santhera

THEIR FUTURE – OUR FOCUS

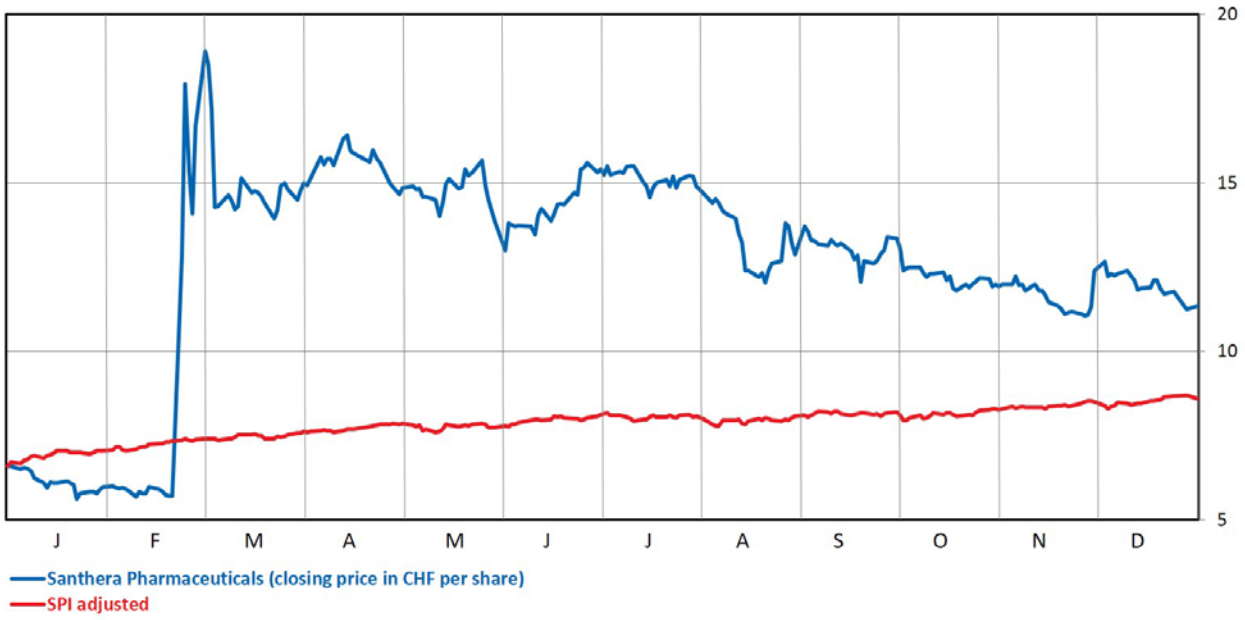
Annual Report 2019

Financial Key Figures

IFRS consolidated, in CHF thousands	**2019**	2018
Revenue from contracts with customers	**75,376**	31,657
Operating expenses	**-80,652**	-78,687
Operating result	**-10,442**	-51,420
Net result	**-18,973**	-54,186
Basic and diluted net result per share (in CHF)	**-1.73**	-7.86
Freely available liquid funds at December 31 *	**31,358**	21,971
Net change in cash and cash equivalents	**9,387**	-23,224

* Cash and cash equivalents

Share Price Development in 2019



High	CHF 18.90 (March 4, 2019)
Low	CHF 5.63 (January 24, 2019)
Share price performance in 2019	+68.2%
Share price at year-end	CHF 11.34
Market capitalization at year-end	CHF 127 million
Average trading volume	43,332 shares/day

(based on closing share prices)

Contents

Letter to Our Shareholders

Dear Shareholders,

Santhera is emerging as a leader in addressing rare neuromuscular diseases and 2019 saw us prepare the business for several significant value inflection points in 2020 for our drug candidates to Duchenne muscular dystrophy (DMD).

A priority for Santhera during the period – and going forward – was to focus on business areas core to our long-term growth strategy, primarily advancing our clinical-stage neuromuscular programs. We have an attractive pipeline with potential for further diversification owing to platform-type molecules in our repertoire. In this context, the licensing agreement with Chiesi Group for rights to Raxone in LHON and other ophthalmological indications creates significant value for shareholders as it has allowed us to re-channel financial resources towards delivering innovation to patients with our neuromuscular pipeline products targeting areas of significant unmet medical need.

Our regulatory dossier for Puldysa (idebenone) is under evaluation by the European Medicines Agency (**EMA**) where we are seeking a conditional marketing authorization (**CMA**) for the treatment of respiratory dysfunction in patients with DMD who are not using glucocorticoids. The review is on track and we are confident to receive an opinion from the European regulators in mid-2020. Our ambition is to be the first approved drug in non-ambulant DMD patients who are in respiratory decline and we are planning for launch in the first European markets by the end of the year. We are nearly launch-ready with an experienced commercial team, an established and proven infrastructure and a launch plan in place. In parallel, we are moving towards completion of enrollment into the SIDEROS trial, the largest ever conducted DMD trial in patients taking glucocorticoids, to support planned follow-on regulatory submissions, particularly in the US.

Our second Duchenne product is vamorolone, a new class of molecule to which we have an option to a sublicense for all indications and all territories worldwide (except Japan and South Korea). The compound is currently being investigated by the originator company ReveraGen in a pivotal study (**VISION-DMD**) in patients with DMD, where our ambition is to replace glucocorticoids as standard of care in still ambulant patients. We expect read-out of topline data from this trial in the fourth quarter 2020, followed by filing of a US new drug application (**NDA**) in the first quarter of 2021. Positive data will also pave the way for Santhera's option exercise.

With Puldysa and vamorolone together, Santhera is building a DMD product portfolio to treat virtually all DMD patients irrespective of causative mutations or disease stage.

Securing financing to complete Santhera's development and commercialization objectives in the longer term is a priority also for the current year. We are evaluating a number of different options of financing and are confident in our ability to successfully conclude these negotiations, despite current adverse market circumstances due to the global spread of COVID-19.

New senior staff strengthening our leadership team

New leadership was put in place with a strong commercial emphasis and we were pleased to welcome Dario Eklund as CEO of Santhera as of December 1, 2019, and Andrew Smith as CFO, effective April 1, 2020. Their broad expertise and profound knowledge will complement our strong team at Santhera towards becoming a leading rare disease company.

On behalf of all employees and Board members of Santhera, we wish to express our sincere gratitude to Thomas Meier, founder and CEO of Santhera until end of November 2019. Over many years he has dedicated his vision, strength, know-how and leadership towards growing Santhera into a neuromuscular rare disease company. We are most grateful that he will continue to contribute his unsurpassed neuromuscular scientific know-how and chair the newly to be formed Scientific Committee of the Board.

Outlook – Neuromuscular franchise a top priority for 2020

Our strategic priority for 2020 is our neuromuscular franchise: Puldysa and vamorolone in DMD and achievement of the respective development and regulatory milestones. In parallel, we are advancing our early-stage clinical products such as POL6014 for cystic fibrosis and are evaluating further diversification of our platform type pipeline products, including development of additional indications in collaboration with partners.

We again thank all of our employees for their dedication and commitment to Santhera in 2019 and the start of 2020. Our thanks also go to our stakeholders including our scientific and clinical partners and advisors for their continued support, our shareholders for their steadfast confidence in Santhera's ambition and, importantly, the patients, their carers and patient groups who are involved in the clinical development of our products.

Sincerely,

Elmar Schnee
Chairman

Dario Eklund
Chief Executive Officer

FINANCIAL HIGHLIGHTS

Santhera's Operations on Track

Santhera achieved robust revenue growth in 2019 from sales of Raxone® which was out-licensed to Chiesi Group from August 2019. Upon closing of the transaction, Santhera received an upfront payment of CHF 49.3 million. Liquid funds (cash and cash equivalents) at year-end amounted to CHF 31.4 million. Santhera is currently evaluating a number of different options to secure additional financing of the Company.

2019 full-year net revenues slightly above guidance

In 2019, Santhera reported net revenues from product sales of CHF 27.9 million (2018: CHF 31.7 million), slightly surpassing the Company's full-year guidance. This includes sales of Raxone for the treatment of Leber's hereditary optic neuropathy (LHON) in Europe in the first seven months of 2019 and in France for the full year.

Full-year sales exceeding guidance

Upfront payment from Chiesi Group following closing of licensing agreement

In August 2019, Santhera received an upfront payment of CHF 49.3 million (EUR 44 million) in connection with entering into the licensing agreement with Chiesi Group. The majority of this payment (CHF 46.4 million) was recognized as revenue in 2019 and the remainder will be accounted for in line with the completion of some related obligations. As previously announced per the agreement, Chiesi Group has in-licensed Raxone for LHON and all other ophthalmologic indications for all territories worldwide except the US and Canada for a total consideration of up to EUR 93 million.

Operating and net result significantly improved

With CHF 80.7 million, total operating expenses slightly surpassed the previous year's level (2018: CHF 78.7 million). The increase in development expenses to CHF 41.2 million (2018: CHF 38.2 million) reflects expenses for ongoing late stage clinical studies such as the Phase 3 SIDEROS trial in DMD, efforts associated with the pending marketing authorization application for Puldysa for DMD in Europe, ongoing post-authorization studies for LHON, as well as clinical work with Santhera's early stage development compound POL6014 for cystic fibrosis. Cost savings were achieved for marketing and sales, which amounted to CHF 20.1 million (2018: CHF 24.9 million), as commercial activities were aligned with market entry for Puldysa expected towards end of 2020. General and administrative expenses increased to CHF 19.2 million (2018: CHF 15.4 million) due to one-time expenses related to the transaction with Chiesi Group. Largely owing to the first installment from Chiesi Group in the context of the licensing agreement, the Company reported a markedly improved operating result of CHF -10.4 million (2018: CHF -51.4 million). For the full-year 2019, Santhera reported a net result of CHF -19.0 million (2018: CHF -54.2 million).

Increased expenses to fund late-stage pipeline projects

FINANCIAL HIGHLIGHTS

Growth plans necessitate additional funds

As of December 31, 2019, freely available liquid funds (cash and cash equivalents) amounted to CHF 31.4 million (August 31, 2019: CHF 43.7 million). In addition, the Company held CHF 1.5 million of restricted cash designated for the interest payments related to the convertible bonds issued in 2017.

Ongoing development activities, ramping up of the commercialization activities relating to Puldysa® and the intention to exercise the option to obtain an exclusive sub-license from Idorsia to commercialize ReveraGen's vamorolone will require substantial additional funding, particularly in the latter part of 2020. Material uncertainties thus remain as to the Company's ability to continue as a going concern until December 31, 2020. Executing the Company's strategy depends on further funding to ensure the continuation of its operations through December 31, 2020.

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.

At the forthcoming Annual General Meeting on April 22, 2020, the Board will propose the increase of authorized capital from CHF 3,000,000 to CHF 5,500,000 and an increase of conditional capital from CHF 2,500,000 to CHF 4,800,000.

Subject to approval by the Company's shareholders, this would enable Santhera to raise new capital later in 2020 to support the achievement of regulatory and commercial milestones for Puldysa and vamorolone, to exercise the license option for vamorolone and to further strengthen its resources, especially in view of important product launches planned for 2020/2021. Furthermore, the Company is currently evaluating a restructuring of the CHF 60 million Senior Unsecured Convertible Bonds due in February 2022 including a significant reduction of the conversion price which would increase the likelihood of conversion into shares rather than repayment.

OUR RARE DISEASE FOCUS

Our Pipeline

Passionate about providing treatment options for rare **neuromuscular** and **pulmonary** diseases with high unmet medical need.

