of Raxone in France

In France, Raxone has been reimbursed by the French Social Security under the so-called 'post-autorisation temporaire d'utilisation' or 'post-ATU' financing scheme since the product was launched in 2016. In December 2019, the French Ministry for Solidarity and Health refused to register Raxone on the list of reimbursed products in France. As a consequence, Santhera may be asked to refund part of the revenues generated from the sale of Raxone in France. Considering the fact that there is no established legal practice regarding the application of the relevant rules and no reference price has been established to date, the high unmet medical need of LHON patients in France, as well as other factors, Santhera concluded that it is highly probable that a significant revenue reversal will not occur in future periods once this uncertainty is resolved. However, should Santhera be required to make a refund, Santhera's financial situation and results of operations may be materially adversely affected. On February 27, 2020 we received an invitation from HAS (Haute Autorité de Santé) for a meeting to be held on March 20, 2020 between HAS, DSS (direction de la sécurité sociale), DGS (direction générale de la santé), patient organizations (Ouvrir les yeux and MaladiesRares) to discuss Raxone and orphan drugs. Due to COVID-19, the meeting was cancelled by HAS on March 16, 2020, and finally held on September 4, 2020. The central departments (DGOS, DGS and DSS) of the Ministry invited Santhera to contact the competent authorities (ANSM/CT) for a reassessment in the event of publication of additional clinical data. Such data were published on September 30, 2020 in the Journal of Neuro-Ophthalmology. On November 12, 2020, the chairman of the CT wrote to us that we should resubmit

our LHON dossier based on the additional data. Such dossier was submitted to HAS on April 8, 2021. On April 27, there has been a virtual meeting with the three Directorates (DGS, DGOS and DSS). These asked Santhera whether it would be willing to provide Raxone for free for the period between the discontinuation of public financing (which Santhera expects to be in August 2021) and a second decision of the Ministers which would grant reimbursement for Raxone (which Santhera expects to be in early 2022). In addition, they indicated that the decision has been made to discontinue the funding of Raxone by Social Security. Santhera shall revert to the Ministry at the latest by May 7, 2021 to inform it about its decision of whether to provide such goods for free in this period.

As of April 1, 2021, Raxone® continues to be on the list of the reimbursed drugs in France.

18 Equity Rights Plans

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

18.1 Stock Option Plans

Employee Stock Option Plans

The Company adopted the ESOP 2010 and ESOP 2015 (collectively the **ESOP**) to provide incentives to the Executive Management, employees and consultants helping to ensure their commitment to Santhera over the long-term. Option grants were made periodically at the discretion of the Board or as contractually agreed with employees. The ESOP contain customary provisions in respect of the adjustment or cancellation of stock options upon termination of employment, retirement, death, disability and certain corporate transactions. All stock option plans are administered under the responsibility of the Board. Each stock option entitles its holder to purchase one Share of the Company at an exercise price defined to be either a) equal to the volume-weighted average share price in the three preceding months for Swiss employees, or b) the closing share price on the SIX Swiss Exchange (**SIX**) at each grant date. In general, 50% of the stock options vest on the second anniversary, 25% on the third anniversary and the remaining 25% on the fourth anniversary of the grant date. At the end of the option term, i.e. after a period of 10 years as from the grant date, unexercised stock options expire without value. Under the ESOP 2010 vested stock options of employees leaving the Company in good faith expire six months after the termination date of the employment. Under the ESOP 2015 vested stock options of employees leaving the Company in good faith do not expire. Unvested stock options of employees leaving the Company are forfeited under all stock option plans. No further grants can be made under the ESOP.

Options outstanding, exercised, forfeited or expired under ESOPs

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

Number of options						2019
	At January 1	Exercised	Granted	Forfeited	Expired	At December 31
ESOP 2010	25,801	-500	0	0	0	25,301
ESOP 2015	223,474	0	0	-4,733	0	218,741
Total	249,275	-500	0	-4,733	0	244,042

Board Stock Option Plans

The Company adopted the BSOP 2015 (collectively the **BSOP**) to provide incentives to members of the Board. The BSOP contains the same customary provisions as under the ESOP described above. Each stock option entitles its holder to purchase one Share of the Company at an exercise price defined to be either a) equal to the volume-weighted average share price in the three preceding months, or b) the closing share price on the SIX at each grant date. In general, 50% of the stock options vest on the second anniversary, 25% on the third anniversary and the remaining 25% on the fourth anniversary of the grant date. At the end of the option term, i.e. after a period of 10 years as from the grant date, unexercised stock options expire without value. Under the BSOP 2015 vested and unvested stock options of Board members leaving the Board in good faith do not expire. No further grants can be made under the BSOP.

Options outstanding, exercised, forfeited or expired under BSOPs

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

Number of options						2019
	At January 1	Exercised	Granted	Forfeited	Expired	At December 31
BSOP 2015	13,562	0	0	0	0	13,562
Total	13,562	0	0	0	0	13,562

Since July 1, 2016, no more stock options are available for future grants under the ESOP 2015 and/or the BSOP 2015. Stock option plans were replaced by Share Appreciation Rights (**SAR**), see note 18.2 "Share Appreciation Rights Plans".

Number of stock options outstanding and exercisable

	Number of options	2020	2019
Outstanding at January 1		257,604	262,837
Granted		0	0
Exercised ¹		0	-500
Forfeited		-456	-4,733
Expired		0	0
Outstanding at December 31		257,148	257,604
Exercisable at December 31		257,148	235,719

¹ No options were exercised in 2020 (the average closing share price of options exercised during 2019 was CHF 11.94).

The value of stock options granted is recognized as personnel expense over the period Santhera receives services. In 2020, previously granted stock options resulted in personnel expenses of TCHF 12 (TCHF 1 related to Development, TCHF 4 related to Marketing and sales (**M&S**) and TCHF 7 to General and administrative (**G&A**)) and in 2019, such grants resulted in personnel expenses of TCHF 368 (TCHF 37 related to Development, TCHF 219 related to M&S and TCHF 112 to G&A).

Terms of options outstanding at December 31

Exercise price range for options (in CHF)	Number outstanding	Weighted average remaining contractual life (years)	2020	Number outstanding	Weighted average remaining contractual life (years)	2019
			Number exercisable			Number exercisable
from 3.89 to 4.53	20,751	2.82	20,751	20,751	3.20	20,751
at 22.25	4,550	3.50	4,550	4,550	4.50	4,550
at 69.30	12,650	5.25	12,650	12,650	6.25	10,275
from 82.10 to 114.50	219,197	4.63	219,653	219,653	5.71	200,143
Total	257,148	4.50	257,604	257,604	5.58	235,719

18.2 Share Appreciation Rights Plans

Starting with July 1, 2016, Santhera switched from stock option plans to Share Appreciation Rights Plans (**SARP**). It introduced Board Share Appreciation Plans (**BSARP**), the BSARP 2016, the BSARP 2017, for the members of its Board and Employee Share Appreciation Rights Plans (**ESARP**), the ESARP 2016, ESARP 2017 ESARP 2018 and the ESARP 2019, for the Executive Management, employees and consultants. Share appreciation rights (**SAR**) grants are made periodically at the discretion of the Board or as contractually agreed with employees. The SARP contain customary provisions in respect of the adjustment or cancellation of SARs upon termination of employment, retirement, death, disability and certain corporate transactions. All SARPs are administered under the responsibility of the Board.

In general, 50% of the SARs vest on the second anniversary, 25% on the third anniversary and the remaining 25% on the fourth anniversary of the grant date. SARPs introduced in 2017 and 2019 (BSARP 2017, ESARP 2017, ESARP 2018 and ESARP 2019) foresee vesting of 1/3 of the SAR on the first anniversary; the remaining 2/3 vest by each following quarter end through the second and third year after the grant date (8 times 1/12 of the SAR granted). At the end of the SAR term, i.e. after a period of 10 years as from the grant date, unexercised SARs expire without

value. Upon exercise of one SAR, participants receive the difference between the price of one Share at the time of exercise and the base value (“exercise price” as defined upon grant), in Shares. Subsequently, participants may sell their Shares.

SAR outstanding, exercised, forfeited or expired under SARP

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

Number of SARs						2019
	At January 1	Exercised	Granted	Forfeited	Expired	At December 31
ESARP 2016	43,312	0	0	0	0	43,312
BSARP 2017	77,779	0	78,944	0	0	156,723
ESARP 2017	589,245	0	0	-28,629	0	560,616
ESARP 2018	20,052	0	0	-1,488	0	18,564
ESARP 2019	0	0	994,018	-15,719	0	978,299
Total	730,388	0	1,072,962	-45,836	0	1,757,514

Fair value calculations for SAR granted

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

	2020	2019
Market price of stock	CHF 2.55 to 12.58	CHF 5.55 to 22.30
Exercise prices	CHF 7.22 to 8.27	CHF 6.61 to 14.50
Weighted average fair value of SAR granted	CHF 3.29	CHF 5.66
Expected volatility ¹	40% to 41%	37% to 40%
CHF risk-free interest rate	0.0% p.a.	0.0% p.a.
SAR term ²	10 years	10 years
Expected dividend yield	0%	0%

¹ The expected volatility was determined on the basis of selected biotech companies.

² After expiration of the vesting period, the SARs become rights similar to American-style options and may be exercised any time until the end of the SAR term. The SAR pricing model takes into consideration certain assumptions about potential early exercises.

Number of SAR outstanding and exercisable

	Number of SAR	2020	2019
Outstanding at January 1		1,757,514	730,388
Granted		1,167,467	1,072,962
Exercised		0	0
Forfeited		-255,675	-45,836
Expired		0	0
Outstanding at December 31		2,669,306	1,757,514
Exercisable at December 31		1,048,192	476,211

The value of SAR granted is recognized as personnel expense over the period Santhera receives services. In 2020, SAR grants resulted in personnel expenses of TCHF 3,017 (TCHF 969 related to Development, TCHF 688 related to M&S and TCHF 1,360 to G&A) and in 2019, such grants resulted in personnel expenses of TCHF 3,745 (TCHF 1,806 related to Development, TCHF 1,509 related to M&S and TCHF 1,430 to G&A). The above expenses of TCHF 3,017 are net of a reversal for SAR forfeited under ESARP 2018 in the amount of TCHF 671 (TCHF 304 related to Development, TCHF 203 related to M&S and TCHF 164 to G&A). In 2019 the expenses of 4,745 were net of a reversal for SAR forfeited under ESARP 2018 in the amount of TCHF 283 (TCHF 97 related to Development, TCHF 87 related to M&S and TCHF 99 to G&A).

Terms of SAR outstanding at December 31

Exercise price range for SAR (in CHF)	Number outstanding	Weighted average remaining contractual life (years)	2020	Number outstanding	Weighted average remaining contractual life (years)	2019
			Number exercisable			Number exercisable
from 6.61 to 18.90	2,067,595	8.87	473,986	1,124,902	9.36	33,410
from 36.70 to 38.70	345,719	6.98	325,241	376,488	8.00	219,393
from 51.75 to 54.85	228,720	5.99	223,368	228,852	7.00	202,793
from 76.50 to 77.80	27,272	6.10	25,272	27,272	7.14	20,615
Total	2,669,306	8.35	1,048,192	1,757,514	8.29	476,211

19 Segment and Geographic Information

Segment information

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

Geographic information

Revenue from contracts with customers

	In CHF thousands	2020	2019
Net sales			
EU		11,245	27,694
Rest of the world		7	196
Subtotal net sales		11,252	27,890
Revenue from out-licensing transactions			
EU		1,597	46,370
Net sales to licensing partner			
EU		2,159	1,116
Total		15,008	75,376

In 2020, net sales, revenue from out-licensing transactions and net sales to licensing partner amounted to CHF 15.0 million with its product Raxone only (2019: CHF 29.0 million). Raxone was sold in 5 European countries, with the majority of sales reached in France (2019: 24 European countries, with the majority of sales reached in France and Germany).

Refer to note 21 Transaction with Chiesi for further information on revenue.

Noncurrent assets (excluding financial instruments, restricted cash and deferred taxes)

	In CHF thousands	2020	2019
Switzerland		69,444	62,874
EU		0	949
North America		131	260
Total		69,575	64,083

20 Restructuring / Reorganization

On November 2, 2020, Santhera announced that, following the discontinuation of Puldysa, it implemented an organizational restructuring in order to focus its activities on vamorolone. In the context of the restructuring up

to 50 persons were laid off across the group. Various tangible, intangible assets and inventories have been impaired.

Additional cost resulted in personnel expenses of TCHF 3,601 (TCHF 691 related to Development, TCHF 2,326 related to M&S and TCHF 584 related to G&A). Further expenses were booked for impairment of assets in the amount of TCHF 2,749 (TCHF 992 related to M&S and TCHF 1,759 to G&A). Inventory held for Puldysa was impaired at a cost of TCHF 6,002 which was booked into the COGS (cost of goods sold). Due to personnel laid-off the defined benefit obligation was calculated in a curtailment and reduced accordingly over TCHF 2,106 (TCHF 1,185 related to Development, TCHF 312 related to M&S and TCHF 609 related to G&A). See note 23 "Employee Expenses and Benefits".

21 Transaction with Chiesi

On August 2, 2019, Santhera announced the closing of a licensing transaction with Chiesi Farmaceutici S.p.A., Parma, Italy (Chiesi), whereby Chiesi in-licensed Raxone for the treatment of Leber's hereditary optic neuropathy (LHON). The transaction was analyzed and found to fall into the scope of IFRS 15, Revenue from Contracts with Customers. As consideration Santhera

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

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

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

The non-refundable upfront payment of EUR 44 million was analyzed and allocated to the different performance obligations. The element of the additional variable consideration in the amount of EUR 49 million depends on certain conditions and milestones, which need to be achieved and which based on the constraint guidance in IFRS 15 have not been included in the transaction price at contract inception and at year end.

Santhera determined the stand-alone selling prices of the different performance obligations and allocated the transaction price accordingly. Based on such allocation, the majority of the transaction price was allocated to the performance obligations, which are recognized at a point in time, when the out-licensing transaction was entered into, in the amount of CHF 46.4 million. An amount of CHF 2.7 million is recognized over time and disclosed as contract liability (current and noncurrent) for services, which are carried out in conjunction of the PAMs and market assistance services. As at December 31, 2020 CHF 1.1 million was included in current contract liabilities to be

recognized in future periods. During the year to 31 December 2020, Santhera recognized revenue for such services in the amount of CHF 1.6 million (2019: 0.5 million). The parties also agreed that Chiesi procures from Santhera the manufactured packs of Raxone for selling in the licensed territory (CHF 2.2 million net sales to licensing partner (2019: CHF 1.1 million)).

22 Operating Expenses by Nature

	In CHF thousands	2020	2019
External development expenses		-25,963	-26,501
Patent and license expenses		-500	-498
Marketing expenses		-3,204	-6,413
Employee expenses		-19,798	-35,580
<i>Of which non-cash-relevant expenses for equity rights plans</i>		-3,029	-6,255
Other administrative expenses		-4,308	-9,479
Depreciation, impairment and amortization		-4,112	-1,732
Facility related expenses		-241	-304
Lease expenses (offices)		-16	-16
Other operating expenses		-205	-129
Total operating expenses		-58,347	-80,652

23 Employee Expenses and Benefits

Employee expenses

	In CHF thousands	2020	2019
Wages and salaries		-13,608	-22,679
Social security and other personnel-related expenses ¹		-3,161	-6,646
<i>Of which non-cash-relevant adjustments of pension fund</i>		2,106	-648
Expenses for equity rights plans		-3,029	-6,255
Total employee costs		-19,798	-35,580

Average number of full-time equivalents²	101.2	118.5
Full-time equivalents at year-end	86.0	112.9
Total headcount at year-end	91	117

¹ Thereof TCHF 283 were expensed for defined contribution plans in North America and some European countries (2019: TCHF 480).

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

Pension plan

In accordance with the Swiss pension fund law “Federal Act on Occupational Old Age, Survivors’ and Invalidation Pension Provision” (**OPA**), all employees of Santhera Pharmaceuticals Holding AG, Pratteln, and Santhera Pharmaceuticals (Schweiz) AG, Pratteln, both in Switzerland, have to be affiliated with a collective independent pension fund. These funds provide for retirement benefits, as well as risk benefits (death and disability). The plans qualify as defined benefit plans under IAS 19 and the assets cannot revert to the employer. Contributions to the plans are such that the employee contributes 40% and the employer the rest. Contributions are computed as percentage of the salary, depending on age. In order to manage these risks, since January 1, 2018, Santhera has an agreement with PKG Pensionskasse (**PKG**). PKG is responsible for the governance of the plan; its board is composed of an equal number of representatives from the employers and employees chosen from all affiliated companies. PKG has set up investment guidelines, defining in particular the strategic allocation with margins. PKG has insured the risks of disability and death before retirement with PKRück AG, Vaduz, Fürstentum Liechtenstein. The accumulated savings capital is allocated to each insured individual and consists of annual contributions, savings credits and interest credits. In certain situations, additional payments or increased periodic contributions by the employer may become due based on the pension plans funded status as measured under Swiss pension rules (**OPA**).

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

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

Changes in defined benefit obligations

	In CHF thousands	2020	2019
Present value of obligation, January 1		26,358	23,275
Current employer service cost		2,500	1,982
Past service cost (plan amendment)		-1,216	0
Past service cost (curtailment due to restructuring)		-2,106	0
Interest cost		92	232
Employee contributions		875	937
Benefits paid / transfer payments		-2,667	1,920
Insurance premiums		-204	-217
Remeasurements ¹		-801	-1,771
Present value of obligation, December 31		22,831	26,358

¹ Details of remeasurements:

	In CHF thousands	2020	2019
Effect of changes in demographic assumptions ¹		0	-2,153
Actuarial gain/loss due to changes in financial assumptions		1,111	2,989
Actuarial gain/loss due to experience adjustments		-1,912	-2,607
Subtotal gain/loss		-801	-1,771
Return/loss on plan assets (excluding interest income)		-39	2,256
Total remeasurements in other comprehensive income gain/loss		-840	485

¹ Demographic assumptions changed due to increase in lump sum probabilities and reduction of disability probabilities in 2019.

Changes in plan assets

	In CHF thousands	2020	2019
Fair value of assets, January 1		17,242	15,292
Interest income on assets		64	161
Employer contributions		1,312	1,405
Employee contributions		875	937
Benefits paid / transfer payments		-2,667	1,920
Insurance premiums		-204	-217
Remeasurements (return/loss on plan assets (excluding interest income))		39	-2,256
Fair value of assets, December 31		16,661	17,242

Net defined benefit asset/obligation

	In CHF thousands	2020	2019
Present value of obligation, December 31		22,831	26,358
Fair value of assets, December 31		16,661	17,242
Net defined asset/obligation		-6,170	-9,116

Asset allocation

	In CHF thousands	2020	2019
Cash		167	190
Debt instruments		7,664	7,724
Equity instruments		4,948	5,259
Property		3,149	3,276
Others		733	793
Total value of assets		16,661	17,242

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

	In %	2020	2019
Discount rate		0.10	0.35
Disability probabilities		80.00	80.00
Lump sum probabilities		30.00	30.00
Expected future salary increases		1.50	1.50

Sensitivity analysis for 2020:

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

Sensitivity analysis for 2019:

In CHF thousands	Defined benefit obligation		Gross (net) service cost	
	Increase assumption	Decrease assumption	Increase assumption	Decrease assumption
Discount rate +/-0.25%	-964	1,036	-182	194
Salary increase +0.25%	259	-	-4	-
Life expectancy +1 year	444	-	45	-

Mortality rate:

Life expectancy at age 65 (in years)	2020	2019
Male	22.8	22.7
Female	24.9	24.8

The expected employer contributions for fiscal year 2021 amount to approximately TCHF 966 (2020: TCHF 1,404). Benefit obligations of pensioners amounted to TCHF 961 at December 31, 2020 (2019: TCHF 941). The duration of the plan liabilities calculated is 18.6 years as of December 31, 2020 (2019: 21.4 years).

24 Financial Income/Expenses**Financial income**

	In CHF thousands	2020	2019
Interests on cash and cash equivalents		3	8
Realized and unrealized foreign exchange gains		1,052	1,648
Total		1,055	1,656

Financial expenses

	In CHF thousands	2020	2019
Interest expenses		-6,796	-5,971
Interest expenses on lease liabilities		-95	-111
Change in fair value of financial derivative instruments		-492	-413
Transaction costs of financial instruments		-8,256	0
Realized and unrealized foreign exchange losses		-780	-3,113
Total		-15,435	-9,608

25 Income Taxes

	In CHF thousands	2020	2019
Current income tax income/expense		7	-343
Deferred tax income/expense		-210	-236
Total		-203	-579

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

	In CHF thousands	2020	2019
Result before taxes		-67,456	-18,393
Tax expense/income at expected group tax rate of 13.45% (2019: 9.3%)		9,072	1,711
Effect of tax rate difference group versus local		-725	-500
Effect of nondeductible expenses		-417	-792
Utilization of previously unrecognized tax losses		41	16
Recognition of previously unrecognized DTL (deferred tax liabilities)		0	0
Recognition of DTA on previously unrecognized tax losses		0	0
Unrecognized deferred taxes		-8'174	-1,014
Effective tax income/expense		-203	-579

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

26 Earnings/Loss per Share

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

	2020	2019
Net result attributable to shareholders (in TCHF)	-67,659	-18,973
Weighted average number of shares issued and outstanding	13,315,912	10,991,497
Basic and diluted net result per share (in CHF)	-5.08	-1.73

For the years ended December 31, 2020 and 2019, basic and diluted net result per share is based on the weighted average number of Shares issued and outstanding and excludes Shares to be issued upon the future exercise of equity rights and upon conversion of the convertible bonds, as they would be anti-dilutive. In case Santhera shows a profit in the future, equity rights and convertible bonds upon conversion may have a dilutive effect on the net profit per Share and will need to be considered for the purpose of this calculation.

27 Related Party Transactions

Board and Executive Management compensation

Total compensation of Board and Executive Management

	In CHF thousands	2020	2019
Compensation (wages, salaries, allowances)		2,147	2,755
Post-employment benefits (pension fund and defined benefit contributions)		602	308
Share-based payment expenses (fair value according to IFRS 2)		1,303	1,722
Total		4,052	4,785

Transactions with members of the Board and Executive Management

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

In 2020, no stock options were exercised by members of the Board (2019: no stock options exercised). During 2020, no stock options were exercised by the Executive Management (2019: no stock options exercised).

28 Risk Management Objectives and Policies

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

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

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

Santhera conducts development activities primarily in Switzerland, the EU and the US and is exposed to a variety of financial risks, such as, but not limited to, foreign exchange rate risk, credit risk, liquidity risk, cash flow and interest rate risk. Part of Santhera's overall risk management focuses on financial risks and the unpredictability of financial markets seeking to minimize potential adverse effects on the financial performance of the Group. Special guidelines and policies approved by the Board exist for overall risk management, financial internal controls and treasury management and are monitored by the Executive Management and the Board on a regular basis. The risk of foreign exchange rate fluctuations on the expenses can partly be managed by entering into foreign exchange derivative contracts. In accordance with the relevant treasury guidelines, Santhera only concludes contracts with selected high-quality financial institutions of good reputation and is not allowed to engage in speculative transactions. In addition, Santhera's treasury guidelines limit the Group to engage in money market deposits or similar instruments with a maturity beyond 6 months.

Foreign exchange rate risk

Santhera holds cash amounts in four major currencies CHF, EUR, USD and GBP to cover the majority of future expected expenses. In addition, in order to reduce its foreign exchange rate exposure, Santhera occasionally enters into derivative currency contracts (forwards, options, structured derivatives) to hedge against additional major foreign currency exchange rate fluctuations. Evaluations based on market values are performed regularly. Any fair value changes of such currency positions are recorded accordingly in the income statement. Santhera's primary exposure to financial risk is due to fluctuation of exchange rates between CHF and EUR. No derivative currency contracts are outstanding as of December 31, 2020 and 2019.

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

	Increase/decrease foreign currency rate	Effect on result before taxes in CHF thousands
EUR positions		
2020	+5%	-2
	-5%	+2
2019	+5%	+415
	-5%	-415

Interest rate risk

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

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

As of the end of 2020, variances of +/-50 basis points were calculated, resulting in fluctuations of +/-TCHF 62 before tax (end of 2019: +/-50 basis points resulting in fluctuations of +/-TCHF 164 before tax).

Additionally, Santhera's interest rate risk arises from long-term debt issued at fixed rates

Credit risk

Santhera has a certain concentration of credit risk. Short-term investments are invested as cash on deposit or in low-risk money market funds. No investment or contract with any single counterparty, except cash on deposit subject to the criteria above, comprises more than 30% of cash and cash equivalents at the date of investment.

Santhera has policies in place to ensure that sales of products or entered partnerships are made to or entered with customers or partners with an appropriate credit history and a commitment to ethical business practices. The maximum credit risk exposure is limited to the carrying amount of its financial assets including derivatives. Santhera estimates its expected credit losses (ECL) based on default probabilities and the ageing of outstanding invoices.

Liquidity risk

Prudent liquidity risk management implies maintaining sufficient cash and cash equivalents. Currently, the Company is financed through equity and convertible bonds (see note 12 "Financial Liabilities"). Santhera's treasury calculates on a rolling basis the needs for aligning the current expenses against the need for optimized financial investments.

Contractual undiscounted cash flows for financial liabilities

Year ended December 31, 2020 In CHF thousands	On demand	Less than 3 months	3 to 12 months	1 to 5 years	Total	Book value
Convertible bonds	0	1,500	1,500	61,500	64,500	57,875
Exchangeable notes (Idorsia and Highbridge) ¹		750	10,000		10,750	10,595
Trade payables	0	3,803	0	0	3,803	3,803
Accrued expenses	0	8,034	0	0	8,034	8,034
Lease liabilities	0	214	617	2,004	2,835	2,696
Total	0	14,301	12,117	63,504	89,922	83,003

Year ended December 31, 2019 In CHF thousands	On demand	Less than 3 months	3 to 12 months	1 to 5 years	Total	Book value
Convertible bonds	0	1,500	1,500	64,500	67,500	56,154
Trade payables	0	6,832	0	0	6,832	6,832
Accrued expenses	0	7,364	0	0	7,364	7,364
Lease liabilities	0	289	814	2,968	4,071	3,840
Total	0	15,985	2,314	67,468	85,767	74,190

¹ Part of these amounts may be settled in shares subject to certain conditions. For settlement conditions refer to note 12 "Financial Liabilities".