INDICATION	MOLECULE	DEVELOPMENT STAGE (Preclin. / Ph 1 / Ph 2 / Pivotal / Filing / Market)	MILESTONE	REMARKS
DUCHENNE MUSCULAR DYSTROPHY	Idebenone[1](oral)	DELOS (GC non-users)	Q2-20: CHMP Opinion	Adressing unmet medical need due to respiratory decline in DMD
		SIDEROS (GC users)	Q2-20: Full enrolment	
	Vamorolone[2] (oral)	VISION DMD — ReveraGen	Q4-20: Top line data	ReveraGen, Idorsia Partnership
CYSTIC FIBROSIS	POL6014 (inhaled)		Q2-20: Completion Ph1b	Licensed from Polyphor
CONGENITAL MUSCULAR DYSTROPHY	Omigapil (oral)		Phase 1a completed	Licensed from Novartis
	Gene therapy		Animal PoC ongoing	Collab. Univ. Basel Innosuisse Grant
Various inflammatory diseases e.g. IBD	Vamorolone		Preclinical biomarker studies published	Rationale for multiple diseases
Diseases associated with high hNE activity	POL6014		Under evaluation	Rationale for multiple diseases

(1) Development program for idebenone in glucocorticoid (GC) non-users and separately in GC users;
(2) Vamorolone option rights to a sub-license from Idorsia/ReveraGen
MAA: Marketing Authorization Application; IBD: Inflammatory Bowel Disease; hNE: human Neutrophil Elastase;
PoC: Proof of concept

At the heart of the late stage portfolio and nearing market readiness are two drug candidates, Puldysa® (idebenone) and vamorolone, which are being developed as treatments for Duchenne muscular dystrophy (**DMD**). A marketing authorization application for Puldysa is currently under review by the European Medicines Agency (**EMA**) and an opinion by the EMA's Committee for Medicinal Products Human Use (**CHMP**) is expected in mid-2020. Santhera has an option to license vamorolone, a first-in-class anti-inflammatory drug candidate with novel mode of action, currently being studied in a pivotal Phase 2 study in patients with DMD to replace standard corticosteroids. With these two investigational medicines, Santhera aims at building a DMD portfolio to treat patients across all stages of the disease and irrespective of the underlying causative mutation.

Anticipated near-term inflection points towards approval for both DMD pipeline candidates Puldysa (idebenone) and vamorolone are:

- mid-2020: CHMP opinion on marketing authorization application for Puldysa in DMD in Europe
- Q4-2020: Launch of Puldysa in first European markets
- Q4-2020: Read-out of topline data of pivotal trial for vamorolone in DMD
- Q1-2021: Filing a New Drug Application for vamorolone in DMD in the US

The early clinical stage pipeline includes POL6014, an innovative new investigational drug to treat cystic fibrosis (**CF**) and other neutrophilic pulmonary diseases as well as omigapil, and an exploratory gene therapy approach targeting congenital muscular dystrophies (**CMD**).

Both vamorolone and POL6014 represent platform type pipeline molecules with potential for development of additional indications in collaboration with partners.

DUCHENNE MUSCULAR DYSTROPHY PIPELINE

DMD – the Disease and our Therapeutic Approach

Duchenne muscular dystrophy (DMD) is a genetic disease characterized by a loss of the protein dystrophin, which is essential for healthy muscle function. It is one of the most common and devastating types of progressive muscle weakness and degeneration starting at an early age. Untreated DMD leads to early morbidity and mortality with respiratory complications as a foremost cause of death.

DMD occurs almost exclusively in males with an incidence of up to 1 in 3,500 live male births worldwide. Based on population figures, Santhera estimates the number of DMD patients in the U.S. to be approximately 14,000 and in the EU and the UK combined approximately 20,000.

Irreversible disease progression in DMD: initial loss of mobility results in loss of ambulation; progressive respiratory failure requires need for assisted ventilation irreversible.

The average age of symptoms onset is between 3 and 5 years. Patients experience progressive muscle weakness which leads to the irreversible loss of ambulation typically in the teenage years. The prime therapeutic goal in ambulant boys with DMD is the **preservation of motor function and delaying time to wheelchair dependence**. Currently, glucocorticoids (a form of corticosteroids) are the standard of care for DMD patients. They are prescribed to delay the decline in muscle strength and function, irrespective of the underlying genetic mutation. However, the effect is only partial and clinical use is significantly limited by well-known side effects from prolonged glucocorticoid usage. A recent study showed that up to 42% of DMD patients aged 10 years and older had either never used steroids or have discontinued their use, usually as they lose the ability to walk.

As the disease progresses, the muscles affected include those needed for breathing (respiration). Progressive respiratory muscle weakness leads to a restrictive respiratory disease pattern, resulting in an ineffective cough, recurrent pulmonary infections and increased risk of acute hospitalization, respiratory insufficiency and ultimately the need for assisted mechanical ventilation in all patients. As the loss of respiratory function progresses to respiratory insufficiency, mechanical ventilation becomes necessary to prolong life beyond the late teenage years into the second or third decade. Therefore, a prime therapeutic goal in non-ambulant teenagers/young adults is the **preservation of respiratory function to delay the need for assisted ventilation**. At present, besides supportive care, there are no approved medicines to treat the loss of respiratory function.

There is a clear unmet medical need and new treatments in DMD are urgently awaited as patients progress through irreversible disease milestones with limited treatment options.

Our pipeline in DMD

With Puldysa (idebenone) and vamorolone, Santhera is **uniquely positioned** to address the medical needs of DMD patients across all disease stages and independent of the specific genetic background of the disease. The DMD portfolio with Puldysa and vamorolone positions Santhera as a leading company in the DMD space.

DUCHENNE MUSCULAR DYSTROPHY PIPELINE

Puldysa® (idebenone) Highlights

With its most advanced product candidate, Puldysa®, Santhera has the ambition to obtain the first marketing authorization for treatment of respiratory dysfunction in DMD patients at a more advanced disease stage, typically teenage boys and young adults, most of whom are non-ambulant. The therapeutic goal with Puldysa is to preserve respiratory function and to delay the time when patients will require mechanical ventilation.

The lack of dystrophin in DMD also results in dysfunction of the mitochondria, the powerhouse of the muscle cell. When mitochondria do not produce enough energy, the muscle cells within the organ do not function properly, become damaged and eventually die leading to inflammation and degeneration of muscle tissue. Idebenone helps to overcome the underlying cause of mitochondrial dysfunction, restore cellular energy production and protects the cell from damage caused oxidative stress, thereby preserving muscle function for longer.

In a pivotal Phase 3 study (DELOS) in patients not taking steroids, idebenone was shown to **slow the loss of respiratory function and reduce bronchopulmonary complications** such as recurrent pulmonary infections. A second Phase 3 study (SIDEROS) is currently ongoing to assess the efficacy of idebenone to slow the loss of respiratory function in patients taking glucocorticoids.

Achievements

- In January 2019, Santhera announced SYROS study results demonstrating that long-term treatment with Puldysa consistently reduced the rate of respiratory function loss in patients with DMD for **up to 6 years in a real-world setting**. This long-term data further supports the potential for Puldysa to modify the course of respiratory function decline and delay the time to clinically relevant milestones.
- In May 2019, Santhera submitted an application for **Conditional Marketing Authorization (CMA) for Puldysa®** to the European Medicines Agency (EMA). The indication for Puldysa sought under CMA is the treatment of respiratory dysfunction in patients with DMD who are not using glucocorticoids. The review by the EMA's Committee for Medicinal Products for Human Use (CHMP) is ongoing and an opinion is expected by mid-2020.
- In June 2019, the UK's Medicines and Healthcare products Regulatory Agency (MHRA) renewed the Early Access to Medicines Scheme (EAMS) scientific opinion for Puldysa for patients with DMD in respiratory function decline who are not taking glucocorticoids for a further year. Under EAMS, patients can obtain access to medicines that do not yet have a marketing authorization when there is a clear unmet medical need.

Near-term targets

- Ambition to obtain the **first marketing authorization of a medicine** for the treatment of respiratory dysfunction in DMD patients at a more advanced disease stage.
- Advance the ongoing double-blind, placebo-controlled Phase 3 clinical trial for patients with DMD who are receiving steroids (SIDEROS) with completion envisaged by the fourth quarter 2021. Successful trial completion would pave the way for an **NDA-filing in the USA** and a label extension in Europe.

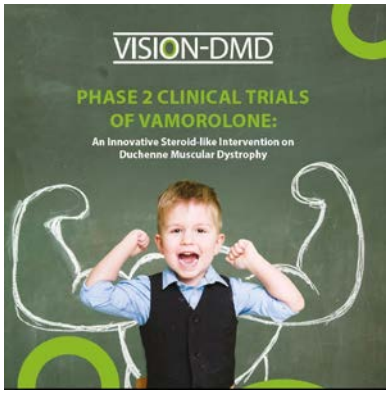
DUCHENNE MUSCULAR DYSTROPHY PIPELINE

Vamorolone Highlights

Santhera has acquired an option to obtain an exclusive sub-license from Idorsia to ReveraGen's vamorolone for all indications and in all territories, except Japan and South Korea. ReveraGen, inventor and developer of vamorolone, is currently conducting the ongoing pivotal Phase 2b VISION-DMD trial which, if successful, will form a basis for a first submission of a New Drug Application (NDA) in the USA.

Glucocorticoids are effective anti-inflammatory agents and current standard of care in DMD. However, their long-term 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 often limit their use and reduce patients' quality of life considerably. Vamorolone, a first-in-class multi-functional anti-inflammatory drug candidate with novel pharmacological properties, has shown in pre-clinical and clinical studies to possess potent anti-inflammatory properties with potentially less undesirable side effects than glucocorticoid drugs.

Achievements



- Building on the promising preliminary clinical data from Phase 1 and 2a studies, ReveraGen is currently conducting the Phase 2b VISION-DMD study (VBP15-004; clinicaltrials.gov: NCT03439670) in 120 boys who have not yet been treated with corticosteroids. 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. ReveraGen is conducting VISION-DMD as a pivotal clinical trial at approximately 30 sites across North America, Europe, Israel and Australia[1].
- 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, in October 2019, the MHRA has designated vamorolone in DMD as a Promising Innovative Medicine, a status similar to a breakthrough therapy designation by the FDA.

Near-term targets

- Top-line data from VISION-DMD study after six months of treatment to become available in the fourth quarter of 2020.
- Subject to favorable VISION-DMD study data and the FDA supporting a US-filing, option exercise to obtain an exclusive sub-license from Idorsia to vamorolone.

[1] Additional information at https://vision-dmd.info/2b-trial-information and www.reveragen.com.

DUCHENNE MUSCULAR DYSTROPHY PIPELINE

Giving Patients a Voice

Living with DMD – ANTHONY

Anthony showed signs of the disease as young as three years old. “Early on it was really hard for me to accept it,” remembers Anthony. As his physical limitations became more obvious to peers, Anthony began honing his ability to overcome the psychological burdens placed on a young man in his position. “My mom came to school and taught the kids about Duchenne,” he remembers. Anthony too, began to speak up about the challenges he and other boys with Duchenne faced—the early premonitions of a patient advocate in-the-making. “I came in and talked to my class and showed them a video about Duchenne. What I like about that is that it shows people that it’s not something to be afraid of just because they didn’t know what it is.” High school was a challenging time for socializing, as Anthony’s disabilities became more obvious to his peers. “At some point I decided to start talking about it. One of my English classes invited me in to speak and then I spoke to every English class at the school.

“Be grateful for what you have. I’m definitely grateful for everything I have. There are a lot of things I can’t do, but there are so many things that I can.” — Anthony

So, I did about 20-30 talks. It really opened people’s eyes, and it allowed me to open up too, because people understood me better.” After graduating from Rutgers in 2015, Anthony found it difficult to transition into the professional world, despite his impressively high marks in school. “The two years after college were a tough time for me,” wrote Anthony on his Facebook page. “I wanted so badly to start my career and be a beneficial member of society.” It seemed that no employer would look beyond his obvious physical limitations—Anthony uses a power wheelchair and a breathing machine—both results of his Duchenne muscular dystrophy (DMD). The neurodegenerative disease took away much of Anthony’s physical abilities, but he refused to let it become a roadblock to sharing his intellect. Anthony started his own web-design company as a high school freshman and later studied Communications in college, graduating Summa Cum Laude.

Despite his skills, Anthony still had to battle the stigma of being “disabled” in a professional sphere designed for the “ablebodied”. “No one seemed to be willing to look past my disability and provide me the opportunity to prove myself.” One day a friend recommended that Anthony try to work in the field of pharmaceuticals—specifically companies that developed treatments for rare diseases.