Categories of financial instruments

Year ended December 31, 2020 (IFRS 9 measurement categories) In CHF thousands	Book value	Financial assets at amortized cost	Other liabilities at amortized cost	At fair value through profit or loss
Assets				
Financial assets long-term	552	552	0	0
Trade receivables	2,323	2,323	0	0
Cash and cash equivalents	12,411	12,411	0	0
Total	15,286	15,286	0	0
Liabilities				
Convertible bonds	57,875	0	57,875	0
Exchangeable notes (Idorsia and High-bridge)	10,595	0	10,595	0
Derivative financial instruments	125	0	0	125
Noncurrent lease liabilities ¹	1,927	0	1,927	0
Trade payables	3,803	0	3,803	0
Accrued expenses	8,034	0	8,034	0
Current lease liabilities ¹	769	0	769	0
Total	83,128	0	83,003	125

¹ Measured in accordance with IFRS 16.

Year ended December 31, 2019 (IFRS 9 measurement categories) In CHF thousands	Book value	Financial assets at amortized cost	Other liabilities at amortized cost	At fair value through profit or loss
Assets				
Financial assets long-term	664	664	0	0
Trade receivables	5,213	5,213	0	0
Other receivables	77	77	0	0
Restricted cash short-term	1,500	1,500	0	0
Cash and cash equivalents	31,358	31,358	0	0
Total	38,812	38,812	0	0
Liabilities				
Convertible bonds	56,154	0	56,154	0
Derivative financial instruments	617	0	0	617
Noncurrent lease liabilities ¹	2,827	0	2,827	0
Trade payables	6,832	0	6,832	0
Accrued expenses	7,364	0	7,364	0
Current lease liabilities ¹	1,013	0	1,013	0
Total	74,807	0	74,190	617

¹ Measured in accordance with IFRS 16.

Capital management

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

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

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

29 Events after the Reporting Date

There were capital increases on February 4, 2021, of 1,600,000 shares, on March 10, 2021, of 480,708 shares and on March 29, 2021, 2,200,000 shares issued out of the existing authorized capital as treasury shares. After issue the number of shares recorded in the commercial register has been increased to 23,229,696 shares. Santhera expects to use these shares for purposes of its financing arrangements.

On February 16, 2021 the Company announced that an existing investor Highbridge Tactical Credit Master Fund, L.P. (a fund managed by Highbridge Capital Management LLC, "Highbridge") committed to increasing its existing financing arrangement to provide up to CHF 18 million in senior secured notes exchangeable by Highbridge (CHF 6 million of which was previously committed), which will be available in tranches and subject to certain drawdown conditions. Between December 31, 2021 and April 26, 2021, CHF 11 million have been drawdown under the previous and amended facility. As at April 26, 2021 a further CHF 6 million remain available subject to certain drawdown conditions.

On March 1, 2021 the Company announced positive results from its multiple ascending dose Phase 1b study with lonodelestat, a potent inhibitor of human neutrophil elastase (hNE), in patients with cystic fibrosis (CF).

On March 3, 2021 the Company announced that the last patient has completed the last visit for the first period of the placebo-controlled pivotal VISION-DMD study with vamorolone in patients with Duchenne muscular dystrophy (DMD), conducted by partner ReveraGen Biopharma Inc. Subject to a positive 6-month topline data readout of this first study phase, this could allow for a regulatory submission to the US FDA in Q1-2022 with the potential to offer an alternative to current standard of care in DMD.

On March 8, 2021 the Company held a meeting of bondholders with a vote on the new terms being offered. The voted resulted in a large majority of 89 % of bondholders represented voting in favor of the resolutions proposed by the Company. These bonds represented 58% of the total bonds outstanding and therefore the required threshold of 2/3 of all bonds outstanding to pass such resolutions was not met.

On March 18, 2021 the Company held an Extraordinary General Meeting where the shareholders supported all motions by the Board and approved an ordinary capital increase by CHF 312,000, an increase of the authorized capital to the statutory limit of 50% of the issued share capital and an increase of the total of the two conditional capitals to the same 50% limit (including an increase of conditional capital for employee participations of CHF 1,850,000). The shareholders also endorsed a both time- and performance-based equity instrument for Executive Management in the form of performance share units (PSU).

On March 25, 2021 the Company announced an offer to exchange its outstanding CHF 60 million 5% Convertible Bonds due 2022 on the same economic terms as previously proposed to the bondholders' meeting of March 8, 2021 and as set out in the Bond prospectus. The Exchange Offer period started on April 6, 2021, and ended at 5:00 p.m. (CEST) on April 19, 2021. The Exchange Offer was declared successful after the expiry of the offer period, with 66% of bondholders tendering exchange and so an additional acceptance period started on April 21, 2021, and ended on April 27, 2021 when it was also announced that 74.7% of bondholders had tendered exchange. The Exchange Offer is planned to be settled on or around May 4, 2021. In parallel to the Exchange Offer, the Company is seeking additional consents to its proposals to the March 8, 2021 bondholders' meeting in order to achieve the requisite two-thirds majority. If the Company obtains the necessary number of additional consents in time, the Exchange Offer will not be completed and the original bond restructuring would be pursued. The Company expects to announce the settlement date or a postponement of the settlement by Monday, May 3, 2021 at the latest.

On April 27, there has been a virtual meeting with the three Directorates (DGS, DGOS and DSS) in relation to supply of Raxone to France (see note 17 Commitments and Contingent liabilities).

Cash and cash equivalents as at April 28, 2021 were CHF 11.7 million, in addition CHF 6 million, subject to certain drawdown conditions being met, is available for drawdown under the Highbridge agreements.

On April 28, 2021 the Company announced new clinical data of 2.5-year treatment outcome with vamorolone in patients with Duchenne muscular dystrophy (DMD). These Phase 2a long-term treatment data demonstrate a maintenance of treatment effect, equivalent to a delay of about two years in decline for time to stand (TTSTAND) velocity, and confirm safety and tolerability benefits of vamorolone over the 2.5-year follow up period. Long-term treatment with vamorolone resulted in significantly fewer corticosteroid-associated adverse events than reported in other clinical trials with other steroids.



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To the General Meeting of
Santhera Pharmaceuticals Holding Ltd, Pratteln

Basle, April 28, 2021

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



Opinion

We have audited the consolidated financial statements of Santhera Pharmaceuticals Holding Ltd and its subsidiaries (the Group), which comprise the consolidated balance sheet as at December 31, 2020 and the consolidated income statement, consolidated statement of comprehensive income, consolidated cash flow statement and consolidated statement of changes in equity 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 22 to 69) give a true and fair view of the consolidated financial position of the Group as at December 31, 2020, and its consolidated financial performance and its consolidated cash flows for the year then ended in accordance with International Financial Reporting Standards (IFRS) and comply with Swiss law.



Basis for opinion

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

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

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



Material uncertainty related to going concern

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



Key audit matters

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the consolidated financial statements of the current period. In addition to the matters described in the *Material uncertainty related to going concern* section of our report, we have determined the matters described below to be the key audit matters to be communicated in our report. These matters were addressed in the context of our audit of the consolidated financial statements as a

whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters. For each matter below, our description of how our audit addressed the matter is provided in that context.

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

Accounting treatment and valuation of financing transactions

Areas of focus In April 2020, the Group entered into a financing agreement with IRIS for the issuance of warrants that entitled IRIS to subscribe to convertible notes with a total value of CHF 12 million. By December 31, 2020, IRIS exercised all warrants and the respective convertible notes have been fully converted into equity. In connection with this agreement, the Group in 2020 received CHF 10.8 million in cash, delivered Santhera shares valued at CHF 14.0 million, and incurred financial expenses of CHF 3.2 million.

In July 2020, the Group signed an equity-linked financing agreement with Highbridge. During the remainder of 2020, the Group issued exchangeable notes in three tranches of in total CHF 14.5 million. Exchangeable notes in the amount of CHF 13.8 million have been converted into equity as of December 31, 2020. In connection with this agreement, the Group in 2020 incurred financial expenses of CHF 7.3 million, received net cash of CHF 13.7 million, and delivered Santhera shares valued at CHF 20.2 million. The outstanding liability of exchangeable notes as of December 31, 2020 amounted to CHF 0.8 million.

The convertible and exchangeable notes issued under these agreements are classified as hybrid contracts under IFRS 9. The transactions are considered a key audit matter based on the magnitude of the transaction value, the subjectivity involved in management's determination of the appropriate accounting treatment, and inherent judgment in the respective valuation of the financial instruments.

Refer to note 2 "Summary of Significant Accounting Policies", note 3 "Critical Accounting Estimates, Assumptions and Judgments", and note 12.1 "Financial liabilities – equity-linked instruments".

Our audit response We analyzed the underlying contractual agreements and the respective accounting position papers prepared by management. We evaluated the appropriateness of the accounting treatment under the requirements of IFRS 9. We assessed the reasonableness of the underlying assumptions and valuation approach applied to determine the value of the financial instruments. We further evaluated sensitivities in the valuation resulting from changes to key assumptions applied.

Our audit procedures did not lead to any reservations regarding the accounting for these two financing transactions in 2020.

Impairment assessment of intangible assets not yet available for use

Areas of focus As of December 31, 2020, the Group has capitalized intangible assets not yet available for use in the amount of CHF 53.4 million. Based on the requirements of IAS 36, such intangible assets need to be tested for impairment at least annually.

The impairment assessment of the intangible assets not yet available for use is a key audit matter based on the magnitude of the balances and the inherent judgement in the respective model and assumptions used as part of management's impairment assessment, specifically those related to 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 Company'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 Company and comparable organizations, as well as considering territory specific factors.

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



Other information in the annual report

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

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

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



Responsibility of the Board of Directors for the consolidated financial statements

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

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



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

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

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



Report on other legal and regulatory requirements

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

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

Ernst & Young Ltd

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

/s/ Diana Vejina
ACCA

Statutory Financial Statements of Santhera Pharmaceuticals Holding AG

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Balance Sheet

	As of December 31, in CHF thousands	Notes	2020	2019
Assets				
Cash and cash equivalents			6,625	7,658
Other receivables from third parties			76	104
Other receivables from shareholdings			189	0
Prepaid expenses and accrued income			5	18
Restricted cash short-term			0	1,500
Current assets			6,895	9,280
Loans to shareholdings		3.1	142,466	118,681
Investments in shareholdings		3.2	404	283
Noncurrent assets			142,870	118,964
Total assets			149,765	128,244
Liabilities and equity				
Trade accounts payable to third parties			226	277
Other accounts payable to third parties			44	16
Other accounts payable to shareholdings			0	68
Accrued expenses			1,660	1,973
Senior unsecured exchangeable notes ¹		2	10,000	0
Current liabilities			11,930	2,334
Senior unsecured convertible bonds ²		2	60,000	60,000
Noncurrent liabilities			60,000	60,000
Total liabilities			71,930	62,334
Share capital		3.3	19,430	11,165
<i>Reserves from capital contributions³</i>			12,080	6,282
<i>Other capital reserves</i>			3,712	3,591
Statutory capital reserves			15,792	9,873
<i>Accumulated result</i>			-39,801	-32,250
<i>Results carried forward</i>			-32,377	-23,622
<i>Net result for the period</i>			-7,424	-8,755
<i>Other voluntary reserves (free reserves)</i>			83,994	77,995
Voluntary accumulated result and other reserves			44,193	45,618
Treasury shares		3.4	-1,580	-746
Total equity			77,835	65,910
Total liabilities and equity			149,765	128,244

1 Non-interest bearing

2 Interest bearing

3 Value as per December 31, 2020, to be confirmed by Swiss Federal Tax Administration (SFTA).

Income Statement

For the year ended December 31, in CHF thousands	Notes	2020	2019
Income from shareholdings	3.5	537	1,217
Other operating income		0	45
Total operating income		537	1,262
General and administrative expenses	3.6	-2,877	-3,896
Employee expenses		-480	-1,589
Other operating expenses		-90	-31
Total operating expenses		-3,447	-5,516
Operating result		-2,910	-4,254
Financial income		79	167
Financial expenses		-4,714	-4,704
Financial result		-4,635	-4,537
Reversal on allowance of investment		121	36
Result before and after taxes / net result		-7,424	-8,755
Direct taxes		0	0
Net result		-7,424	-8,755

Notes to the Statutory Financial Statements

1 Introduction

Santhera Pharmaceuticals Holding AG (the Company or Santhera) is the parent company of Santhera Group. The Company has its registered offices at Hohenrainstrasse 24 in 4133 Pratteln, Switzerland.

Material uncertainties and ability to continue operations

The statutory financial statements of Santhera have been prepared under the going concern assumption despite several material uncertainties present that may be contrary to this assumption.

Following the announcement of the discontinuation of its Phase 3 SIDEROS study with Puldysa[®] (idebenone) in patients with Duchenne muscular dystrophy (DMD), in October 2020, the Company decided to implement a restructuring plan for the business with a focus on retaining key functions for bringing DMD drug candidate vamorolone to patients and execute on its other pipeline programs. The discontinuation of Puldysa[®] development also resulted in Santhera not being able to utilize fully the financing facility entered into with Highbridge or to enter into an equity financing anticipated on a successful study outcome. The Company required additional funds in order to reach the next inflection, the topline results of the pivotal Phase 2b study in DMD of vamorolone point then anticipated in the first quarter of 2021.