Since Anthony was young, he had been interacting with members of the Duchenne community as well as the larger rare disease community, drug developers, and members of Congress. His friend thought that perhaps a company that prides itself on curing rare disease would be ready to see Anthony’s experience as a valuable asset, not a hindrance. “I’ve always been big on patient advocacy,” says Anthony.

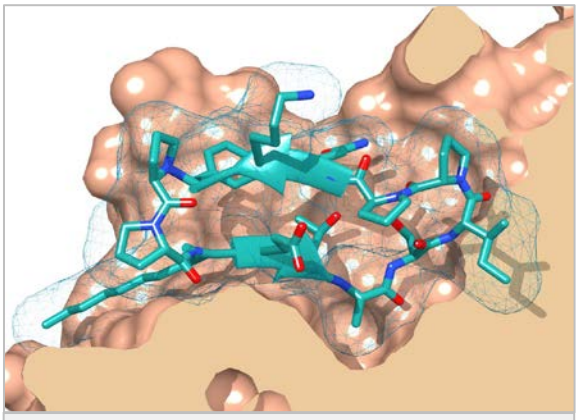
Extract from “LIMITLESS - Stories of Defiance, Opportunity, and Ability”. Created by Living in the Light in partnership with Santhera. Read the full article at www.santhera.com/patients/patient-stories

EARLY-STAGE PIPELINE

POL6014 in Cystic Fibrosis

POL6014, a selective inhibitor of an enzyme called human neutrophil elastase (hNE), is believed to have potential to treat cystic fibrosis (CF) and other lung diseases associated with increased neutrophil elastase activity such as non-cystic fibrosis bronchiectasis, alpha-1 antitrypsin deficiency, and primary ciliary dyskinesia.

CF is a rare, life-threatening, progressive genetic disease affecting primarily the lung but also the digestive system. The symptoms in the lung are characterized by build-up of mucus obstructing the airways and leading to persistent infection and chronic inflammation, thereby limiting the ability to breathe over time. CF is typically diagnosed in young children mostly within the first year of age. High levels of hNE play a central role in the deterioration of lung function associated with CF. Pre-clinical research suggests that POL6014, a cyclic peptide, is a highly potent and selective inhibitor of hNE and may thereby stop or slow damage to lung tissue, help preserve lung function and may help improve the overall quality of life for individuals with CF.



POL6014 in complex with human neutrophil elastase shows binding of POL6014, occupying a large part of the enzyme pocket

Santhera estimates that approximately 80,000 patients worldwide have CF at any point in time and believes that POL6014 has the potential to be applied in all CF patients, as it is not mutation-specific.

Achievements

- Currently, a Phase 1b/2a multiple ascending dose (**MAD**, ClinicalTrials.gov Identifier: NCT03748199) trial with POL6014 in patients with CF is ongoing with results expected to be available in the second half of 2020. The study is designed to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of orally inhaled multiple doses of POL6014 in up to 40 patients with CF.
- Improved, cost-efficient peptide manufacturing process suitable for large-scale production.

Near-term targets

- Subject to a positive outcome of the MAD-trial, prepare for Phase 2 efficacy trial of POL6014 in CF in 2020.
- Establish potential for partnering for additional indications of this platform-type compound.

EARLY-STAGE PIPELINE

Our Approach to CMD

Santhera has been evaluating a two-fold approach to treating congenital muscular dystrophies (CMD) with omigapil and a novel gene therapy approach in collaboration with the Biozentrum, University of Basel.

CMD is a group of inherited neuromuscular conditions that causes progressive and potentially life-threatening loss of muscle tissue, affecting frequently newborns and children. Approximately 50% of all CDM cases present with one of two subtypes of CMD, called COL6-MD or LAMA2-MD[2]. Children born with CMD often have muscle weakness or "floppiness" and can also have stiffness of the joints, hip dislocation and a type of curvature of the spine (known as kyphoscoliosis). The progressive loss of muscle tissue leads to loss of ambulation at young age and early mortality. Currently, no medicinal product is approved for CMD and therapy is confined to a treatment of symptoms.

Potential gene therapy for LAMA2-MD

In May 2019, Santhera has entered in a collaboration with the group of Prof. Markus Rüegg from the Biozentrum, University of Basel, who pioneered a novel gene therapy approach for the treatment of LAMA2-MD. The preclinical research conducted suggests that the simultaneous transgenic expression of specifically designed small protein domains, so-called linker proteins, may help overcome the structural and functional loss of muscle fibers. The researchers expect that these linker proteins, if expressed simultaneously, could ameliorate muscle membrane stability by compensating the deficient functionality of LAMA2-MD. In animal models for LAMA2-MD this approach has led to restoration of muscle fiber basement membranes, recovery of muscle force and size, increased overall body weight and markedly prolonged survival.

BIOZENTRUM
Universität Basel
The Center for
Molecular Life Sciences

The preclinical research collaboration between Santhera and the University of Basel will explore the feasibility of gene delivery by standard viral vectors as a basis for subsequent clinical work. The program is supported by public funding for innovation in Switzerland through a grant from Innosuisse - the Suisse Innovation Agency.

Omigapil in CMD

Omigapil is a so-called deprenyl analogue that has been shown to prevent cell death pathways (apoptosis). In preclinical research, omigapil has been shown to prevent apoptosis and loss of muscle tissue and increased body weight and survival of a disease-relevant animal model organism for CMD.

The CALLISTO Phase 1 trial (ClinicalTrials.gov identifier NCT01805024) established a favorable pharmacokinetic profile of a liquid formulation of omigapil and demonstrated that the drug was safe and well tolerated in the 20 patients that participated in the study. However, in 2019, opinions sought from scientific experts led to the conclusion that additional non-clinical work would be needed before a pivotal clinical trial could be conducted in CMD patients. With the start of investigating the possibility of gene therapy for CMD, the further clinical development of omigapil in CMD has been down-prioritized for the time being.

[2] LAMA2-MD: laminin alpha 2 muscular dystrophy. Col6-MD: Collagen 6 muscular dystrophy.

EARLY-STAGE PIPELINE

Giving Patients a Voice

Living with CMD – OLIVIA

"Come on! Let's play," exclaims Olivia, her enthused, high-pitched voice trailing behind as she races down the road in her hot-pink power wheelchair. At age six, she's got the energy of a hummingbird, and her rare condition of congenital muscular dystrophy (CMD) does not stop her from going where she wants, at top speed. Olivia lives with LAMA2-MD, a type of muscular dystrophy related to a specific mutation in the laminin protein. The condition takes two forms: either a severe, early-onset form or a milder form that appears later in life. Olivia's condition was early-onset, though when she was born, her health appeared to be fine.

Although Olivia's diagnosis came early, at times it was deceiving, as she showed to be advanced in many ways. Not only was she a very early talker and excellent communicator, but around age two, she taught herself how to read. "Her reading was wild," remembers Olivia's mother Sara. "She literally learned to read, self-taught, out of the blue. She memorized words immediately."

Olivia's parents, Matt and Sara keep up with the hurdles of learning how to best care for their daughter. "We need her to be here, and we need her to be healthy. And healthy doesn't mean you have to walk." They are focusing now on her spine and breathing support, to keep her lungs strong. "She's currently very healthy, in good weight. We want her to maintain independent eating and breathing," says Sara.

"We talk about resilience—Olivia is the epitome of it. She's the most resilient kid, and human I've ever been around." – Matt (father)

Olivia picks out another color from her set of fifty markers. "Will you pass me eggplant purple please?" she asks. She knows the full name of every color, and rotates between ten as she fills in the gemstones on a paper tiara. When asked to pose for a picture, she obliges, but only for a moment. "But I'm coloring! Can I go back to my very important coloring now?" On the one hand, Olivia is focused on typical six-year old stuff—making art, playing with friends, and playing games. But she also does the extraordinary—she speaks out about her condition and advocates for herself. "We talk about resilience. Olivia is the epitome of it," says Matt. "She's the most resilient kid, and human, I've ever been around."

Extract from "LIMITLESS - Stories of Defiance, Opportunity, and Ability". Created by Living in the Light in partnership with Santhera. Read the full article at www.santhera.com/patients/patient-stories

THIS IS US

Our Vision, Our Promise, Our Values

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

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

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

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

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

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

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

THIS IS US

Meet the Team

Santhera is led by an experienced team[3] 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


Kristina Sjöblom Nygren, CMO & Head Development


Oliver Strub, Group General Counsel

[3] 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	2019	2018
Assets			
Tangible assets	5	5,604	2,269
Intangible assets	6	58,479	61,467
Financial assets long-term		664	690
Restricted cash long-term	11	0	1,500
Deferred tax assets	14	1,049	1,285
Noncurrent assets		**65,796**	**67,211**
Prepaid expenses		637	969
Inventories	8	6,859	9,282
Trade and other receivables	9	8,901	7,861
Restricted cash short-term	10	1,500	3,000
Cash and cash equivalents	10	31,358	21,971
Current assets		**49,255**	**43,083**
Total assets		**115,051**	**110,294**
Equity and liabilities			
Share capital	11	11,165	10,665
Capital reserves and share premium		448,084	435,795
Retained earnings		-433,240	-414,267
Employee benefit reserve		-3,160	-2,675
Treasury shares	11	-745	-904
Translation differences		-857	-785
Total equity		**21,247**	**27,829**
Convertible bonds	12	56,154	54,569
Derivative financial instruments	12	617	204
Noncurrent contract liabilities	19	1,126	0
Noncurrent lease liabilities	12	2,827	0
Pension liabilities	21	9,116	7,983
Total noncurrent liabilities		**69,840**	**62,756**
Trade and other payables	14	9,532	8,306
Accrued expenses	15	11,427	11,041
Income tax payable		395	362
Current contract liabilities	19	1,597	0
Current lease liabilities	12	1,013	0
Total current liabilities		**23,964**	**19,709**
Total liabilities		**93,804**	**82,465**
Total equity and liabilities		**115,051**	**110,294**

Consolidated Income Statement

For the year ended December 31, in CHF thousands	Notes	**2019**	2018
Net sales	18	27,890	31,657
Revenue from out-licensing transactions	19	46,370	0
Net sales to licensing partner	19	1,116	0
Revenue from contracts with customers		**75,376**	**31,657**
Cost of goods sold		-5,450	-4,702
Of which amortization intangible assets		*-3,039*	*-3,039*
Other operating income		284	312
Development	20	-41,244	-38,240
Marketing and sales	20	-20,096	-24,884
General and administrative	20	-19,184	-15,365
Other operating expenses	20	-128	-198
Operating expenses	**20**	**-80,652**	**-78,687**
Operating result		**-10,442**	**-51,420**
Financial income	22	1,656	4,371
Financial expenses	22	-9,608	-6,815
Result before taxes		**-18,394**	**-53,864**
Income taxes	23	-579	-322
Net result		**-18,973**	**-54,186**
Basic and diluted earnings/loss per share (in CHF)	24	-1.73	-7.86

Consolidated Statement of Comprehensive Income

For the year ended December 31, in CHF thousands	Notes	**2019**	2018
Net result		**-18,973**	**-54,186**
Items never to be reclassified to net income in subsequent periods:			
Actuarial gains/losses on defined benefit plans	21	-485	2,230
Items to be reclassified to net income in subsequent periods:			
Currency translation differences		-72	-71
Other comprehensive result		**-557**	**2,159**
Total comprehensive result		**-19,530**	**-52,027**