In November 2020, the Company provided an update on the organizational restructuring resulting in a 50% reduction in workforce, initiated further measures to reduce operational costs and announced an amendment to its financing facilities to provide up to CHF 15 million which together with other initiatives were anticipated to provide funding into early 2021 and to the 6-month vamorolone readout to an updated timeline of the second quarter 2021

The series of events through 2020 continued the existence of a limited short term cash runway through the year resulting in cash and cash equivalents amounted to CHF 12.4 million as of December 31, 2020. However, because the current funds are insufficient to allow the Company to reach the value inflection points after the vamorolone readout, material uncertainties remain as to the Company's ability to continue as a going concern until December 31, 2021. Executing the Company's strategy significantly depends on the following

- The vamorolone pivotal study 6-month topline readout expected in the second quarter 2021,
- Further funding to ensure the continuation of its operations through December 31, 2021 in any scenario (i.e. also in vamorolone pivotal study 6-month topline results are positive).
- Continued revenue from Raxone, as well as no material adverse advents as it relates the reimbursement status of Raxone in France (see note 17 Commitments and Contingent Liabilities)
- Ability to settle current debt obligations

The outcome of the pivotal Phase 2b study with vamorolone in ambulant patients with DMD, being conducted by ReveraGen, expected during the second quarter of 2021 is uncertain. In the event of positive results, the Management and Board of Directors plan to raise additional funds through a capital increase in the second half of 2021 in order to finance further development to support an NDA submission and pre-commercialization activities. In the event that results are inconclusive, the Management and the Board of Directors still plan to raise additional funds in order to reach the completion of the 12-month treatment period expected during the fourth quarter of 2021, the results of which will then be further assessed during the fourth quarter of 2021. As of the date of these financial statements no additional financing has yet been committed under any scenario. Further if in the second quarter

2021 the results of the vamorolone 6-month topline readout results are negative, it is probable that the vamorolone development in DMD would be discontinued. If vamorolone in DMD is discontinued at either the 6-month or 12-month timepoints, the Company would initiate a further organizational restructuring measures and likely cessation of all business activities and monetization of the assets (e.g. milestones receivable from out-licensing Rax-one, lonodelestat or vamorolone in non DMD indications) that may incur termination cost.

The early clinical program for vamorolone to date has established a wide therapeutic safety margin with early Phase 1 data demonstrating no dose limiting toxicity across a twenty-fold dose range. Furthermore, the first phase of the multiple ascending Phase 2a study program in DMD patients aged 4 to less than 7 years old, demonstrating a clear dose relationship to pharmacodynamic markers of disease, after which patients entered into an extension phase with the aim to explore the efficacy, safety and tolerability of vamorolone over 2.5 years on well-established clinical outcome measures. The Phase 2a program demonstrated a dose dependent and clinical improvement across all timed function clinical outcomes compared to baseline for up to 18 months but importantly showed no growth stunting and a much-reduced incidence of behavioral changes, Cushingoid appearance with weight gain only occurring in a minority of patients at the higher dose that were down titrated but continued treatment. Comparison to external natural history data in treated and untreated cohorts, indicates that vamorolone offers similar anti-inflammatory benefits of current glucocorticoids but has a clear and well differentiated safety profile meeting market, physician and patient needs in avoiding many of the adverse effects that lead to early discontinuation of treatment that will lead to avoidance of many of the costly chronic adverse conditions currently burdening healthcare systems. The Phase 2a long term extension study 30-month (2.5 year) data is currently being analyzed but early analyses have indicated a consistent profile that that previously published. In summary the Phase 2a program has demonstrated a clinically important improvement or disease stabilization across several well-established clinical outcome measures whilst importantly delivering data supporting a safety profile consistent with an improved tolerability profile enabling longer term use. The pivotal Phase 2b VISION-DMD study is in the same target population, utilizing the 2 higher doses and same clinical outcome measures as explored in the Phase 2a study. The study successfully completed recruitment in September 2020 with last patient last visit in March 2021, however, uncertainty remains over the upcoming results expected within the second quarter of 2021

During February 2021 the Company increased its financing facility, by CHF 12 million with Highbridge to increase the runway beyond the next inflection point and allow for increased time to raise additional finance after the vamorolone results. The availability of funds from this facility is subject to certain conditions being met. In order to achieve an equity financing during 2021, Management and the Board of Directors also decided it was necessary to wholly or partially restructure Santhera's CHF 60 million Convertible Bond maturing in February 2022. Actions are currently ongoing to restructure this debt. As announced on April 27, 2021 74.7% of bonds held had been tendered for exchange and in parallel a consent solicitation process is continuing in order to seek a two third majority of all bondholders in order to restructure 100% of the convertible bond to the new terms offered. In any event a minimum amount of 74.7% of the convertible bond will be exchanged providing a new maturity date of August 2024 and a reduction in the nominal value, such that the CHF 60 million previously maturing in February 2022 would become CHF 15.2 million with the remaining revised nominal value and CHF 44.8 million maturing in August 2024. In addition to assist with short term liquidity the interest due on the exchanged bond at the Company's election may be paid in shares rather than cash.

Shareholders should note that whilst the Management and Board of Directors consistently continue to apply best efforts to evaluate and execute available options, there is no guarantee that the development studies will be successful, and any transaction can be realized or that such transaction would generate sufficient funds to finance operations through December 31, 2021. This material uncertainty may cast significant doubts about the going concern of the Company. If going concern cannot be supported, statutory financial statements would have to be

prepared using liquidation values. In this case, a serious concern of over-indebtedness in the sense of article 725 para. 2 CO would exist and the relevant provisions would have to be complied with.

The results show that the group was overindebted as at December 31, 2020 on a consolidated basis, while the Company on a standalone basis was not overindebted it continued to have a positive equity. As noted above, the Company has highlighted a number of material uncertainties. While the Board and management continue to take the necessary steps with the intent to maintain a going concern, events could lead to the Company becoming overindebted or presenting a capital loss which would then require the Company to take further steps under Art. 725 CO to safeguard the interests of creditors and its shareholders.

However, the Management and the Board of Directors of the Company are prepared to secure additional funds needed in order to operate its business as planned with the objective to meet all of its obligations until December 31, 2021. Hence, the statutory financial statements have been prepared on a going concern basis.

2 Principles

General

The statutory financial statements of the Company are prepared in accordance with the general accepted accounting principles as set out in Art. 957 to Art. 963b, of the Swiss Code of Obligations (**CO**). Since Santhera prepares consolidated financial statements in accordance with International Financial Reporting Standards (**IFRS**) of the International Accounting Standards Board (**IASB**), a recognized accounting standard, the Company has, in accordance with the CO, elected to forego presenting the statement of cash flows, the additional disclosures and the management report otherwise required by the CO.

Cash

Santhera holds cash balances, denominated mainly in Swiss francs (**CHF**) which include cash deposited in demand bank accounts, money market investment accounts and other liquid investments and interest earned on such cash balances.

Financial assets short-term

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

Current assets and liabilities

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

Loans to shareholdings

These are valued at their acquisition cost adjusted for impairment losses.

Investments in shareholdings

Investments in shareholdings are recorded at acquisition cost less adjustments for impairment of value. Investments in subsidiaries are evaluated for impairment annually and an impairment loss is recorded when the carrying

amount of such assets exceeds the fair value. Fair value estimates of investments are predominantly based on the income approach.

Convertible bonds

On February 17, 2017, Santhera issued senior unsecured convertible bonds in the nominal amount of CHF 60 million. The bonds were issued at 100% of the principal amount and will also mature at 100% of that amount on February 17, 2022, unless previously redeemed, converted or repurchased and cancelled. The bonds, listed on the SIX, are interest bearing (5%) with a maximum term of 5 years and are convertible into registered Shares of Santhera with a nominal value of CHF 1 each. The initial conversion price was fixed at CHF 86.4006 and was reset in accordance with the terms of the bonds in February 2018 to CHF 64.80. In addition, Santhera may call the convertible bonds at any time on or after the second anniversary of the issue date at par, plus accrued interest, if any, if the VWAP of the Shares is at least 160% of the conversion price.

Exchangeable notes

On September 2, 2020, Santhera exercised its option to obtain worldwide rights to vamorolone in Duchenne muscular dystrophy (DMD). Agreements with Idorsia Ltd, Allschwil, ReveraGen BioPharma, Rockville, MD, give Santhera immediate control over vamorolone. As consideration for the assignment of its licensing option for vamorolone to Santhera, Idorsia did receive 366,667 Santhera shares, and non-interest bearing exchangeable notes in the amount of CHF 10 million. The exchangeable notes are payable up to 65% in Santhera Shares, at Santhera's discretion, and have a maximum term of 12 months. They are non-interest bearing.

Treasury shares

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

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

Related parties

In the meaning of the Swiss Accounting Law, related parties are only considered to be shareholders, direct and indirect subsidiaries (shareholdings) and the Board of Directors.

3 Information on Balance Sheet and Income Statement Items

3.1 Loans to shareholdings

Loans are granted to shareholdings primarily to fund the development and marketing activities of the Santhera Group (December 31, 2020: CHF 314.8 million; December 31, 2019: CHF 291 million). Until the end of 2015 the balance consisted of fully impaired and subordinated loans to Santhera Pharmaceuticals (Schweiz) AG. To finance the activities in development and the commercialization of LHON, in 2016 the loan granted to Santhera Pharmaceuticals (Schweiz) AG was increased (with the additional loans also being subordinated). As part of the annual reassessment as of December 31, 2020, Executive Management concluded that approximately 45% of the total

loan balance is recoverable considering a more positive outlook, in terms of market success of the development progress in different indications (mainly vamorolone in DMD).

3.2 Investments in shareholdings

In 2020 and 2019, the following companies are direct subsidiaries of Santhera Pharmaceuticals Holding AG (100% ownership and 100% voting rights):

	Share capital at December 31	2020	2019
Santhera Pharmaceuticals (Schweiz) AG Pratteln, Switzerland	CHF	125,000	125,000
Santhera Pharmaceuticals (Deutschland) GmbH Lörrach, Germany	EUR	25,000	25,000
Santhera Pharmaceuticals (USA), Inc. Burlington, US	USD	1,000	1,000
Santhera Pharmaceuticals (Canada), Inc. Montréal, Canada	CAD	1,000	1,000
Oy Santhera Pharmaceuticals (Finland) Ltd Helsinki, Finland	EUR	2,500	2,500

Santhera Pharmaceuticals (Schweiz) AG is the primary operational entity while Santhera Pharmaceuticals (Deutschland) GmbH holds the market authorization for the EU. Oy Santhera Pharmaceuticals (Finland) Ltd is not employing any personnel.

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

	Share capital at December 31	2020	2019
Santhera Pharmaceuticals (Liechtenstein) AG Ruggell, Fürstentum Liechtenstein	CHF	50,000	50,000
Santhera (Italy) S.r.l. - <i>in liquidation</i> Milano, Italy	EUR	50,000	50,000
Santhera (Germany) GmbH München, Germany	EUR	50,000	50,000
Santhera (Netherlands) B.V. Nieuwegein, The Netherlands	EUR	50,000	50,000
Santhera (UK) Limited London, United Kingdom	GBP	50,000	50,000
Santhera Pharmaceuticals (Spain), S.L.U Irun, Spain	EUR	50,000	50,000

3.3 Share capital

During 2020, the share capital was increased by a total amount of CHF 8,264,633 to CHF 19,429,696 as of December 31, 2020 (2019: CHF 11,165,063): The increase consisted of 1) increases through the issuance of 4,569,291

Shares from the authorized share capital for equity financing purposes (e.g. convertible notes) and 2) increases through the issuance of 3,695,342 Shares from the conditional share capital for equity financing transactions with Highbridge.

On occasion of the Annual General Meeting, held April 22, 2020, the shareholders approved the increase of authorized the share capital at any time until April 21, 2022, through the issuance of up to 4,630,000 Shares with a nominal value of CHF 1. The shareholders further approved the increase of the conditional share capital by a maximum amount of up to 4,800,000 Shares with a nominal value of CHF 1 through the exercise of warrants/options and/or notes granted in connection with bonds or similar debt instruments linked with option and/or conversion rights granted by the Company.

3.4 Treasury shares

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

	No of Shares	TCHF
December 31, 2018	53,290	904
Purchase	139,543	1,837
Sale	-137,941	-1,996
December 31, 2019	54,892	745
<i>Purchase for market making</i>	<i>137,327</i>	<i>922</i>
<i>Sale for market making</i>	<i>-134,228</i>	<i>-1,330</i>
Subtotal	57,991	337
<i>Shares created for financing purposes</i>	<i>4,569,291</i>	<i>4,569</i>
<i>Shares used for financing purposes</i>	<i>-3,326,207</i>	<i>-3,326</i>
Subtotal	1,243,084	1,243
December 31, 2020	1,301,075	1,580

3.5 Income from shareholdings

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

3.6 General and administrative expenses

	In CHF thousands	2020	2019
Administrative expenses		1,668	1,662
Consulting expenses		1,209	1,808
Expenses in connection with capital increase		0	426
Total		2,877	3,896

4 Other Information

4.1 Full-time equivalents

The number of full-time equivalents at period end was not above 10 in 2020 and 2019.