Consolidated Cash Flow Statement

For the year ended December 31, in CHF thousands	Notes	2019	2018
Result before taxes		**-18,393**	**-53,864**
Depreciation of tangible assets	5	1,653	605
Amortization of intangible assets	6	3,118	3,136
Expenses for equity rights plans	17, 20	6,255	7,426
Change in fair value of derivatives		413	-2,588
Change in fair value of financial assets short-term		0	293
Other non-cash items (Polyphor clinical material)		0	290
Change in pension liabilities	21	648	1,838
Taxes paid		-343	-365
Change in net working capital		5,776	5,959
Total financial result	22	7,952	2,445
Interest received		8	1
Interest paid		-4,492	-3,041
Cash flow used in operating activities		**2,595**	**-37,865**
Investments in tangible assets	5	-98	-1,348
Investments in intangible assets	6	-131	-20,294
Disposal of other financial assets short-term		0	12,718
Change in investments in other long-term financial assets		18	15
Change in restricted cash	10	3,000	3,000
Cash flow from/used in investing activities		**2,789**	**-5,909**
Capital increase	11	7,125	23,500
Capital increases from options exercised	11	2	17
Proceeds from sale of treasury shares	11	1,830	2,278
Purchase of treasury shares	11	-1,837	-3,413
Proceeds from current loan		4,732	0
Repayment of current loan		-4’732	0
Payment of principal portion of lease liabilities	12	-1,055	0
Cost of issuance share capital		-1,936	-1,738
Cash flow from financing activities		**4,129**	**20,644**
Effects of exchange rate changes on cash and cash equivalents		-126	-94
Net increase/decrease in cash and cash equivalents		**9,387**	**-23,224**
Cash and cash equivalents at January 1		21,971	45,195
Cash and cash equivalents at December 31		**31,358**	**21,971**

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, 2018		**6,289**	**392,002**	**-360,081**	**-4,905**	**-335**	**-714**	**32,256**
Net result		0	0	-54,186	0	0	0	**-54,186**
Other comprehensive result	21	0	0	0	2,230	0	-71	**2,159**
Total comprehensive result for the period		**0**	**0**	**-54,186**	**2,230**	**0**	**-71**	**-52,027**
Transactions for equity rights plans	17, 20	0	7,426	0	0	0	0	**7,426**
Capital increase from options exercise	10	4	13	0	0	0	0	**17**
Capital increase Polyphor	10	239	6,261	0	0	0	0	**6,500**
Capital increase Idorsia	10	1,000	13,540	0	0	0	0	**14,540**
Capital increase	10	3,133	20,367	0	0	0	0	**23,500**
Cost of issuance share capital	10	0	-3,248	0	0	0	0	**-3,248**
Change in treasury shares	10	0	-566	0	0	-569	0	**-1,135**
Balance at December 31, 2018		**10,665**	**435,795**	**-414,267**	**-2,675**	**-904**	**-785**	**27,829**
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	21	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	17, 20	0	6,255	0	0	0	0	**6,255**
Capital increase from options exercise	10	0	2	0	0	0	0	**2**
Capital increase	10	500	6,625	0	0	0	0	**7,125**
Cost of issuance share capital	10	0	-426	0	0	0	0	**-426**
Change in treasury shares	10	0	-167	0	0	159	0	**-8**
Balance at December 31, 2019		**11,165**	**448,084**	**-433,240**	**-3,160**	**-745**	**-857**	**21,247**

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 March 23, 2020. They are subject to approval by the Annual General Meeting of Shareholders (**AGM**) on April 22, 2020.

2 Summary of Significant Accounting Policies

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

Basis of preparation

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

The consolidated financial statements are based on the financial statements of the individual Santhera companies prepared for the same reporting period using consistent accounting policies. The consolidated financial statements are prepared using the historical cost convention except for the revaluation to fair value of certain financial assets and financial liabilities.

The presentation currency is Swiss francs (**CHF**). All figures included in these financial statements and notes to the financial statements are rounded to the nearest CHF 1,000 except where otherwise indicated.

Material uncertainties and ability to continue operations

In May 2019, Santhera filed an application for conditional marketing authorization (**CMA**) for Puldysa® (idebenone) in Europe for the treatment of respiratory dysfunction in patients with Duchenne muscular dystrophy (**DMD**) with the European Medicines Agency (**EMA**). The opinion by the Committee for Medicinal Products for Human Use (**CHMP**) for this CMA filing is expected around mid-2020, and upon receiving Marketing Authorization (**MA**) Santhera intends to commercialize Puldysa in Europe with its existing commercial team. The Company is also expecting the topline results in the fourth quarter of 2020 of the pivotal Phase 2b study in DMD of vamorolone, being conducted by ReveraGen, in ambulant patients with DMD. Santhera has the option to acquire global rights for all indications of this investigational drug from Idorsia (excluding the territories of Japan and South Korea). If the

Company would exercise such option, the exercise price amounts to CHF 30 million. However, there is no obligation by the Company to exercise such option, irrespective of the results of the ongoing pivotal study.

Santhera's cash and cash equivalents amounted to CHF 31.4 million as of December 31, 2019. Due to cost saving measures already implemented, these funds are expected to fund the operations of the Company up to the first value inflection point, the CHMP opinion on Puldysa, expected in mid-2020. However, because the current funds are insufficient to allow the Company to reach the second value inflection point later in 2020, the vamorolone pivotal study 6-month topline readout, expected in the fourth quarter of 2020, material uncertainties remain as to the Company's ability to continue as a going concern until December 31, 2020. Executing the Company's strategy depends on further funding to ensure the continuation of its operations through December 31, 2020.

Should the CHMP opinion for Puldysa be positive, the Management and the Board of Directors plan to raise additional funds through a capital increase in the second half of 2020. In case of a negative CHMP opinion, whereby the commercial launch would become obsolete, the Management and the Board would immediately initiate restructuring measures to further significantly reduce its cost base. For the latter scenario, the Management and the Board estimate that a minimum of CHF 20 million will have to be raised to provide sufficient funds to continue operations until December 31, 2020, which would then also include the second value inflection point, the vamorolone pivotal study readout, expected in the fourth quarter of 2020.

In January and February 2020, the Company was pursuing plans to raise additional funds through the issuing of equity to investors and was in advanced discussions with interested parties. However, this initiative had to be postponed due to the sudden downturn in the capital markets as a consequence of the global spread of the Coronavirus (COVID-19). This situation continues to limit the Company's ability to raise equity-based funds. The Company is therefore in discussions with several potential investors about alternative financing measures to raise the required CHF 20 million, which include debt financing, royalty financing, standby equity distribution agreement as well as the monetization of receivables. Given the recent downturn in market sentiment due to the impact of the Coronavirus, material uncertainties remain as to whether the Company will succeed in securing such financing to support the going concern assumption to December 31, 2020.

In addition to the above measures, the Management and the Board of Directors are currently in evaluation with bondholders to restructure the CHF 60 million Senior Unsecured Convertible Bonds due in February 2022; such restructuring could likely include a significant reduction of the conversion price.

Shareholders should note that whilst the Management and Board of Directors continue to apply best efforts to evaluate available options, there is no guarantee that any transaction can be realized or that such transaction would generate sufficient funds to finance operations through December 31, 2020. This material uncertainty may cast significant doubts about the going concern of the Company.

However, the Management and the Board of Directors believe that the Company is 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, 2020. 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; 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.

IFRS standards effective with January 1, 2019

IFRS 16 was issued in January 2016 and it replaces IAS 17 *Leases*, IFRIC 4 *Determining whether an Arrangement Contains a Lease*, SIC-15 *Operating Leases - Incentives* and SIC-27 *Evaluating the Substance of Transactions Involving the Legal Form of a Lease*. IFRS 16 sets out the principles for the recognition, measurement, presentation and disclosure of leases and requires lessees to account for leases under a single on-balance sheet model similar to the accounting for finance leases under IAS 17.

Santhera introduced IFRS 16 using the modified retrospective method of adoption with the date of initial application of January 1, 2019. Under this method, the standard is applied retrospectively with the cumulative effect of initially applying the standard recognized at the date of initial application. The Group has opted to apply the transition practical expedient according to which the standard may be applied only to contracts that were previously identified as leases in accordance with IAS 17 and IFRIC 4 at the date of initial application. The Group has also elected to use the recognition exemptions for lease contracts that, at the commencement date, have a lease term of 12 months or less and do not contain a purchase option ("short-term leases"), and lease contracts for which the underlying asset is of low value ("low-value assets").

a) Nature of the effect of adoption of IFRS 16

The Group has lease contracts for offices and equipment (vehicles). Before the adoption of IFRS 16, all the Group leases were classified as operating leases.

Upon adoption of IFRS 16, the Group applied a single recognition and measurement approach for all leases, except for short-term leases and leases of low-value assets. The standard provides specific transition requirements and practical expedients, which have been applied by Santhera. The Group has recognized right-of-use (ROU) assets and lease liabilities for its leases previously classified as operating leases, except for short-term leases and leases of low-value assets. The right-of-use assets were recognized based on the amount equal to the lease liabilities. Lease liabilities were recognized based on the present value of the remaining lease payments, discounted using the incremental borrowing rate at the date of initial application.

The Group also applied the available practical expedients; this means that it:

- used a single discount rate to a portfolio of leases with reasonably similar characteristics.
- applied the short-term leases exemptions to leases with lease terms that end within 12 months at the date of initial application.
- used subsequent consideration in determining the lease term where the contract contains options to extend or terminate the lease.

Based on the foregoing, as at January 1, 2019:

- Right-of-use (ROU) assets of CHF 4.4 million were recognized within tangible assets.
- Lease liabilities of CHF 4.4 million were recognized (current and noncurrent).

The lease liabilities as at January 1, 2019 can be reconciled to the operating lease commitments as at December 31, 2018 as follows:

	In CHF thousands
Operating lease commitments as at December 31, 2018	**2,626**
Weighted average incremental borrowing rate as at January 1, 2019	2.81%
Operating lease commitments at January 1, 2019 (discounted)	2,567
Less:	
Commitments relating to short-term leases	-62
Add:	
Commitments relating to early cancellation right not exercised	1,872
Lease liabilities as at January 1, 2019	**4,377**

b) Summary of new accounting policies

Set out below are the new accounting policies of the Group upon adoption of IFRS 16, which have been applied from the date of initial application:

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.

c) Amounts recognized in the Balance Sheet and Income Statement

Right of use assets and lease liabilities in the amount of TCHF 4,377 were recognized at January 1, 2019 (initial recognition). See note 5 *"Tangible Assets"* and note 12 *"Financial Assets and Liabilities"*.

The following new, revised or amended standards became effective January 1, 2019, but did not have an impact on these Consolidated Financial Statements.

- IFRIC 23 Uncertainty over Income Tax Positions (effective January 1, 2019)
- IFRS 9 Amendments to IFRS 9, Prepayment Features with negative Compensation (effective January 1, 2019)
- IAS 28 Amendments to IAS 28, Long-term Interests in Associates and Joint Ventures (effective January 1, 2019)
- IAS 19 Amendments to IAS 19, Plan Amendment, Curtailment or Settlement (effective January 1, 2019)
- Various Annual Improvements to IFRS Standards 2015-2017 Cycle (effective January 1, 2019)

The following new, revised or amended standards have been published but are not yet effective and have not been early adopted by the Group. They are not expected to have a significant impact on the 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)
- IFRS 17 Insurance Contracts (effective January 1, 2021)
- Various Amendments to References to Conceptual Framework in IFRS Standards (effective January 1, 2020)
- 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 lifetime 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. 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.

Group as a lessee

Accounting policy until December 31, 2018

Operating lease payments are recognized as an operating expense in the statement of profit or loss on a straight-line basis over the lease term.

Accounting policy as of January 1, 2019

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.

The accounting policies are disclosed under section 2 under Changes in accounting policies.

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.

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.

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 the convertible bonds, see note 12 "*Financial Assets and 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 17 "*Equity Rights Plans"*.
- Recognition of revenue from licensing at point in time and over period, identification of performance obligations and determination of transaction price, see note 19 *"Transaction with Chiesi"*.
- Actuarial valuations in the context of defined benefit pension plans where various assumptions on e.g. discount rates, salary increase rates and mortality rates, etc. bear significant uncertainties due to the long-term nature of the plans, see note 21 *"Employee Expenses and Benefits"*.