4.2 Significant shareholders (>5%)

Pursuant to information from the Company's share register and the disclosure of participations made to the Company in accordance with applicable stock exchange regulation, the following shareholders owned 5% or more of the Company's share capital as registered in the commercial register at December 31, 2020: 19,429,696 shares (December 31, 2019: 11,164,563 shares):

	2020 Shares	2020 %	2019 Shares	2019 %
Idorsia Pharmaceuticals Ltd., Switzerland	1,700,000	8.7	1,333,333	11.9
Bertarelli Group (WDI Invest L.P. = direct shareholder; UBS AG, Jersey)	759,371	4.0	759,371	6.8

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

As of December 31, 2020:

	Number of Shares	Number of vested equity rights	Number of unvested equity rights	Total number of equity rights
<i>Board of Directors</i>				
Elmar Schnee, Chairman	12,000	31,688	56,145	87,833
Martin Gertsch, Director	38,109	35,620	45,865	81,485
Philipp Gutzwiller, Director	7,100	22,300	39,509	61,809
Thomas Meier, Director	82,902	75,595	54,008	129,603
Patrick Vink, Director	1,000	25,571	43,814	69,385
<i>Executive Management</i>				
Dario Eklund, CEO	0	0	184,248	184,248
Günther Metz, Head Business Development	0	59,271	54,477	113,748
Kristina Sjöblom Nygren, Chief Medical Officer & Head Development until December 31, 2020	0	45,683	66,910	112,593
Andrew Smith, Chief Financial Officer	0	0	162,138	162,138
Oliver Strub, General Counsel and Secretary to the Board	0	52,524	54,969	107,493

As of December 31, 2019:

	Number of Shares	Number of vested equity rights	Number of unvested equity rights	Total number of equity rights
<i>Board of Directors</i>				
Elmar Schnee, Chairman	12,000	13,035	33,465	46,500
Martin Gertsch, Vice-Chairman	38,109	17,534	31,803	49,337
Philipp Gutzwiller, Director	7,100	9,178	23,545	32,723
Thomas Meier, Director		--- See below ---		
Patrick Vink, Director	1,000	11,053	26,184	37,237
<i>Executive Management</i>				
Dario Eklund, CEO	0	0	184,248	184,248
Thomas Meier, CEO until November 30, 2019	82,902	43,548	58,598	102,146
Günther Metz, Head Business Development	0	37,597	39,386	76,983
Christoph Rentsch, Chief Financial Officer until December 31, 2019	0	44,217	51,305	95,522
Kristina Sjöblom Nygren, Chief Medical Officer & Head Development	0	19,011	50,882	69,893
Oliver Strub, General Counsel and Secretary to the Board	0	30,217	40,511	70,728

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

	2020 Quantity	2020 Value (in TCHF) ¹	2019 Quantity	2019 Value (in TCHF) ¹
Board of Directors	165,332	551	78,944	463
Executive Management	283,127	901	359,521	2,024
Employees of Santhera Group	719,008	2,386	634,497	3,583
Total	1,167,467	3,838	1,072,962	6,070

¹ Value of the equity rights calculated in accordance with the Hull-White model at the date of allocation in accordance with the terms of the award. The tax value of equity rights is 0 until they would be exercised. Such equity rights values are theoretical values and do not reflect income tax values and do also take into consideration certain vesting provisions. For information about the underlying equity rights plans, see note 18 "Equity Rights Plans" in the consolidated financial statements. For information about the Company's compensation procedures, consult the Corporate Governance Report and the Compensation Report.

4.5 Contingencies and guarantees

Guarantee towards Swiss VAT authorities

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

Guarantee towards Santhera Pharmaceuticals (Schweiz) AG

The Company guarantees to pay for the liabilities of its subsidiary Santhera Pharmaceuticals (Schweiz) AG until the Annual General Meeting in 2022.

Declaration of liability towards Arval Deutschland GmbH

The Company guarantees to pay for the liabilities of its subsidiary Santhera (Germany) GmbH for contractual duties and obligations.

4.6 Events after the reporting date

There were capital increases on February 4, 2021, of 1,600,000 shares, on March 10, 2021, of 480,708 shares and on March 29, 2021, 2,200,000 shares issued out of the existing authorized capital as treasury shares. After issue the number of shares recorded in the commercial register has been increased to 23,229,696 shares. Santhera expects to use these shares for purposes of its financing arrangements.

On February 16, 2021 the Company announced that an existing investor Highbridge Tactical Credit Master Fund, L.P. (a fund managed by Highbridge Capital Management LLC, "Highbridge") committed to increasing its existing financing arrangement to provide up to CHF 18 million in senior secured notes exchangeable by Highbridge (CHF 6 million of which was previously committed), which will be available in tranches and subject to certain drawdown conditions. Between December 31, 2021 and April 26, 2021, CHF 11 million have been drawdown under the previous and amended facility. As at April 26, 2021 a further CHF 6 million remain available subject to certain drawdown conditions.

On March 1, 2021 the Company announced positive results from its multiple ascending dose Phase 1b study with lonodelestat, a potent inhibitor of human neutrophil elastase (hNE), in patients with cystic fibrosis (CF).

On March 3, 2021 the Company announced that the last patient has completed the last visit for the first period of the placebo-controlled pivotal VISION-DMD study with vamorolone in patients with Duchenne muscular dystrophy (DMD), conducted by partner ReveraGen Biopharma Inc. Subject to a positive 6-month topline data readout of this first study phase, this could allow for a regulatory submission to the US FDA in Q1-2022 with the potential to offer an alternative to current standard of care in DMD.

On March 8, 2021 the Company held a meeting of bondholders with a vote on the new terms being offered. The voted resulted in a large majority of 89 % of bondholders represented voting in favor of the resolutions proposed by the Company. These bonds represented 58% of the total bonds outstanding and therefore the required threshold of 2/3 of all bonds outstanding to pass such resolutions was not met.

On March 18, 2021 the Company held an Extraordinary General Meeting where the shareholders supported all motions by the Board and approved an ordinary capital increase by CHF 312,000, an increase of the authorized capital to the statutory limit of 50% of the issued share capital and an increase of the total of the two conditional capitals to the same 50% limit (including an increase of conditional capital for employee participations of

CHF 1,850,000). The shareholders also endorsed a both time- and performance-based equity instrument for Executive Management in the form of performance share units (PSU).

On March 25, 2021 the Company announced an offer to exchange its outstanding CHF 60 million 5% Convertible Bonds due 2022 on the same economic terms as previously proposed to the bondholders' meeting of March 8, 2021 and as set out in the Bond prospectus. The exchange offer period started on April 6, 2021, and ended at 5:00 p.m. (CEST) on April 19, 2021. The Exchange Offer was declared successful after the expiry of the offer period, with 66% of bondholders tendering exchange and so an additional acceptance period started on April 21, 2021, and ended on April 27, 2021 when it was also announced that 74.7% of bondholders had tendered exchange. The Exchange Offer is planned to be settled on or around May 4, 2021. In parallel to the Exchange Offer, the Company is seeking additional consents to its proposals to the March 8, 2021 bondholders' meeting in order to achieve the requisite two-thirds majority. If the Company obtains the necessary number of additional consents in time, the Exchange Offer will not be completed and the original bond restructuring would be pursued. The Company expects to announce the settlement date or a postponement of the settlement by Monday, May 3, 2021 at the latest.

On April 28, 2021 the Company announced new clinical data of 2.5-year treatment outcome with vamorolone in patients with Duchenne muscular dystrophy (DMD). These Phase 2a long-term treatment data demonstrate a maintenance of treatment effect, equivalent to a delay of about two years in decline for time to stand (TTSTAND) velocity, and confirm safety and tolerability benefits of vamorolone over the 2.5-year follow up period. Long-term treatment with vamorolone resulted in significantly fewer corticosteroid-associated adverse events than reported in other clinical trials with other steroids.

Proposal of the Board of Directors to the Annual General Meeting

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

	In CHF	2020	2019
Result carried forward		-32,377,063	-23,622,409
Net result of the year		-7,424,032	-8,754,654
Accumulated result		-39,801,095	-32,377,063
Result to be carried forward		-39,801,095	-32,377,063

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

	In CHF
Reserves from capital contribution after Annual General Meeting (April 22, 2020)	282,156
Share premium of capital increases during 2020	11,797,403
Reserves from capital contribution	12,079,559
Transfer from reserves from capital contribution to other voluntary reserves (free reserves)	-12,000,000
Reserves from capital contribution	79,559

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

	In CHF
Other voluntary reserves (free reserves) after Annual General Meeting (April 22, 2020)	83,994,714
Transfer from reserves from capital contribution	12,000,000
Free reserves	95,994,714



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To the General Meeting of
Santhera Pharmaceuticals Holding Ltd, Pratteln

Basle, April 28, 2021

Report of the statutory auditor on the financial statements

As statutory auditor, we have audited the financial statements of Santhera Pharmaceuticals Holding Ltd, which comprise the balance sheet, income statement and notes (pages 75 to 86), for the year ended December 31, 2020.



Board of Directors' responsibility

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



Auditor's responsibility

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

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



Opinion

In our opinion, the financial statements for the year ended December 31, 2020 comply with Swiss law and the company's articles of incorporation.



Emphasis of matter

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



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



Report on key audit matters based on the circular 1/2015 of the Federal Audit Oversight Authority
Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the financial statements of the current period. In addition to the matters described in the *Emphasis of matter* section of our report, we have determined the matters described below to be the key audit matters to be communicated in our report. These matters were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters. For each matter below, our description of how our audit addressed the matter is provided in that context.

We have fulfilled the responsibilities described in the *Auditor's responsibilities* 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 judgement around assumptions used, including prospective financial information 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 as well as discount rates used. We evaluated the historical accuracy of the Company'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.



Report on other legal requirements

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

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

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

Ernst & Young Ltd

/s/ Frederik Schmachtenberg

Licensed audit expert
(Auditor in charge)

/s/ Diana Vejina

ACCA

Compensation Report

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Introduction

This Compensation Report (**Report**) describes the principles of the compensation system of Santhera's Board of Directors (**Board**) and Executive Management (**EM**) members (**Executives**) and how the respective decisions are made. Furthermore, the Report discloses the compensation made to the Board and EM for 2020, as well as shareholdings of the members of the Board and EM members.

Compensation Governance

The Role and Powers of the Compensation Committee

The Compensation Committee (**CC**) currently consists of the two members of the Board, Patrick Vink as Chairman and Elmar Schnee as Member. The CC annually reviews the compensation system of the members of the Board and EM and ensures that the Company's regulations and Articles of Incorporation remain in compliance with requirements of the Ordinance against Excessive Compensation (**OaEC**), the SIX Swiss Exchange, as well as Swiss and international best corporate governance practices.

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

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

The CC reviews and approve

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

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

Compensation Periods and Approvals by Shareholders

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

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

	Previous year	Current year	Next year
Advisory vote on the Compensation Report	Compensation Framework	●	
Total Board compensation (AGM to AGM)		● Compensation Period	
Fixed EM compensation (following year)		●	Compensation Period
Variable EM compensation (previous year)	Compensation Period	●	

● Voting at AGM

Voting procedures at the AGM 2021

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

1. Consultative vote on the Compensation Report 2020.
2. Board
 - The maximum total amount of the compensation for the period between the AGM 2021 and the AGM 2022.
3. Executive Management
 - 3.1. The maximum total amount of the fixed compensation for the period from January 1, 2022 to December 31, 2022.
 - 3.2. The maximum total amount of the variable compensation for the period from January 1, 2020 to December 31, 2020.

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

Compensation Principles

Santhera's compensation policy is designed to attract, motivate and retain talent in order to support the achievement of the Company's financial and strategic objectives and also to ensure that the total compensation package is market competitive. By combining short- and long-term incentive elements, the Board believes that the compensation system is designed in a way that the interests of the management are aligned with the interests of the Company and its shareholders. The Company's compensation system does not set any unintended enticements or contain any components that could be counterproductive to the objectives of the compensation system. The compensation system shall ensure compliance and best practice. In addition, compensation elements are focused on rewarding the delivery of outstanding and sustainable results without inappropriate risk-taking.

Market competitiveness

The compensation structure and level of the EM members is reviewed locally on a regular basis in order to ensure market competitiveness. Such review takes into consideration comparable functional and financial responsibilities. The benchmark analysis, conducted by Kienbaum in the year 2017 provided an in-depth benchmark analysis of the compensation of the EM members. No benchmark analysis was conducted since then.

With respect to total compensation (base salary, allowances, annual cash bonus and long term incentive plans), we position ourselves at the market median at target.

Compensation Elements

Board of Directors Compensation Elements

The compensation for members of the Board consists of:

- Annual cash fees (50% of the total compensation)
- Annual grant of Share Appreciation Rights (**SAR**; 50% of the total compensation)

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

Annual SAR grants typically foresee vesting of 1/3 of the SAR on the first anniversary; the remaining 2/3 vest by each following quarter end through the second and third year after the grant date (8 times 1/12 of the SAR granted). The exercise period of SAR is 10 years from the grant date of the respective SAR grant. For more information about the underlying Plan, see note 18 "*Equity Rights Plans*" in the consolidated financial statements.

Executive Management Compensation Elements

The compensation for members of Executive Management generally consists of:

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

Fixed compensation

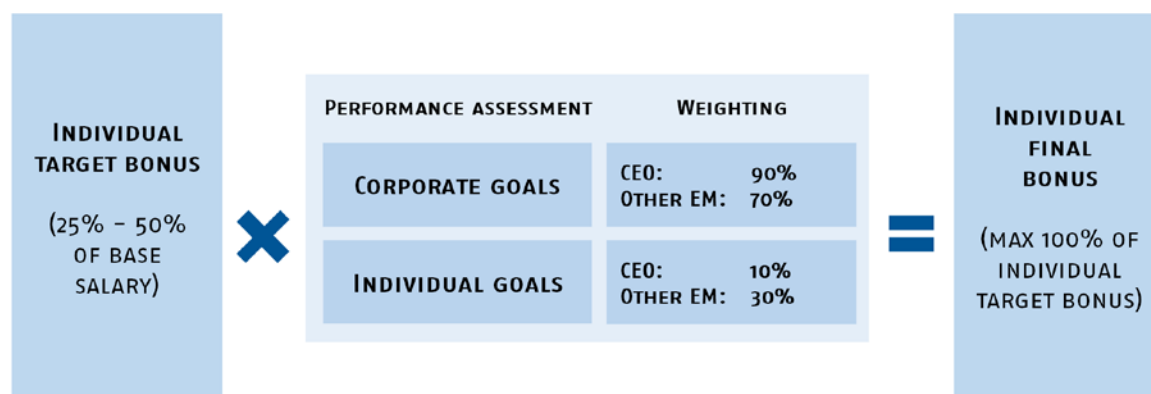
The fixed compensation for the EM members includes base salary, allowances, social security contributions and payments to the pension fund by the Company. The base salary takes into account the position, responsibilities, experience and skills of an individual EM member. Base salaries are reviewed annually by the CC.

Annual cash bonus

The annual cash bonus is based on the achievement of Company and individual goals and will be paid after the AGM until end of December of the same year, subject to the shareholders' approval. The target bonus, i.e. cash bonus to be paid if Santhera's financial situation allows for a cash bonus and 100% of corporate and individual goals are met, is determined individually for each EM member as percentage of the base salary, ranging from 25% to 50%.

The weightings of the corporate and individual goals are individual for each EM member and vary depending on the position. In general, the weight of corporate goals increases with the level of the EM position. For the Chief Executive Officer (CEO), the weighting of the achievement of corporate goals has been 90%. The weighting of the achievement of corporate goals for the other Executives has been 70%.

Calculation of the individual annual bonus for EM members

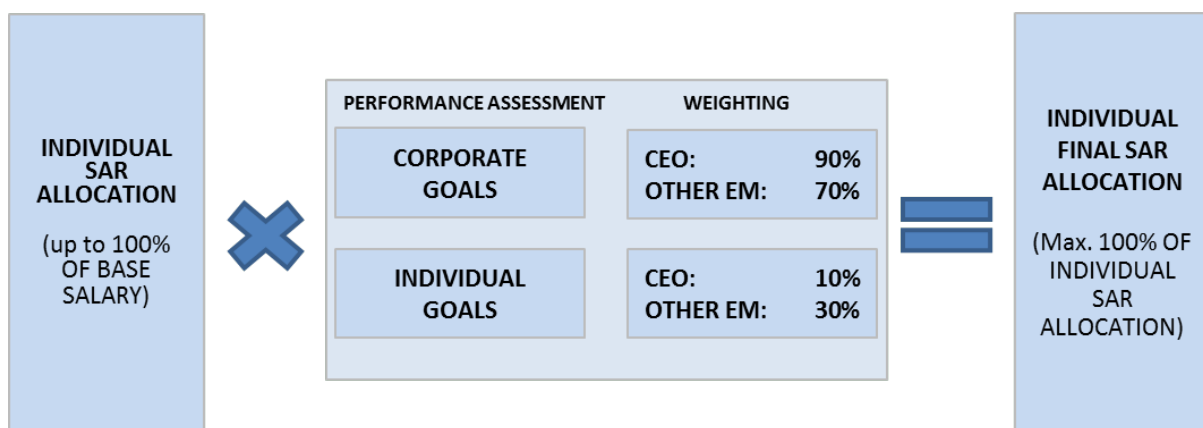


Long Term Incentive Plan

Until the financial year 2020 and under the Long Term Incentive Plan members of the EM received Share Appreciation Rights (SAR) annually. The annual individually allocated amount of Share Appreciation Rights (SAR) was calculated as follows:

The Board defines a certain percentage of the base salary for each EM function, which is the basis for the SAR calculation. The target percentage, i.e. the percentage if 100% of corporate and individual goals are met, is determined individually for each EM member as percentage of the base salary, up to 100%.

The individual SAR amount is based on the achievement of corporate and individual goals. The percentage is limited to a maximum of 100% of the target percentage.



The final calculated amount is then divided by the fair market value of a SAR resulting in a maximum number of SAR, which is adjusted based upon the total available quantum of SAR issued in a year. The fair market value is calculated by applying the option model “Hull-White”.

Since the financial year 2019, the grant date for SAR is one business day after the AGM of a particular year.

Annual SAR grants typically foresee vesting of 1/3 of the SAR on the first anniversary; the remaining 2/3 vest by each following quarter end through the second and third year after the grant date (8 times 1/12 of the SAR granted). The exercise period of SAR is 10 years from the grant date of the respective SAR grant. For more information about the underlying Plan, see note 18 “Equity Rights Plans” in the consolidated financial statements.

The Company intends to discontinue the current SAR program and to replace it with a time and performance dependent equity-based plan from the year 2021 onwards.

Compensation awarded to the Board of Directors in 2020

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

Annual cash fees

At the AGM 2020, the shareholders approved a total cash compensation for the entire Board of a maximum of CHF 594,000 for the period between the AGM 2020 and the AGM 2021, including social security contributions. The cash compensation is expected to amount only to CHF 352,013 (including social security contributions) as the majority of Board members voluntarily waived half of their cash fees due to the discontinuation of the Puldysa (idebenone) program. Only the Chairman of the Scientific Committee did not voluntarily waived half of his cash fees and maintains the cash fees at the approved level of CHF 110,000 for the period between the AGM 2020 and the AGM 2021 due to cancellation of the 2019 bonus amount in his capacity of the former CEO of the Company.

Share Appreciation Rights (SAR)

At the AGM 2020, the shareholders approved a total maximum amount of CHF 594,000 to be granted in SAR for the period until the AGM 2021. In accordance with the Board Share Appreciation Rights Plan (**BSARP 2017**), 165,332 SARs were granted to the Board members as of May 23, 2020. The exercise price was the closing price of Santhera’s share on May 23, 2020 and amounted to CHF 7.96 (2019: CHF 14.50).

The table below represents the approved maximum compensation for the Board, the actual amounts paid in 2020 and those still payable until AGM 2021. The difference between the approved maximum compensation and the expected compensation for the period from the AGM 2020 to the AGM 2021 is due to the voluntary forfeiture of some parts of the cash remuneration by the BoD members.

	Approved AGM 2020 – AGM 2021	Paid/payable AGM 2020 – AGM 2021
Board fees (CHF)	594,000	352,013
SAR ¹ (CHF)	594,000	594,003
Total (CHF)	1,188,000	946,016
SAR (number)	n/a	165,332

¹ The shareholders approved a fix amount in CHF which was converted into a number of SAR based on the fair market value of such SAR including assumed social security contributions on the first trading day immediately following the AGM 2020 (CHF 3.3319).

Disclosure of compensation of members of the Board for the financial years 2020 and 2019 (audited)

In CHF	Annual cash fees	SAR ¹	Social security ^{1, 2}	Total compensation	Number of SAR granted
2020					
Elmar Schnee	92,813	137,717	10,783	241,313	41,333
Martin Gertsch	71,996	107,114	14,030	193,140	32,148
Philipp Gutzwiller	60,532	96,912	12,332	169,776	29,086
Thomas Meier	67,662	102,013	22,826	192,500	30,617
Patrick Vink	65,630	107,114	13,531	186,276	32,148
Total	358,632	550,870	73,503	983,005	165,332
2019					
Elmar Schnee	148,500	137,500	10,312	296,312	23,423
Martin Gertsch	127,315	127,315	19,461	274,091	21,688
Philipp Gutzwiller	96,759	96,760	14,790	208,309	16,483
Thomas Meier ³	0	0	0	0	0
Patrick Vink	101,852	101,850	15,568	219,270	17,350
Total	474,426	463,425	60,131	997,982	78,944

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 SAR is CHF 0 until such 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 To be in line with the market practice, the Board has decided to disclose the social security from 2015 onwards not on exercised but on the fair market value of allocated options/SAR. For all SARs held by Board members as of December 31, 2020, the social security contribution is CHF 0 since the SARs have not been exercised. The total value of social security payments on options/SAR exercised by members of the Board during 2020 is CHF 0 (2019: CHF 0).

³ Thomas Meier did not receive any compensation as a Board member.

Compensation awarded to the members of the Executive Management in 2020

Comparison of the approved and paid EM fixed compensation

At the AGM 2019, shareholders approved a maximum total compensation for the EM for 2020 as follows: CHF 3,000,000 for the fixed compensation in cash.

In CHF	Approved 2020	Paid 2020
Fixed Compensation	3,000,000	2,725,330

Comparison of the approved and paid EM variable compensation

The AGM 2020 has approved a maximum total amount of variable compensation of the members of the Executive Management for the period from January 1, 2019, to December 31, 2019, of CHF 1,635,000, consisting of CHF 705,000 for the payment of a cash bonus and of an amount of a maximum of CHF 930,000 for the allocation of Share Appreciation rights (SAR). The Board expected to pay the cash bonus only if Santhera would reach certain key inflection points over the coming months following the AGM 2020. As this has not been achieved, no cash bonus payment had been made to members of the Executive Management for the period from January 1, 2019, to December 31, 2019 in the year 2020.

In CHF	Approved 2020	Paid 2020
Maximum amount Variable Compensation	1,635,000	427,549 ¹
Thereof		
Cash Bonus	705,000	0
Allocation of SAR	930,000	427,549 ¹

¹ Included in the amounts are social security payments on the fair market value of allocated SAR.

Disclosure of compensation of members of the Executive Management for the years 2020 and 2019 (audited)

In CHF	Base salary	Allowances	Cash bonus	SAR ¹	Social security and pension ⁴	Total compensation	2020 adjustment ⁶	Total adjusted compensation	Number of SAR granted
2020									
Andrew Smith ⁷	240,030	32,445	0	500,001 ²	94,032	866,508	0	866,508	162,138 ²
Dario Eklund	500,004	66,177	0	0	114,870	681,050	0	681,050	0
Other 3 members of EM ⁷	950,040	0	0	400,752	254,528	1,605,320	0	1,605,320	120,989 ⁵
Total	1,690,074	98,622	0	900,753	463,430	3,152,879	0	3,152,879	283,127
2019									
Dario Eklund	41,667	3,782	18,340 ⁶	1,000,006 ³	78,502 ⁸	1,147,433	-18,340 ⁶	1,123,957	184,248 ³
Other 4 members of EM	1,696,710	0	523,798⁶	510,113	402,256⁸	3,279,540	-523,798⁶	2,609,079	175,273⁵
Total	1,738,377	3,782	542,138⁶	1,510,119	480,758⁸	4,426,973	-542,138⁶	3,733,036	359,521

¹ Reflects value of share-based payments in accordance with IFRS 2 at grant, i.e. the value of unvested stock options/SAR attributable at grant; the tax value of such stock options/SAR is CHF 0 until stock options/SAR are exercised. Such stock option/SAR values are theoretical values and do not reflect income tax values and do also take into consideration certain vesting provisions.

² The amount represents an initial grant number of 162,138 SAR at a fair market value of CHF 3.0838 as of the grant date of April 1, 2020 (the first day of employment) to attract and retain the CFO for a period of three years. The initial grant is forfeited in case the employment agreement terminates prior to April 1, 2023.

³ The amount represents an initial grant number of 184,248 SAR at a fair market value of CHF 5.4275 as of the grant date of December 2, 2020 (the first business day of employment) to attract and retain the CEO for a period of three years. The initial grant is forfeited in case the employment agreement terminates prior to December 1, 2022.

⁴ Included in the amounts are social security payments on the fair market value of allocated SAR.

⁵ Number of SAR granted in the financial year 2020 represents the annual grant for the year 2019. Number of SAR granted in the financial year 2019 represents the annual grant for the year 2018.

⁶ The approved 2019 Cash bonus for EM members totaling CHF 542,138 (CHF 18,340 for Dario Eklund and CHF 523,798 for other 4 members of the EM) and which was included in the 2019 audited financial statements based upon the assumption, that Santhera would meet the short term inflection points, was not paid out in 2020 due to not achieving such short term inflection points. For more details, refer to section "Comparison of the approved and paid EM variable compensation".

⁷ Highest paid in the year 2021 due to the one time SAR grant, refer to footnote 2 above.

⁸ The 2019 audited financial statements showed a total amount of CHF 632,557 (CHF 83,638 for Dario Eklund and CHF 548,919 for other 4 members of the EM), which included an amount of CHF 151,799 for social security and pension on the 2019 Cash bonus payable in the year 2020 (CHF 5,135 for Dario Eklund and CHF 146,664 for other 4 members of the EM), which was not paid out. For more details, refer to section "Comparison of the approved and paid EM variable compensation".

Changes in the Executive Management in 2020

Chief Financial Officer (CFO): Andrew Smith was appointed CFO of the Company effective April 1, 2020. His predecessor Christoph Rentsch had left the Company effective December 31, 2019.

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

Event	Date	Number of Executives
Andrew Smith assumes CFO position	April 1, 2020	5
Resignation Kristina Sjöblom Nygren	October 30, 2020 ¹	4 ²

¹ Date of Resignation

² As of January 1, 2021 Kristina Sjöblom Nygren functioned not as an EM member anymore until the Termination Date.

Executive Contracts

The employment contracts with the EM members are compliant with the OaEC and the Company's Articles of Incorporation. Any noncompeting clauses for the period after termination of an employment agreement shall not exceed one year with the maximum compensation for such period of the last total annual compensation of an EM member in question.

Indirect Benefits

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

Loans and Credits

In accordance with the Articles of Incorporation, loans to members of the Board and EM may only be on market terms and may only be made by the Company or by any of its directly or indirectly controlled companies, whereas the total sum of total outstanding loans to a particular member, including the amount to be granted, shall not exceed twice the most recent annual compensation to such member. In 2020, 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 (2019: CHF 0) for such payments in 2020.