4 Exchange Rates of Principal Currencies

	Income statement in CHF average rates		**Balance sheet in CHF** year-end rates	
	2019	**2018**	**2019**	**2018**
1 Euro (**EUR**)	1.1128	1.1547	1.0858	1.1265
1 US dollar (**USD**)	0.9937	0.9779	0.9683	0.9850
1 British pound (**GBP**)	1.2690	1.3052	1.2739	1.2546
1 Canadian dollar (**CAD**)	0.7489	0.7547	0.7430	0.7236

5 Tangible Assets

In CHF thousands	Right-of-use assets vehicles	Right-of-use assets offices	Equip-ment	IT hard-ware	Leasehold improve-ments	**2019**
Cost						
At January 1	**0**	**0**	**879**	**1,060**	**1,615**	**3,554**
IFRS 16 first-time adoption January 1, 2019	612	3,765	0	0	0	**4,377**
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**

In CHF thousands	Equip-ment	IT hard-ware	Leasehold improve-ments	**2018**
Cost				
At January 1	**362**	**1,106**	**1,469**	**2,937**
Additions	538	38	147	**723**
Disposals	-15	-81	0	**-96**
Exchange differences	-6	-3	-1	**-10**
At December 31	**879**	**1,060**	**1,615**	**3,554**
Accumulated depreciation				
At January 1	**212**	**514**	**54**	**780**
Additions	106	251	248	**605**
Disposals	-15	-81	0	**-96**
Exchange differences	-3	-2	1	**-4**
At December 31	**300**	**682**	**303**	**1,285**
Net book value	**579**	**378**	**1,312**	**2,269**

[1] 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 Assets and Liabilities"* for further information on leases.

6 Intangible Assets

In CHF thousands	Option to vamorolone sub-license (in process R&D)	POL6014 (in process R&D)	Idebenone	Fipame-zole	IT soft-ware/ patents	**2019**
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**

In CHF thousands	Option to vamorolone sub-license (in process R&D)	POL6014 (in process R&D)	Idebenone	Fipame-zole	IT soft-ware/ patents	**2018**
Cost						
At January 1	**0**	**0**	**30,387**	**3,918**	**654**	**34,959**
Additions	34,780	6,210	0	0	54	**41,044**
Disposals	0	0	0	0	-42	**-42**
At December 31	**34,780**	**6,210**	**30,387**	**3,918**	**666**	**75,961**
Accumulated amortiza-tion						
At January 1	**0**	**0**	**7,091**	**3,918**	**390**	**11,399**
Additions	0	0	3,039	0	98	**3,137**
Disposals	0	0	0	0	-42	**-42**
At December 31	**0**	**0**	**10,130**	**3,918**	**446**	**14,494**
Net book value	**34,780**	**6,210**	**20,257**	**0**	**220**	**61,467**

During 2019 there was a trigger for impairment of intangible assets in use (see to note 7 "*Impairment Test for Intangible Assets*"). "Idebenone" represents the main intangible asset currently in use of Santhera. It has become available for use in September 2015 and has an estimated useful life of 10 years.

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) which constituted a triggering event for an impairment assessment (see note 19 "*Transaction with Chiesi*"). The result of the test showed that the carrying amount of the intangible asset continues to be supported by the program for launching Puldysa for patients with DMD, for which Santhera had filed an application for conditional marketing authorization for Puldysa (idebenone) in Europe for the treatment of respiratory dysfunction, with the EMA in May 2019.

POL6014 and Option to Vamorolone Sub-license

"POL6014" and "Option to vamorolone sub-license" are intangible assets which were added in 2018. 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 2020 through 2032 (for option to vamorolone sub-license) and 2036 (for POL6014). 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, 2019, Santhera made general estimates for:

	2019	**2018**
WACC	10.4%	10.4%
Tax rate	13.45%	9.3%

Considering the markets and respective risk-profile for both assets, Santhera used the same WACC and tax rate assumptions for the impairment testing of POL6014 and the option to vamorolone sub-license. Other input elements for the calculation of the rNPV are based on the individual agreement with Polyphor or Idorsia 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. Probability of reaching the market lies between 20% (2018: 22%) for POL6014 and 27% (2018: 27%) for the option to vamorolone sub-license, reflecting the uncertainty as to whether a final and successful market registration can be achieved for POL6014 and the sub-license vamorolone.

The impairment test of the recoverable amount of the intangible assets performed, as of December 31, 2019 and 2018, 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 2019 did not reveal any indicators of impairment as at the reporting date.

8 Inventories

In CHF thousands	2019	2018
Raw material (active pharmaceutical ingredients)	5,632	7,488
Semi-finished goods	694	628
Finished goods	533	1,166
Total at December 31	**6,859**	**9,282**

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 (no write-down in 2018). Semi-finished and finished goods were written-down due to limited shelf life in the amount of CHF 0.65 million (no write-down was made in 2018).

9 Trade and Other Receivables

In CHF thousands	2019	2018
Trade receivables (gross)	5,359	5,536
Other receivables	3,688	2,402
Allowance for expected credit losses	**-146**	**-77**
Total at December 31	**8,901**	**7,861**

Trade receivables in 2019 result from product sales, see note 18 *"Segment and Geographic Information"*. Other receivables consist mainly of amounts due from the government for tax reimbursements (e.g. VAT). They are due within 30 to 120 days and bear no interest.

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, 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**

	Current	0-30 days	31-60 days	61-90 days	91-180 days	181-360 days	>360 days	**As of Dec. 31, 2018**
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)	3,785	725	318	226	304	149	29	**5,536**
Expected credit loss (in TCHF)	12	7	7	9	22	16	4	**77**

As of December 31, 2019, an allowance for expected credit losses (ECL) of TCHF 146 was recognized on the trade receivables (as of December 31, 2018: TCHF 77).

In CHF thousands	2019	2018
Expected credit losses January 1	**-77**	**-55**
Allowance for doubtful debts	0	0
Reversal of allowance for ECL	0	55
Increase in allowance ECL	-69	-77
Outstanding at December 31	**-146**	**-77**

10 Cash and Cash Equivalents and Restricted Cash

10.1 Cash and cash equivalents

In CHF thousands	2019	2018
Cash at banks and on hand		
In CHF	19,285	9,111
In EUR	7,875	10,149
In GBP	1,243	493
In USD	2,769	2,036
In CAD	112	138
Other currencies	74	44
Total at December 31	**31,358**	**21,971**
Of which: Short-term deposits		
In CHF	127	0

10.2 Restricted cash

in CHF thousands	Dec. 31, 2019	Dec. 31, 2018
Long-term	0	1,500
Short-term	1,500	3,000
Total at period end	**1,500**	**4,500**

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

11 Share Capital

Ordinary share capital

As of January 1, 2018, the share capital amounted to CHF 6,288,555, divided into 6,288,555 shares ("Shares") at a nominal value of CHF 1 each. In February 2018, 238,924 Shares were issued out of the authorized share capital in connection with the agreement with Polyphor. In November 2018, 1,000,000 Shares were issued out of the authorized share capital in connection with the first step of the agreement with Idorsia. In December 2018, 3,133,334 Shares were issued in connection with the second step of the agreement with Idorsia (based on the approval of the shareholders on the occasion of an Extraordinary General Meeting). During 2018, 3,750 Shares were issued from conditional capital upon the exercise of stock options. As a result, as of December 31, 2018, the share capital amounted to CHF 10,664,563, divided into 10,664,563 Shares at a nominal value of CHF 1 each.

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.

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, 2019, Santhera held 54,892 treasury Shares (2018: 53,290 treasury Shares).

Authorized share capital

In April 2019, 500,000 Shares were issued out of the authorized share capital in connection with a private placement. On the occasion of the AGM on May 28, 2019, the shareholders approved the increase of the authorized share capital as well as an extension. The Board is authorized to increase the share capital at any time until May 27, 2021, through the issuance of up to 3,000,000 Shares with a nominal value of CHF 1 each.

Conditional share capital

At the AGM on May 28, 2019, the shareholders approved the increase of the conditional share capital by an aggregate amount of CHF 2,500,000 through the issuance of a maximum of 2,500,000 Shares.

As of December 31, 2019, the Company had a conditional share capital, pursuant to which the share capital may be increased by

- a maximum amount of CHF 687,052 (2018: CHF 687,552) through the issuance of up to 687,052 (2018: 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 17 *"Equity Rights Plans"*, and
- a maximum amount of CHF 2,500,000 (2018: CHF 930,000) by issuing up to 2,500,000 (2018: 930,000) 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 Assets and 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 assets short-term

Financial assets (units in a fund) were held for trading and measured at fair value based on quoted prices (Level 1) through profit or loss. No instruments were held in 2019. The instruments were sold in 2018, generating proceeds of CHF 12.7 million. A loss of TCHF 293 (financial expenses) resulted in 2018.

12.2 Financial liabilities

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%) 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, 2019, amounts to CHF 39.5 million (2018: CHF 41.7 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, 2019, was 86% (December 31, 2018: 71%).
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, 2018, the value was CHF 0.2 million and at December 31, 2019 CHF 0.6 million. The change in the fair value was recognized in the financial result and amounted in 2019 to TCHF -413 (2018: TCHF 2,588).

Sensitivity analysis:

	December 31, 2019		December 31, 2018	
	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%	-77	+5%	-55
	-5%	63	-5%	84

Changes in liabilities arising from financing activities

In CHF thousands	Convertible bonds	Derivative financial instruments	Current loan
December 31, 2017	**53,111**	**2,792**	**0**
Change in fair value of derivative financial instruments	0	-2,588	0
Effective interest/amortized cost calculation	1,458	0	0
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**

Lease liabilities

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

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

13 Deferred Taxes

Net deferred taxes recorded

In CHF thousands	2019	2018
Temporary differences on inventory	1,049	1,285
Deferred tax assets recognized	**1,049**	**1,285**
Temporary differences on intangible assets, net	2,037	1,657
Temporary differences on intercompany loans	0	13,449
Temporary differences on convertible bonds	434	409
Tax loss carryforwards	-2,471	-15,515
Deferred tax liabilities recognized	**0**	**0**
Tax loss carryforwards	156,132	343,389
Of which recorded	-18,373	-187,824
Of which unrecorded	**137,759**	**155,565**
Expiring in		
1 year	4,223	39,311
2 years	0	4,223
3 years	2,535	0
4 years	41,999	0
5 years	41,237	41,104
More than 5 years	19,570	41,624
Without expiration	28,195	29,303
Total unrecorded tax loss carryforwards	**137,759**	**155,565**

Due to the uncertainty surrounding the future results of operations and the uncertainty as to whether Santhera can use the loss carryforwards for tax purposes, deferred tax assets on tax loss carryforwards were only considered to the extent that they offset taxable temporary differences within the same taxable entity. As there are no temporary differences associated with investments in subsidiaries, no deferred tax liability has to be recognized. No deferred tax assets are calculated on temporary differences related to pension obligations from IAS 19 (TCHF 9,116 at December 31, 2019, and TCHF 7,983 at December 31, 2018, respectively).

14 Trade and Other Payables

In CHF thousands	2019	2018
Trade payables	6,832	7,194
Other payables (nonfinancial)	2,700	1,112
Total at December 31	**9,532**	**8,306**

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

15 Accrued Expenses

In CHF thousands	2019	2018
Development programs	3,743	4,046
Liabilities to employees	4,458	3,665
Accruals for pricing and reimbursement	510	501
Accrued marketing and sales expenses	305	505
Accruals for audit, consulting and other	1,303	1,207
Accruals for interest expenses	1,108	1,117
Total at December 31	**11,427**	**11,041**

16 Commitments and Contingent Liabilities

Commitments

Commitments for operating lease (noncancellable)

In CHF thousands	2019	2018
Within 1 year	10	1,200
After 1 year through to 5 years	0	1,426
After 5 years	0	0
Total at December 31	**10**	**2,626**

Commitments to future payments under license agreements

Option to sub-license with Idorsia

On November 21, 2018, Santhera announced that it had entered into an agreement to acquire an option from Idorsia Ltd, Allschwil, Switzerland, for an exclusive sub-license of dissociative steroid vamorolone. Under the terms of the agreement, Idorsia will grant Santhera the option to obtain an exclusive sub-license for vamorolone in all indications and all territories except Japan and South Korea. Santhera may exercise the option upon receipt of data from the Phase 2b VISION-DMD study (VBP15-004) and following a one-time consideration to Idorsia of USD 30 million.