Disclosure of compensation of former Board members for the years 2020 and 2019 (audited)

In CHF	Total payment
2020	
n/a	–
Total	0
2019	
n/a	–
Total	0

With regard to the former EM members, Santhera made payments of CHF 322,573 in 2020 (2019: CHF 41,225).

Disclosure of compensation of former EM members for the years 2020 and 2019 (audited)

In CHF	Total payment
2020	
Thomas Meier ¹⁾	322,573
Total	322,573
2019	
Thomas Meier	41,225
Total	41,225

¹ The amount reflects gross payments made in the year including social security cost. T. Meier did not receive the 2019 cash bonus, which amounted to CHF 176,060 (excl. social security cost). The approved 2019 Cash bonus for EM members, which was intended to be paid out only upon meeting short term inflection points, was not paid out in the year 2020 due to not achieving the short term inflection points. For more details, refer to section "Comparison of the approved and paid EM variable compensation".

Shareholdings of Members of the Board and Executive Management

Disclosure of shareholdings in the Company of Board members for the years 2020 and 2019 (audited)

December 31, 2020	Number of shares	Number of stock options (vested)	Number of stock options (unvested)	Number of SAR (vested)	Number of SAR (unvested)
Elmar Schnee	12,000	0	0	31,688	56,145
Martin Gertsch	38,109	6,281	0	29,339	45,865
Philipp Gutzwiller	7,100	0	0	22,300	39,509
Thomas Meier	82,902	14,875	0	60,720	54,008
Patrick Vink	1,000	0	0	25,571	43,814
Total	141,111	21,156	0	169,618	239,341
December 31, 2019	Number of shares	Number of stock options (vested)	Number of stock options (unvested)	Number of SAR (vested)	Number of SAR (unvested)
Elmar Schnee	12,000	0	0	13,035	33,465
Martin Gertsch	38,109	5,461	820	12,073	30,983
Philipp Gutzwiller	7,100	0	0	9,178	23,545
Thomas Meier ¹⁾	0	0	0	0	0
Patrick Vink	1,000	0	0	11,053	26,184
Total	58,209	5,461	820	45,339	114,177

¹ Thomas Meier's shareholdings are listed in the table below.

Disclosure of shareholdings in the Company of Executive Management members for the years 2020 and 2019 (audited)

December 31, 2020	Number of shares	Number of stock options (vested)	Number of stock options (unvested)	Number of SAR (vested)	Number of SAR (unvested)
Dario Eklund	0	0	0	0	184,248
Günther Metz	0	19,120	0	40,151	54,477
Kristina Sjöblom Nygren	0	0	0	45,683	66,910
Andrew Smith	0	0	0	0	162,138
Oliver Strub	0	11,241	0	41,283	54,969
Total	0	30,361	0	127,117	522,742

December 31, 2019	Number of shares	Number of stock options (vested)	Number of stock options (unvested)	Number of SAR (vested)	Number of SAR (unvested)
Dario Eklund	0	0	0	0	184,248
Thomas Meier	82,902	13,282	1,593	30,266	57,005
Günther Metz	0	18,340	780	19,257	38,606
Christoph Rentsch	0	20,250	1,750	23,967	49,555
Kristina Sjöblom Nygren	0	0	0	19,011	50,882
Oliver Strub	0	10,431	810	19,786	39,701
Total	82,902	62,303	4,933	112,287	419,997

Outlook for Board compensation

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

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 or SC	20,000	2	40,000
Member of the CC or SC	10,000	2	20,000
Total			740,000

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

At minimum, 50 percent of the total compensation is made in the form of restricted shares. The Board of Directors proposes that the 2021 ordinary AGM approves Board remuneration totaling not more than CHF 900,000 (excluding legally required employer's contributions to AHV/IV/ALV) for the period ending at the 2022 ordinary AGM.

Outlook for Executive Management compensation

Outlook for fixed compensation

The AGM 2020 has already approved the fix compensation for 2021 in the amount of CHF 3,000,000.

For the fix compensation for 2022, the Board will propose an amount of CHF 4,100,000 to the AGM 2021 which would be based on the planned six Executives, including a reserve amount which would allow increasing the fix compensation of the EM if deemed appropriate by the Board.

Outlook for Variable compensation

Annual cash bonus

The annual cash bonus for 2020 is based on the achievement of Company and individual goals. The Company goals included the successful completion of a financing, achieving milestones to pursue the development of vamorolone and the positive opinion of the EMA on the Marketing Authorization Application dossier for DMD.

Overall Company targets were only partially achieved. Based upon the futility of the Phase 3 SIDEROS study with Puldysa (idebenone), the company had to realign its operations to focus on progressing mainly vamorolone for DMD and lonodelestat for cystic fibrosis and other lung diseases.

The proposal to shareholders at the AGM 2021 is not to award a cash bonus for the year 2020.

Long Term Incentive Plan – annual grant

The Company intends to discontinue the current SAR program and to replace it with a time and performance dependent equity-based plan, a combination of options and Performance Share Units (PSU) from the year 2021 onwards.

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

The Board intends to propose to shareholders at the AGM 2021 to issue time and performance based criteria stock options as the annual grant under the LTI program up to a total value of CHF 1,550,000 in aggregate to EM members.

In CHF	For Approval in 2021
Maximum amount Variable Compensation	1,550,000
Thereof	
Cash Bonus	0
Stock Options / PSU	1,550,000



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To the General Meeting of
Santhera Pharmaceuticals Holding Ltd, Pratteln

Basle, April 28, 2021

Report of the statutory auditor on the compensation report

We have audited the compensation report of Santhera Pharmaceuticals Holding Ltd for the year ended December 31, 2020. The audit was limited to the information according to articles 14–16 of the Ordinance against Excessive Compensation in Stock Exchange Listed Companies (Ordinance) contained in the tables labeled “audited” on pages 92 to 104 of the compensation report.



Board of Directors' responsibility

The Board of Directors is responsible for the preparation and overall fair presentation of the compensation report in accordance with Swiss law and the Ordinance. The Board of Directors is also responsible for designing the compensation system and defining individual compensation packages.



Auditor's responsibility

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

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

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



Opinion

In our opinion, the compensation report for the year ended December 31, 2020 of Santhera Pharmaceuticals Holding Ltd complies with Swiss law and articles 14 – 16 of the Ordinance

Ernst & Young Ltd

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

/s/ Diana Vejjan
ACCA

Corporate Governance Report

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General Information

The Company's corporate governance principles are laid out in its articles of incorporation (**Articles**), the organizational rules (**Organizational Rules; Organisationsreglement**), by-laws of the Company's Audit, Compensation and Scientific Committees adopted by the Board of Directors (**Board**) and a comprehensive set of Group directives, including insider trading rules that require a trading preclearance for the Board and the Company's officers and employees, as well as an internal control system, and a risk management process. All the above documents can be downloaded from: <http://www.santhera.com/investors-and-media/investor-toolbox/governance>.

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

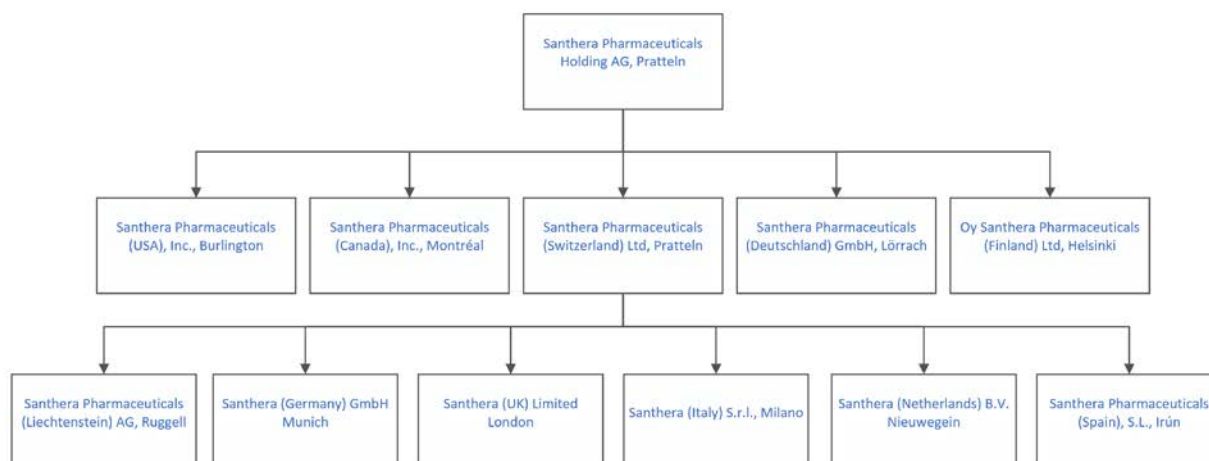
Group Structure and Shareholders (DCG 1)

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 53 million (December 30, 2020)
Website	www.santhera.com
Duration of Company	Not limited
Subsidiaries	See following section as well as note 3.2 " <i>Investments in shareholdings</i> " to the statutory financial statements of the Company.

Santhera operates through its wholly owned subsidiaries (DCG 1.1.3):



Company	Share Capital	Domicile	Activities
Santhera Pharmaceuticals (Schweiz) AG	CHF 125,000	Pratteln, CH	Headquarters; development of pharmaceutical drugs, administrative functions
Santhera Pharmaceuticals (Liechtenstein) AG	CHF 50,000	Ruggell, LI	Logistics/distribution
Santhera (Germany) GmbH	EUR 50,000	München, DE	Dormant
Santhera (Netherlands) B.V.	EUR 50,000	Nieuwegein, NL	Dormant
Santhera (UK) Limited	GBP 50,000	London, GB	Dormant
Santhera (Italy) S.r.l.	EUR 50,000	Milano, IT	In voluntary liquidation
Santhera Pharmaceuticals (Spain), S.L.U	EUR 50,000	Irún, ES	Dormant
Santhera Pharmaceuticals (Canada), Inc.	CAD 1,000	Montréal, CA	Development of pharmaceutical drugs
Santhera Pharmaceuticals (USA), Inc.	USD 1,000	Burlington, Massachusetts, US	Advocacy/patient liaison
Santhera Pharmaceuticals (Deutschland) GmbH	EUR 25,000	Lörrach, DE	Regulatory and development in the EU
Oy Santhera Pharmaceuticals (Finland) Ltd	EUR 2,500	Helsinki, FI	Administrative

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 US (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, the majority of this subsidiaries in the EU have become dormant, or are being liquidated.

Significant shareholders (DCG 1.2)

See note 4.2 “Significant Shareholders” to the statutory financial statements of the Company.

Cross-shareholdings (DCG 1.3)

There are no cross-shareholdings.

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

The Company has one class of registered shares with a nominal value of CHF 1 each (**Shares**). As of December 31, 2019, it had the following ordinary, authorized and conditional share capital:

Type of capital	Capital as per commercial register		Effectively outstanding capital		Expiry	Section in Articles
	Amount in CHF	As % of ordinary capital	Amount in CHF	As % of ordinary capital		
Ordinary capital	18,983,321	100.0	19,316,552	100.0		3
Authorized capital	2,080,709	11.0	2,080,709	10.8	April 21, 2022	3a
Conditional capital for warrants/option rights granted in connection with debt instruments	1,551,033	8.2	1,218,802	6.3	For conversion rights: 10 years from issue date. For options: 7 years from issue date.	3c
Conditional capital for ESOP/BSOP/EIP	687,052	3.6	687,052	3.6		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 <http://www.santhera.com/investors-and-media/investor-toolbox/articles-of-incorporation>, and the section on DCG 2.7 below.

For details with regard to the Company’s ESOP, BSOP, ESARP and BSARP and EIP, see note 18 “Equity Rights Plans” to the consolidated financial statements.

Changes in share capital (DCG 2.3)

For changes in capital that occurred in 2018 and 2019, see the Company’s Annual Report 2019, which can be downloaded at http://www.santhera.com/assets/files/financial_reports/2019-Santhera-Annual-Report_final.pdf. For changes that took place in 2020, see note 11 “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, 2020, the Company had one single class of registered Shares with a nominal value of CHF 1 each. All Shares were fully paid in and are nonassessable. The Company has not issued any participation certificates or any profit-sharing certificates.

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

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

Limitations on transferability and nominee registrations (DCG 2.6)

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

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

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

Convertible bonds and warrants/options (DCG 2.7)

Convertible bonds

On February 10, 2017, the Company had placed CHF 60 million senior unsecured convertible bonds (**Convertible Bonds**) due 2022. The Convertible Bonds have a 5-year maturity and a coupon of 5.00% per annum. The Conversion Price was fixed at CHF 86.4006, representing a premium of 20% over the volume weighted average price (**VWAP**) of the Santhera shares between the launch and pricing of the Convertible Bonds (**Reference Share Price**; CHF 71.9969). The Convertible Bonds were issued at 100% of their principal amount and, unless previously redeemed, converted or repurchased and cancelled, will mature on February 17, 2022, at 100% of their principal amount. Each bond (with a denomination of CHF 5,000) was initially convertible into 57.87 Shares. With an issue volume of CHF 60 million, this would have required a maximum of 694,440 Shares to be issued at conversion.

Santhera may call the Convertible Bonds at any time on or after the second anniversary of the issue date at par, plus accrued interest, if any, if the VWAP of the shares is at least 160% of the Conversion Price. Since the average VWAP of the Santhera Share was below the Reference Share Price on 20 trading days within one year from the launch of the Bond, the

Conversion Price was adjusted to CHF 64.80. Each bond is now convertible into 77.16 Shares. With an issue volume of CHF 60 million, this would require a maximum of 925,920 Shares to be issued at conversion. These shares would be issued from the Company's conditional capital.