Following the exercise of the worldwide vamorolone license option by Idorsia and exercise of the vamorolone sub-license option for all territories worldwide except Japan and South Korea by Santhera, Santhera will pay to Idorsia regulatory and commercial milestone payments of up to USD 80 million in the DMD indication and four one-time sales milestone payments of up to USD 130 million in aggregate. Regulatory milestone payments by Santhera to Idorsia 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 on the annual net sales of vamorolone to Idorsia.

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 4.7 million (to be delivered in 2020).
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.

17 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.

17.1 Stock Option Plans

Employee Stock Option Plans

The Company adopted the ESOP 2004, ESOP 2008, 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 2008 and ESOP 2010 vested stock options of employees leaving the Company in good faith expire six months after the termination date of the employment. Under the ESOP 2015 vested stock options of employees leaving the Company in good faith do not expire. Unvested stock options of employees leaving the Company are forfeited under all stock option plans. No further grants can be made under the ESOP.

Options outstanding, exercised, forfeited or expired under ESOPs

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**

Number of options						**2018**
	At January 1	Exercised	Granted	Forfeited	Expired	At December 31
ESOP 2010	29,551	-3,750	0	0	0	25,801
ESOP 2015	245,329	0	0	-21,855	0	223,474
Total	**274,880**	**-3,750**	**0**	**-21,855**	**0**	**249,275**

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						**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**

Number of options						**2018**
	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 17.2 *"Share Appreciation Rights Plans".*

Number of stock options outstanding and exercisable

Number of options	**2019**	**2018**
Outstanding at January 1	**262,837**	**288,442**
Granted	0	0
Exercised[1]	-500	-3,750
Forfeited	-4,733	-21,855
Expired	0	0
Outstanding at December 31	**257,604**	**262,837**
Exercisable at December 31	**235,719**	**190,188**

[1] The average closing share price of options exercised during the reporting period 2019 was CHF 11.94 (2018: CHF 7.30).

The value of stock options granted is recognized as personnel expense over the period Santhera receives services. In 2019, previously granted stock options resulted in personnel expenses of TCHF 368 (TCHF 37 related to Development, TCHF 219 related to Marketing and sales (**M&S**) and TCHF 112 to General and administrative (**G&A**)) and in 2018, such grants resulted in personnel expenses of TCHF 1,077 (TCHF 127 related to Development, TCHF 594 related to M&S and TCHF 356 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)	**2019 Number exercisable**	Number outstanding	Weighted average remaining contractual life (years)	**2018 Number exercisable**
from 3.89 to 4.53	20,751	3.20	20,751	21,251	4.20	21,251
at 22.25	4,550	4.50	4,550	4,550	5.50	4,550
at 69.30	12,650	6.25	10,275	13,150	7.25	7,400
from 82.10 to 114.50	219,653	5.71	200,143	223,886	6.61	156,987
Total	**257,604**	**5.58**	**235,719**	**262,837**	**6.37**	**190,188**

17.2 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, the ESARP 2017 and the ESARP 2018, 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. SARP introduced in 2017 (BSARP 2017 and ESARP 2017) 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). Besides the usual terms ESARP 2018 contains an additional vesting condition, which is based on Santhera obtaining a positive opinion of the Committee for Medicinal Products for Human Use (**CHMP**) with respect to the marketing authorization of idebenone for the treatment of patients with DMD in the European Union (**EU**). In January 2019, Santhera has introduced ESARP 2019 which has the same terms as SARP since 2017, but states that annual grants shall be made the day after the Annual General Meeting. 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						**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**

Number of SARs						**2018**
	At January 1	Exercised	Granted	Forfeited	Expired	At December 31
ESARP 2016	85,589	0	0	-42,277	0	43,312
BSARP 2017	15,120	0	62,659	0	0	77,779
ESARP 2017	259,401	0	479,751	-149,907	0	589,245
ESARP 2018	0	0	79,872	-59,820	0	20,052
Total	**360,110**	**0**	**622,282**	**-252,004**	**0**	**730,388**

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:

	2019	**2018**
Market price of stock	CHF 5.55 to 22.30	CHF 5.80 to 41.15
Exercise prices	CHF 6.61 to 14.50	CHF 16.20 to 36.70
Weighted average fair value of SAR granted	CHF 5.66	CHF 12.11
Expected volatility[1]	37% to 40%	37%
CHF risk-free interest rate	0.0% p.a.	0.0 to 0.05% 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	**2019**	**2018**
Outstanding at January 1	**730,388**	**360,110**
Granted	1,072,962	622,282
Exercised	0	0
Forfeited	-45,836	-252,004
Expired	0	0
Outstanding at December 31	**1,757,514**	**730,388**
Exercisable at December 31	**476,211**	**155,424**

The value of SAR granted is recognized as personnel expense over the period Santhera receives services. In 2019, SAR grants resulted in personnel expenses of TCHF 4,745 (TCHF 1,806 related to Development, TCHF 1,509 related to M&S and TCHF 1,430 to G&A) and in 2018, such grants resulted in personnel expenses of TCHF 5,641 (TCHF 2,178 related to Development, TCHF 1,957 related to M&S and TCHF 1,506 to G&A). The above expenses of TCHF 4,745 are 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). In 2018 the expenses of 5,641 were net of a reversal for SAR forfeited under ESARP 2018 in the amount of TCHF 525 (TCHF 180 related to Development, TCHF 185 related to M&S and TCHF 160 to G&A).

In the course of allocating SAR annually to its employees as part of the long-term incentive (LTI), Santhera plans to grant up to 785,000 SAR after the Annual General Meeting (AGM) which is to be held in April 2020. These SAR form part of the long-term incentive (**LTI**) award to employees for the year ended December 31, 2019. Although these SAR were not legally granted in 2019, Executive Management considers it appropriate to recognize expenses in 2018 as employees have been rendering services in 2019 in expectation of the annual LTI allocation. Personnel expenses in 2019 for this amounted to TCHF 1,142 (TCHF 589 related to Development, TCHF 383 related to M&S and TCHF 170 related to G&A) based on an estimate of fair value (in 2018 personnel expenses for this amounted to TCHF 708 (TCHF 298 related to Development, TCHF 207 related to M&S and TCHF 203 related to G&A)). The allocation of these SAR is conditional for the Executive Management and becomes unconditional once the compensation is approved on the occasion of the AGM, to be held on April 22, 2020. After the AGM the grant date fair value of the SAR will be determined and the cumulative expense and number of SAR to be granted adjusted.

Terms of SAR outstanding at December 31

Exercise price range for SAR (in CHF)	Number outstanding	Weighted average remaining contractual life (years)	**2019 Number exercisable**	Number outstanding	Weighted average remaining contractual life (years)	**2018 Number exercisable**
from 6.61 to 18.90	1,124,902	9.36	33,410	67,659	9.32	0
from 36.70 to 38.70	376,488	8.00	219,393	402,999	9.00	11,087
from 51.75 to 54.85	228,852	7.00	202,793	232,458	8.00	132,921
from 76.50 to 77.80	27,272	7.14	20,615	27,272	8.08	11,416
Total	**1,757,514**	**8.29**	**476,211**	**730,388**	**9.04**	**155,424**

18 Segment and Geographic Information

Segment information

Santhera operates in one operating segment, the development and commercialization of specialty niche products for the treatment of 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	2019	2018
Net sales		
EU	27,694	31,544
Rest of the world	196	113
Subtotal net sales	27,890	31,657
Revenue from out-licensing transactions		
EU	46,370	0
Net sales to licensing partner		
EU	1,116	0
Total	**75,376**	**31,657**

In 2019, net sales and net sales to licensing partner amounted to CHF 29.0 million with its product Raxone only (2018: CHF 31.7 million). Raxone was sold in 24 European countries, with the majority of sales reached in France and Germany (2018: 20 European countries).

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

In CHF thousands	2019	2018
Switzerland	62,874	63,504
EU	949	164
North America	260	68
Total	**64,083**	**63,736**

19 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 by 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. Since the closing of the transaction in August until the end of 2019, Santhera recognized revenue for such services in the amount of CHF 0.5 million. The parties also agreed that Chiesi procures from Santhera the manufactured packs of Raxone for selling in the licensed territory (CHF 1.1 million net sales to licensing partner).

Santhera also accepted to reimburse Chiesi for costs to be incurred in relation to rights transferred with the license. This consideration payable to Chiesi amounts to CHF 0.7 million, of which the outstanding amount is disclosed as a liability (payment is expected in 2020).

In connection with the transaction Santhera incurred costs to obtain the contract in the amount of CHF 4 million. These were expensed in 2019 and are included within general and administrative expenses in the consolidated income statement.

20 Operating Expenses by Nature

In CHF thousands	2019	2018
External Development expenses	-26,501	-24,208
Patent and license expenses	-498	-621
Marketing expenses	-6,413	-10,113
Employee expenses	-35,580	-36,125
Of which non-cash-relevant expenses for equity rights plans	*-6,255*	*-7,426*
Other administrative expenses	-9,479	-5,415
Depreciation and amortization	-1,732	-703
Facility related expenses	-304	-445
Lease expenses (offices)	-16	-859
Other operating expenses	-129	-198
Total operating expenses	**-80,652**	**-78,687**

21 Employee Expenses and Benefits

Employee expenses

In CHF thousands	2019	2018
Wages and salaries	-22,679	-20,926
Social security and other personnel-related expenses[1]	-6,646	-7,773
Of which non-cash-relevant adjustments of pension fund	*-648*	*-1,838*
Expenses for equity rights plans	-6,255	-7,426
Total employee costs	**-35,580**	**-36,125**

Average number of full-time equivalents[2]	**118.5**	**109.6**
Full-time equivalents at year-end	**112.9**	**114.9**
Total headcount at year-end	**117**	**119**

[1] Thereof TCHF 480 were expensed for defined contribution plans in North America and some European countries (2018: TCHF 458).

[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 Invalidity Pension Provision" (**OPA**), all employees of Santhera Pharmaceuticals Holding AG, Pratteln, and Santhera Pharmaceuticals (Schweiz) AG, Pratteln, both in Switzerland, have to be affiliated with a collective independent pension fund. These funds provide for retirement benefits, as well as risk benefits (death and disability). The plans qualify as defined benefit plans under IAS 19 and the assets cannot revert to the employer. Contributions to the plans are such that the employee contributes 40% and the employer the rest. Contributions are computed as percentage of

the salary, depending on age. In order to manage these risks, since January 1, 2018, Santhera has an agreement with PKG Pensionskasse (**PKG**). PKG is responsible for the governance of the plan; its board is composed of an equal number of representatives from the employers and employees chosen from all affiliated companies. PKG has set up investment guidelines, defining in particular the strategic allocation with margins. PKG has insured the risks of disability and death before retirement with PKRück AG, Vaduz, Fürstentum Liechtenstein. The accumulated savings capital is allocated to each insured individual and consists of annual contributions, savings credits and interest credits. In certain situations, additional payments or increased periodic contributions by the employer may become due based on the pension plans funded status as measured under Swiss pension rules (**OPA**).

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

Changes in defined benefit obligations

In CHF thousands	**2019**	**2018**
Present value of obligation, January 1	**23,275**	**24,152**
Current employer service cost	1,982	2,302
Past service cost[1]	0	702
Interest cost	232	181
Employee contributions	937	824
Benefits paid / transfer payments	1,920	-2,375
Insurance premiums	-217	-179
Remeasurements[2]	-1,771	-2,332
Present value of obligation, December 31	**26,358**	**23,275**

1 Increase of obligation due to higher savings contributions and changes in the conversion rates for the over-mandatory part of the retirement capital.