On February 16, 2021, the Company announced its plans to restructure the Convertible Bonds. For additional information, please see <https://www.santhera.com/investors-and-media/investor-toolbox/share-bondholder-meetings> and <https://www.santhera.com/investors-and-media/investor-toolbox/bond-exchange-offering>.

Options, warrants

See the statutory financial statements of the Company and note 18 "Equity Rights Plans" to the consolidated financial statements.

Board of Directors (DCG 3)

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

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

	Year of birth	Nationality	First elected	BoD	AC	CC	SC
Elmar Schnee ¹	1959	CH	2017	●		○	
Martin Gertsch	1965	CH	2006	○	●		
Philipp Gutzwiller ¹	1968	CH	2017	○	○		
Thomas Meier ^{1, 2}	1962	DE	2017	○			●
Patrick Vink ^{1, 3}	1963	NL	2017	○		●	○

● = Chairman ○ = Member

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

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

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

Elmar Schnee

Elmar Schnee, born 1959, Swiss citizen, is Santhera's Chairman of the Board and Member of the Compensation Committee since 2017. He is both a non-executive and an independent Board Member. Elmar Schnee has a Master Degree in Marketing and General Management from SIB Zurich.

From 2011 to 2015, he served as CEO/Chairman of Cardiorientis AG, from 2005 to 2011, he was General Partner and member of the Executive Board of Merck KGaA. From 2003 to 2005 he was Executive Chairman of Merck Sante. From 1996 to 2003 he held various senior roles in marketing, licensing, strategy, business development and as managing director with UCB Pharma, Sanofi-Synthelabo, Migliara Kaplan and Fisons.

Currently, he serves as chairman of the boards of Moleac Pte Ltd (Singapore), Advanz Pharma (UK) and Calliditas Therapeutics AB (Sweden). He is a member of the boards of directors of Jazz Pharmaceuticals (Ireland) and several privately held life science companies.

Martin Gertsch

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

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

Currently, he serves as board member and chairman of the audit committee the University Center of Dentistry (Switzerland) and is chairman of the board of Artidis AG (Switzerland).

Philipp Gutzwiller

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

Since 2020, he is Digital Product Lead, Corporate and Institutional Clients, Lloyds Banking Group. From 2014 to 2019, he served as Managing Director, Head of Retail Corporate Coverage (2018-2019), Global Head Consumer & Healthcare (2018) and Global head Healthcare (2014-2018), Lloyds Bank/Banking Group. From 2011 to 2014, he was Managing Director, DC Advisory Partners, from 2008 to 2011 Managing Partner, CFS Advisors LLP, from 1999 to 2007 Managing Director, UBS Investment Bank and from 1994 to 1999 Corporate Finance Executive, Roche.

He has no other activities and vested interests.

Thomas Meier

Thomas Meier, born 1962, German citizen, is a Member of Santhera's Board and its Delegate since 2017. Since December 1, 2019, when he stepped down as CEO, he is no longer an executive Board Member; as per the Swiss Code of Best Practice for Corporate Governance, he is not considered an independent Member as a consequence of his former role as CEO. Thomas Meier completed his post-doctoral training at the University of Colorado Health Sciences Center (USA) and was Lecturer for Neurosciences at the Biozentrum, University of Basel. He has a PhD (Biology) from the University of Basel.

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.

He is chairman of the board of PharmaBiome AG and a board member of Novaremed Ltd., both privately held.

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.

Patrick Vink serves as chairman of the boards of F2G (United Kingdom), Targovax ASA (Norway), NMD Pharma (Denmark), as non-executive chairman of the board of Acacia Pharma Ltd. (USA; until April 7, 2020) and as member of the boards of directors of Spero Pharmaceuticals (United Kingdom) and Amryt Pharma plc (Ireland). He is also an advisor to Private Equity and Venture Capital Funds.

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

See note 27 “Related Party Transactions” to the consolidated financial statements.

Other activities and vested interests (DCG 3.2)

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

Permitted mandates in other companies (DCG 3.3)

See table in section on DCG 4.3.

Elections and terms of office (DCG 3.4)

According to the Company’s Articles, the Board consists of no more than eight members. All members of the Board, including the Chairman in his function as a chairman, are appointed or removed exclusively by a resolution of the shareholders. The Board members are elected on an individual basis for a term of office which must not exceed one year, whereby a year means the period between two AGMs. The terms of the Board members end at the 2021 AGM.

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

Allocation of tasks within the Board (DCG 3.5.1)

In accordance with the Organizational Rules of the Company, the Chairman convenes and presides over the Board meetings. After consultation with the CEO, the CFO and the GC, who also acts as the Secretary to the Board, he decides on agenda items and motions. The other Board members may request that items be placed on the agenda. In case of urgency, the Chairman may approve transactions and measures on behalf of the full Board. The Board also approves the Company’s news releases.

The Board committees (DCG 3.5.2)

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

The Audit Committee consists of two Board members, Martin Gertsch (Chairman) and Philipp Gutzwiller (member). Chairman and member of the AC 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 the Executive Management. The Board’s nontransferable and inalienable duties include the following:

- The ultimate management of the Company, by determining the strategy of the Company based on discussions with Executive Management, e.g. whether to evaluate, pursue or execute a financing, M&A or licensing transaction or a regulatory strategy before regulatory authorities such as the European Medicines Agency (**EMA**) and the US 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 (both bottom up and top down), variance analyses, regular latest estimates.
- 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 and the AGM, 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, HR, clinical operations, medical affairs).

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

Board

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

Audit Committee

The Audit Committee (**AC**) reviews, discusses with management and recommends for approval by the BoD the financial statements and the financial information contained in news releases that. It reviews and discusses with management significant financial reporting issues, significant changes to the accounting principles, the adequacy of the internal controls, any special audits, and the effect of regulatory and accounting initiatives. The AC can invite the Company's auditors, consultants and legal advisers to any of its meetings and discuss any AC related topic with such parties. The AC monitors the integrity of the financial statements of the Company, assesses the independent audit firm's and its representatives' qualifications, the performance of the Company's internal audit function and independent public accountants, and the compliance of the Company with legal and regulatory requirements.

The AC has the authority to suggest to the whole BoD the appointment or replacement of the auditors.

Compensation Committee

The tasks of the Compensation Committee are described in the Compensation Report under "Compensation Governance" (on page 91).

Scientific Committee

The charter of Scientific Committee (**SC**) has been approved by the Board on March 12, 2020. 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 (a.i.) / Head Medical Affairs, Head Business Development and Secretary to the Board participate in

such meetings. The SC reports its actions and recommendations to the Board at the meeting of the Board following each SC meeting. Its core tasks include to provide strategic advice to the Board regarding current and planned research and development programs and activities, to evaluate the effectiveness of the Company's R&D Operations and activities, to evaluate in-licensing or partnering opportunities and monitor compliance with the Company's standards of scientific integrity.

Meetings in 2020

Corporate Body	In person meetings	Tele- and Vide- conferences	Circular resolutions	Average duration in hrs
Board of Directors	2	23	2	Almost 2
Audit Committee	2	2	0	More than 2
Compensation Committee	0	6	1	Almost 1
Scientific Committee	1	0	0	Ca. 4¾

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

As a rule, all Executives participate in the Board meetings and report to the Board on the current course of business and all significant issues and transactions. Other members of senior management may be invited to attend to present and discuss certain agenda items covering their area of expertise, for example, to discuss results and progress of clinical studies and submissions to regulatory authorities. From time to time, the Board also invites the Company's auditors and tax or legal advisors to its meetings.

In the year under review, the Board discussed the Company's strategy, major projects and risks. The BoD resolved to in-license the rights to vamorolone. It put in place two equity-linked financings. After an interim analysis had shown the futility of the SIDEROS study, it decided to discontinue the development of Puldysa and to restructure the Company.

Among the key risks identified at the beginning of 2020 were the financial situation of the Company, the regulatory risk in the EU with respect to the marketing authorization application of idebenone for the treatment of patients with DMD, potential loss of key personnel, compliance (**GxP** compliance and compliance with respect to interactions with health care professionals and qualification and validation of computerized systems) and an out of stock risk, also in connection with Brexit. For all these risks, mitigation strategies had been put in place.

On a monthly basis, the Board received the Management Report from Management. Such report contains - inter alia - monthly income statement, balance sheet, overview of cash flows and liquid funds, including sales figures, operating expenses, net operating cash flow, COGS, gross profit, EBIT and EBT, headcount and FTE numbers.

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

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

Executive Management (DCG 4 and 3.6)

The Executive Management consisted of five Executives.

Executive	Function	Nationality	Year of Birth
Dario Eklund	CEO	AT/FI	1968
Günther Metz	Head Business Development, EVP	DE	1958
Kristina Sjöblom Nygren¹	Chief Medical Officer & Head Development, EVP	SE	1961
Andrew Smith²	CFO	GB	1962
Oliver Strub	Group General Counsel & Secretary to the Board, EVP	CH	1963

¹ On garden leave since January 1, 2021. The effective date of termination is April 30, 2021.

² Since April 1, 2020.

Members of the Executive Management are appointed by the Board upon proposal by the CEO with the exception of the CEO himself who is appointed upon proposal by the Chairman of the Board.

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

The CEO, together with Executive Management, is responsible for implementation of the strategy and the decisions taken by the Board and its Committees within the approved budget. With the support of the management team - consisting of the members of Executive Management, the Chief of Staff, the Head Region Western Europe, the Head Technical Development & Operations and the Interim Head Santhera US & Global Launch Lead Vamorolone - he prepares the business strategy and business plan for decision by the Board. The CEO approves material contracts, decides on the Company's intellectual property rights and the handling of lawsuits. He also allocates financial, personnel and other resources within Santhera and supervises the members of the management team. The management team has regular meetings that usually cover the following topics: product revenues, alliance management, development programs and clinical studies, regulatory strategies, resource allocation, business development, competitive situation, risk management and internal control system, corporate affairs including important contracts, supply chain and information on subsidiaries, financing situation and strategies, internal and external financial reporting, financial controlling, public and investor relations, human resources, taxes, legal and compliance.

Dario Eklund

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

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

He has no other activities and vested interests.

Günther Metz

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

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

He has no other activities and vested interests.

Kristina Sjöblom Nygren

Kristina Sjöblom Nygren, born 1961, Swedish citizen, joined Santhera as Chief Medical Officer (CMO) and Head of Development and member of Santhera's Executive Management effective January 1, 2017.

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

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

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

Andrew Smith

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

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

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

He has no other activities and vested interests.

Oliver Strub

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

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

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

He has no other activities and vested interests.

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 beginning on page 91 of this Annual Report.

Shareholders' Participation (DCG 6)

Voting rights restrictions and representation (DCG 6.1)

There are no voting rights restrictions, no statutory group clauses and hence no rules on making exceptions. As a consequence, there is neither a procedure nor a condition for their cancellation.

A shareholder may be represented by his legal representative, the independent proxy or by another shareholder. Shareholders can instruct the independent proxy by completing an instruction form. There are no provisions in the Company's Articles of Incorporation that differ from statutory provisions where the participation of shareholders in the AGM is concerned (DCG 6.1.5).

Statutory quora (DCG 6.2)

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

Convocation of the Shareholders' Meeting (DCG 6.3)

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

Agenda rules (DCG 6.4)

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

Registrations in the share register (DCG 6.5)

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

Changes of Control and Defense Measures (DCG 7)**Duty to make an offer (DCG 7.1)**

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

Clauses on changes of control (DCG 7.2)

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

Other than that, as of December 31, 2020, agreements and plans from which members of the Board and/or the Executive Management or other members of senior management benefit or may benefit contain no clauses on changes of control.

Auditors (DCG 8)**Duration of the mandate and term of office of the lead auditor (DCG 8.1)**

Ernst & Young, Basel, assumed the existing auditing engagement for Santhera's predecessor company MyoContract in 2002 (DCG 8.1.1). The Shareholders' Meeting elects the Company's auditors for a term of office of one year. The auditor in charge is Frederik Schmachtenberg. He assumed his responsibility in 2017 (DCG 8.1.2).

Auditing fees and additional fees (DCG 8.2/8.3)

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

	In CHF thousands	2020	2019
Audit services		416	413
Audit-related services		108	33

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

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

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

Information Policy (DCG 9)

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

The most important information tools are news releases, the AGMs, the Annual Report, the Interim Reports and the website www.santhera.com.

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

Corporate events 2021

The 2021 Annual General Meeting will be held on June 22, 2021 where potentially personal attendance will be impossible. See also www.santhera.com/investors-and-media/corporate-calendar.

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About Santhera

Santhera Pharmaceuticals (SIX: SANN) is a Swiss specialty pharmaceutical company focused on the development and commercialization of innovative medicines for rare neuromuscular and pulmonary diseases with high unmet medical need. Santhera has an exclusive license for all indications worldwide to vamorolone, a first-in-class dissociative steroid with novel mode of action, currently investigated in a pivotal study in patients with Duchenne muscular dystrophy (DMD) as an alternative to standard corticosteroids. The clinical stage pipeline also includes lonodelestat (POL6014) to treat cystic fibrosis (CF) and other neutrophilic pulmonary diseases as well as an exploratory gene therapy approach targeting congenital muscular dystrophies. Santhera out-licensed ex-North American rights to its first approved product, Raxone® (idebenone), 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.

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Their Future. Our Focus.

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