2 Details of remeasurements:

In CHF thousands	**2019**	**2018**
Effect of changes in demographic assumptions[1]	-2,153	0
Actuarial gain/loss due to changes in financial assumptions	2,989	-1,206
Actuarial gain/loss due to experience adjustments	-2,607	-1,126
Subtotal gain/loss	**-1,771**	**-2,332**
Return/loss on plan assets (excluding interest income)	2,256	102
Total remeasurements in other comprehensive income gain/loss	**485**	**-2,230**

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

Changes in plan assets

In CHF thousands	2019	2018
Fair value of assets, January 1	**15,292**	**15,777**
Interest income on assets	161	114
Employer contributions	1,405	1,233
Employee contributions	937	824
Benefits paid / transfer payments	1,920	-2,375
Insurance premiums	-217	-179
Remeasurements (return/loss on plan assets (excluding interest income))	-2,256	-102
Fair value of assets, December 31	**17,242**	**15,292**

Net defined benefit asset/obligation

In CHF thousands	2019	2018
Present value of obligation, December 31	26,358	23,275
Fair value of assets, December 31	17,242	15,292
Net defined asset/obligation	**-9,116**	**-7,983**

Asset allocation

In CHF thousands	2019	2018
Cash	190	107
Debt instruments	7,724	6,881
Equity instruments	5,259	4,557
Property	3,276	2,906
Assets from insurance contracts	0	0
Others	793	841
Total value of assets	**17,242**	**15,292**

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

In %	2019	2018
Discount rate	0.35	1.00
Disability probabilities	80.00	100.00
Lump sum probabilities	30.00	0.00
Expected future salary increases	1.50	1.50

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	-

Sensitivity analysis for 2018:

In CHF thousands	Defined benefit obligation		Gross (net) service cost	
	Increase assumption	Decrease assumption	Increase assumption	Decrease assumption
Discount rate +/-0.25%	-941	1,017	-154	165
Salary increase +0.25%	223	-	0	-
Life expectancy +1 year	394	-	40	-

Mortality rate:

Life expectancy at age 65 (in years)	**2019**	**2018**
Male	22.7	22.6
Female	24.8	24.7

The expected employer contributions for fiscal year 2020 amount to approximately TCHF 1,404 (2019: TCHF 1,193). Benefit obligations of pensioners amounted to TCHF 941 at December 31, 2019 (2018: TCHF 2,988). The duration of the plan liabilities calculated is 21.4 years as of December 31, 2019 (2018: 20.9 years).

22 Financial Income/Expenses

Financial income

In CHF thousands	**2019**	**2018**
Interests on cash and cash equivalents	8	1
Change in fair value of financial derivative instruments	0	2,588
Income from financial assets	0	92
Realized and unrealized foreign exchange gains	1,648	1,690
Total	**1,656**	**4,371**

Financial expenses

In CHF thousands	2019	2018
Interest expenses	-5,971	-4,501
Interest expenses on lease liabilities	-111	0
Change in fair value of financial derivative instruments	-413	0
Expenses from financial assets	0	-429
Realized and unrealized foreign exchange losses	-3,113	-1,885
Total	**-9,608**	**-6,815**

23 Income Taxes

In CHF thousands	2019	2018
Current income tax income/expense	-343	-365
Deferred tax income/expense	-236	43
Total	**-579**	**-322**

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

In CHF thousands	2019	2018
Result before taxes	-18,393	-53,864
Tax expense/income at expected group tax rate of 9.3%	1,711	5,009
Effect of tax rate difference group versus local	-500	-417
Effect of nondeductible expenses	-792	-1,382
Utilization of previously unrecognized tax losses	16	19
Recognition of previously unrecognized DTL (deferred tax liabilities)	0	0
Recognition of DTA on previously unrecognized tax losses	0	0
Unrecognized deferred taxes	-1,014	-3,551
Effective tax income/expense	**-579**	**-322**

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

24 Earnings/Loss per Share

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

	2019	2018
Net result attributable to shareholders (in TCHF)	-18,973	-54,186
Weighted average number of shares issued and outstanding	10,991,497	6,891,610
Basic and diluted net result per share (in CHF)	**-1.73**	**-7.86**

For the years ended December 31, 2019 and 2018, 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.

25 Related Party Transactions

Board and Executive Management compensation

Total compensation of Board and Executive Management

In CHF thousands	2019	2018
Compensation, wages and salaries	2,755	2,859
Post-employment benefits (pension fund and defined benefit contributions)	308	353
Share-based payment expenses (fair value according to IFRS 2)	1,722	2,333
Total	**4,785**	**5,545**

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 2019, no stock options were exercised by members of the Board (2018: no stock options exercised). During 2019, no stock options were exercised by the Executive Management (2018: 3,750 stock options exercised).

26 Risk Management Objectives and Policies

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

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

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

Santhera conducts development activities primarily in Switzerland, the EU and the US and is exposed to a variety of financial risks, such as, but not limited to, foreign exchange rate risk, credit risk, liquidity risk, cash flow and interest rate risk. Part of Santhera's overall risk management focuses on financial risks and the unpredictability of financial markets seeking to minimize potential adverse effects on the financial performance of the Group. Special guidelines and policies approved by the Board exist for overall risk management, financial internal controls and treasury management and are monitored by the Executive Management and the Board on a regular basis. The risk of foreign exchange rate fluctuations on the expenses can partly be managed by entering into foreign exchange derivative contracts. In accordance with the relevant treasury guidelines, Santhera only concludes contracts with selected high-quality financial institutions of good reputation and is not allowed to engage in speculative transactions. In addition, Santhera's treasury guidelines 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, EUR, USD and GBP CAD. No derivative currency contracts are outstanding as of December 31, 2019 and 2018.

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		
2019	+5%	+415
	-5%	-415
2018	+5%	+488
	-5%	-488

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 2019, variances of +/-50 basis points were calculated, resulting in fluctuations of +/-TCHF 164 before tax (end of 2018: +/-50 basis points resulting in fluctuations of +/-TCHF 132 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 Assets and 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, 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**

Year ended December 31, 2018 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	67,500	70,500	54,569
Trade payables	0	7,194	0	0	7,194	7,194
Accrued expenses	0	7,738	0	0	7,738	7,738
Total	**0**	**16,432**	**1,500**	**67,500**	**85,432**	**69,501**

Categories of financial instruments

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.

Year ended December 31, 2018 (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	690	690	0	0
Restricted cash long-term	1,500	1,500	0	0
Trade receivables	5,459	5,459	0	0
Other receivables	98	98	0	0
Restricted cash short-term	3,000	3,000	0	0
Cash and cash equivalents	21,971	21,971	0	0
Total	**32,718**	**32,718**	**0**	**0**
Liabilities				
Convertible bonds	54,569	0	54,569	0
Derivative financial instruments	204	0	0	204
Trade payables	7,194	0	7,194	0
Accrued expenses	7,738	0	7,738	0
Total	**69,705**	**0**	**69,501**	**204**

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 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. In 2017, minor changes in goals and policies of the treasury management have been made, such as e.g. the extension from 20% to 30% for short-term investments with one counterparty or the possibility of physical cash deposits.

27 Events after the Reporting Date

See note 2 *"Summary of Significant Accounting Policies"*.

Building a better working world

Ernst & Young Ltd
Aeschengraben 9
P.O. Box
CH-4002 Basle

Phone +41 58 286 86 86
Fax +41 58 286 86 00
www.ey.com/ch

To the General Meeting of
Santhera Pharmaceuticals Holding Ltd, Pratteln

Basle, March 23, 2020

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, 2019 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 20 to 65) give a true and fair view of the consolidated financial position of the Group as at December 31, 2019, 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 IESBA Code of Ethics for Professional Accountants, 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.

Revenue recognition from licensing transaction with Chiesi Farmaceutici S.p.A.

Areas of focus	The Group in August 2019 announced the closing of an out-licensing transaction with Chiesi Farmaceutici S.p.A. (Chiesi), whereby Chiesi in-licensed Raxone for the treatment of Leber's hereditary optic neuropathy (LHON) in certain markets. Under the terms of the agreement, the Group received a non-refundable upfront payment of EUR 44 million and is eligible to receive up to EUR 49 million in additional milestone payments upon achievement of defined milestones. In 2019, the total revenue recognized related to this out-licensing transaction amounted to CHF 46.4 million. The related contract liability as of December 31, 2019 amounted to CHF 2.7 million. Management concluded that the upfront payment is for separate performance obligations with different timing patterns for revenue recognition. We consider the revenue recognition of the out-licensing transaction to be a key audit matter given the magnitude of the upfront payment, the judgments involved in determining the stand-alone selling prices as well as the service period used to recognize revenue. *Refer to note 2 "Summary of Significant Accounting Policies", note 3 "Critical Accounting Estimates, Assumptions and Judgments", and note 19 "Transaction with Chiesi".*
Our audit response	We have read the underlying contractual agreement and the respective accounting position paper prepared by management. We discussed with management and the Audit Committee the substance of the contractual agreement focusing on the rights and obligations of each party. As part of our assessment we considered alternative accounting treatments, including an assessment of whether some of the performance obligations should be treated as a combined performance obligation. We also performed a sensitivity analysis on how changes in fair value would change the allocation of the transaction price as well as the revenue recognized. Our audit procedures did not lead to any reservations regarding the accounting for this out-licensing transaction.

Impairment assessment of intangible assets not yet available for use

Areas of focus	As a result of the transactions with Polyphor and Idorsia in 2018, the Group capitalized intangible assets not yet available for use in the amount of CHF 41.0 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/ Karina Gawron
Licensed audit expert

Statutory Financial Statements of Santhera Pharmaceuticals Holding AG

Contents

Balance Sheet

As of December 31, in CHF thousands	Notes	2019	2018
Assets			
Cash and cash equivalents		7,658	7,348
Other receivables from third parties		104	77
Prepaid expenses and accrued income		18	141
Restricted cash short-term		1,500	3,000
Current assets		**9,280**	**10,566**
Loans to shareholdings	3.1	118,681	118,451
Investments in shareholdings	3.2	283	246
Restricted cash long-term		0	1,500
Noncurrent assets		**118,964**	**120,197**
Total assets		**128,244**	**130,763**
Liabilities and equity			
Trade accounts payable to third parties		277	1,386
Other accounts payable to third parties		16	230
Other accounts payable to shareholdings		68	0
Accrued expenses		1,973	1,768
Current liabilities		**2,334**	**3,384**
Senior unsecured convertible bonds[1]	2	60,000	60,000
Noncurrent liabilities		**60,000**	**60,000**
Total liabilities		**62,334**	**63,384**
Share capital	3.3	11,165	10,665
Reserves from capital contributions[2]		*6,282*	*17,581*
Other capital reserves		*3,591*	*6,165*
Statutory capital reserves		9,873	23,746
Accumulated result		*-32,250*	*-23,623*
Results carried forward		*-23,622*	*-13,752*
Net result for the period		*-8,755*	*-9,871*
Other voluntary reserves (free reserves)		*77,995*	*57,495*
Voluntary accumulated result and other reserves		45,618	33,872
Treasury shares	3.4	-746	-904
Total equity		**65,910**	**67,379**
Total liabilities and equity		**128,244**	**130,763**

1 Interest bearing

2 Value as per December 31, 2019, to be confirmed by Swiss Federal Tax Administration (SFTA).

Income Statement

For the year ended December 31, in CHF thousands	Notes	2019	2018
Income from shareholdings	3.5	1,217	1,218
Other operating income		45	0
Total operating income		**1,262**	**1,218**
General and administrative expenses	3.6	-3,896	-6,243
Employee expenses		-1,589	-1,139
Other operating expenses		-31	-20
Total operating expenses		**-5,516**	**-7,402**
Operating result		**-4,254**	**-6,184**
Financial income		167	370
Financial expenses		-4,704	-4,105
Financial result		**-4,537**	**-3,735**
Reversal on allowance of investment		36	49
Result before and after taxes / net result		**-8,755**	**-9,870**
Direct taxes		0	0
Net result		**-8,755**	**-9,870**

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

In May 2019, Santhera filed an application for conditional marketing authorization (**CMA**) for Puldysa® (idebenone) in Europe for the treatment of respiratory dysfunction in patients with Duchenne muscular dystrophy (**DMD**) with the European Medicines Agency (**EMA**). The opinion by the Committee for Medicinal Products for Human Use (**CHMP**) for this CMA filing is expected around mid-2020, and upon receiving Marketing Authorization (**MA**) Santhera intends to commercialize Puldysa in Europe with its existing commercial team. The Company is also expecting the topline results in the fourth quarter of 2020 of the pivotal Phase IIb study in DMD of vamorolone, being conducted by ReveraGen, in ambulant patients with DMD. Santhera has the option to acquire global rights for all indications of this investigational drug from Idorsia (excluding the territories of Japan and South Korea). If the Company would exercise such option, the exercise price amounts to CHF 30 million. However, there is no obligation by the Company to exercise such option, irrespective of the results of the ongoing pivotal study.

Cash and cash equivalents of Santhera Group amounted to CHF 31.4 million as of December 31, 2019. Due to cost saving measures already implemented, these funds are expected to fund the operations of the Company up to the first value inflection point, the CHMP opinion on Puldysa, expected in mid-2020. However, because the current funds are insufficient to allow the Company to reach the second value inflection point later in 2020, the vamorolone pivotal study 6-month topline readout, expected in the fourth quarter of 2020, material uncertainties remain as to the Company's ability to continue as a going concern until December 31, 2020. Executing the Company's strategy depends on further funding to ensure the continuation of its operations through December 31, 2020.

Should the CHMP opinion for Puldysa be positive, the Management and the Board of Directors plan to raise additional funds through a capital increase in the second half of 2020. In case of a negative CHMP opinion, whereby the commercial launch would become obsolete, the Management and the Board would immediately initiate restructuring measures to further significantly reduce its cost base. For the latter scenario, the Management and the Board estimate that a minimum of CHF 20 million will have to be raised to provide sufficient funds to continue operations until December 31, 2020, which would then also include the second value inflection point, the vamorolone pivotal study readout, expected in the fourth quarter of 2020.

In January and February 2020, the Company was pursuing plans to raise additional funds through the issuing of equity to investors and was in advanced discussions with interested parties. However, this initiative had to be postponed due to the sudden downturn in the capital markets as a consequence of the global spread of the Coronavirus (COVID-19). This situation continues to limit the Company's ability to raise equity-based funds. The Company is therefore in discussions with several potential investors about alternative financing measures to raise the required CHF 20 million, which include debt financing, royalty financing, standby equity distribution agreement as well as the monetization of receivables. Given the recent downturn in market sentiment due to the impact of the Coronavirus, material uncertainties remain as to whether the Company will succeed in securing such financing to support the going concern assumption to December 31, 2020.

In addition to the above measures, the Management and the Board of Directors are currently in evaluation with bondholders to restructure the CHF 60 million Senior Unsecured Convertible Bonds due in February 2022; such restructuring could likely include a significant reduction of the conversion price.

Shareholders should note that whilst the Management and Board of Directors continue to apply best efforts to evaluate available options, there is no guarantee that any transaction can be realized or that such transaction would generate sufficient funds to finance operations through December 31, 2020. This material uncertainty may cast significant doubts about the going concern of the Company.

However, the Management and the Board of Directors believe that the Company is 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, 2020. Hence, the consolidated financial statements have been prepared on a going concern basis.

2 Principles

General

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

Cash

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

Financial assets short-term

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

Current assets and liabilities

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

Loans to shareholdings

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

Investments in shareholdings

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

Convertible bonds

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.

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.

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, 2019: CHF 291 million; December 31, 2018: CHF 290.8 million). Until the end of 2015 the balance consisted of fully impaired and subordinated loans to Santhera Pharmaceuticals (Schweiz) AG. To finance the activities in development and the commercialization of LHON, in 2016 the loan granted to Santhera Pharmaceuticals (Schweiz) AG was increased (with the additional loans also being subordinated). As part of the annual reassessment as of December 31, 2019, Executive Management concluded that approximately 41% of the total loan balance is recoverable considering a more positive outlook, in terms of market success of the development progress in different indications (e.g. idebenone and vamorolone in DMD).

3.2 Investments in shareholdings

In 2019 and 2018, the following companies are direct subsidiaries of Santhera Pharmaceuticals Holding AG (100% ownership and 100% voting rights):

	Share capital at December 31	**2019**	**2018**
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	**2019**	**2018**
Santhera Pharmaceuticals (Liechtenstein) AG Ruggell, Fürstentum Liechtenstein	CHF	50,000	50,000
Santhera (Italy) S.r.l. 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 2019, the share capital was increased by a total amount of CHF 500,500 to CHF 11,165,063 as of December 31, 2019 (2018: CHF 10,664,563): The increase consisted two parts: 1) an increase through the issuance of 500,000 Shares from the authorized share capital in connection with a private placement and 2) an increase through the exercise of 500 employee stock options (from conditional capital).
On occasion of the Annual General Meeting, held May 29, 2019, the shareholders approved the increase of authorized the share capital at any time until May 27, 2021, through the issuance of up to 3,000,000 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 2,500,000 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, 2017	**9,921**	**335**
Purchase	157,436	3,413
Sale	-114,067	-2,844
December 31, 2018	**53,290**	**904**
Purchase	139,543	1,837
Sale	-137,941	-1,996
December 31, 2019	**54,892**	**745**

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	2019	2018
Administrative expenses	1,662	1,268
Consulting expenses	1,808	1,727
Expenses in connection with convertible bonds	0	0
Expenses in connection with capital increase	426	3,248
Total	**3,896**	**6,243**

4 Other Information

4.1 Full-time equivalents

The number of full-time equivalents at period end was not above 10 in 2019 and 2018.

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, 2019: 11,164,563 shares (December 31, 2018: 10,660,813 shares):

	2019 Shares	2019 %	2018 Shares	2018 %
Idorsia Pharmaceuticals Ltd., Switzerland	1,333,333	11.9	1,333,333	12.5
Bertarelli Ernesto, Guichard-Bertarelli Donata and Bertarelli Maria-Iris, Switzerland	759,371	6.8	759,371	7.1

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, 2019:

	Number of Shares	Number of vested equity rights	Number of unvested equity rights	Total number of equity rights
Board of Directors				
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
Executive Management				
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

As of December 31, 2018:

	Number of Shares	Number of vested equity rights	Number of un-vested equity rights	Total number of equity rights
Board of Directors				
Elmar Schnee, Chairman	12,000	2,244	20,833	23,077
Martin Gertsch, Vice-Chairman	38,109	5,970	21,679	27,649
Philipp Gutzwiller, Director	7,100	1,581	14,659	16,240
Thomas Meier, Director		--- See below ---		
Patrick Vink, Director	1,000	1,662	18,225	19,887
Executive Management				
Thomas Meier, CEO	79,402	20,670	38,366	59,036
Günther Metz, Head Business Development	0	23,201	23,956	47,157
Christoph Rentsch, Chief Financial Officer	0	22,979	33,920	56,899
Kristina Sjöblom Nygren, Chief Medical Officer & Head Development	0	0	36,937	36,937
Giovanni Stropoli, Chief Commercial Officer Europe and Rest of World, until September 30, 2018 [1]	250	20,751	0	20,751
Oliver Strub, General Counsel and Secretary to the Board	0	15,478	24,492	39,970

[1] Number of Shares as of March 31, 2018

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

	2019	**2019**	**2018**	**2018**
	Quantity	Value (in TCHF)[1]	Quantity	Value (in TCHF)[1]
Board of Directors	78,944	463	62,659	463
Executive Management	359,521	2,024	139,194	1,266
Employees of Santhera Group	634,497	3,583	420,429	5,809
Total	**1,072,962**	**6,070**	**622,282**	**7,538**

[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 17 *"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.

After the Annual General Meeting to be held in April 2020, it is planned to grant up to 785,000 share appreciation rights (**SAR**s) to employees of Santhera. These SARs are part of the bonus award for the year 2019 to employees of the Group. These SARs will be granted under ESARP 2019 (see note 17 *"Equity Rights Plans"*).

	Quantity	Value (in TCHF)[1]
Executive Management	112,500	510
Employees of Santhera Group	672,500	3,058
Total	**785,000**	**3,568**

[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 17 *"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 2021.

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

See note 1 *"Introduction"*.

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	2019	2018
Result carried forward	**-23,622,409**	**-13,751,583**
Net result of the year	-8,754,654	-9,870,826
Accumulated result	**-32,377,063**	**-23,622,409**
Result to be carried forward	**-32,377,063**	**-23,622,409**

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 (May 28, 2019)	81,192
Share premium from option exercise during 2019	1,614
Share premium of capital increase April 2019	6,199,350
Reserves from capital contribution	**6,282,156**
Transfer from reserves from capital contribution to other voluntary reserves (free reserves)	-6,000,000
Reserves from capital contribution	**282,156**

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 (May 28, 2019)	**77,994,714**
Transfer from reserves from capital contribution	6,000,000
Free reserves	**83,994,714**

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Ernst & Young Ltd
Aeschengraben 9
P.O. Box
CH-4002 Basle

Phone +41 58 286 86 86
Fax +41 58 286 86 00
www.ey.com/ch

To the General Meeting of
Santhera Pharmaceuticals Holding Ltd, Pratteln

Basle, March 23, 2020

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 71 to 80), for the year ended December 31, 2019.

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, 2019 comply with Swiss law and the company's articles of incorporation.

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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/ Karina Gawron
Licensed audit expert

Compensation Report

Contents

Introduction

This Compensation Report (**Report**) describes the principles of the compensation system of Santhera's Board of Directors (**Board**) and Executive Management (**EM**) members (**Executives**) and how the respective decisions are made. Furthermore, the Report discloses the compensation made to the Board and EM for 2019, 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:

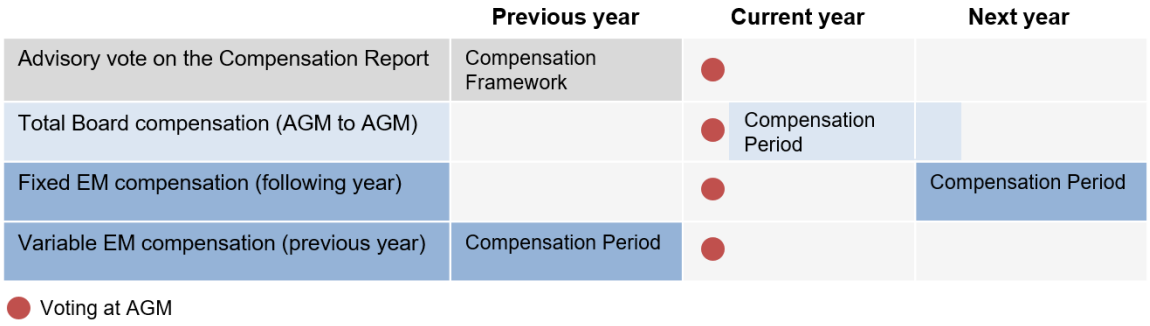
- The shareholders' resolutions with regard to the total compensation (fix cash and equity compensation) for the Board members;
- The respective shareholders' resolutions with regard to the compensation of the members of Executive Management The compensation shall include a fix base salary, a variable 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 Board may assign other tasks to the CC.

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 corporate and individual goals by the Executives.



Voting procedures at the AGM 2020

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

1. Consultative vote on the Compensation Report 2019.
2. Board

   The maximum total amount of the fixed compensation for the period between the AGM 2020 and the AGM 2021.
3. Executive Management

   3.1. The maximum total amount of the fixed compensation for the period from January 1, 2021 to December 31, 2021.

   3.2. The maximum total amount of the variable compensation for the period from January 1, 2019 to December 31, 2019.

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. The basis for comparison consists of almost 30

Swiss and international Biotech and Pharma companies[4] from which most of our talents are likely to join from. No benchmark analysis was conducted in the year 2019.

With respect to total compensation (base salary, allowances, annual cash bonus & share appreciation rights (**SAR**) entitlement), 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 assumes the payment of employer's social security contributions due on these amounts. Board members do not receive any variable compensation.

For more information about the underlying Plan, see note 17 *"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 bonus paid in cash
    - Annual grant of SAR

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, considering individual performance and the results of the external benchmarking.

Annual cash bonus

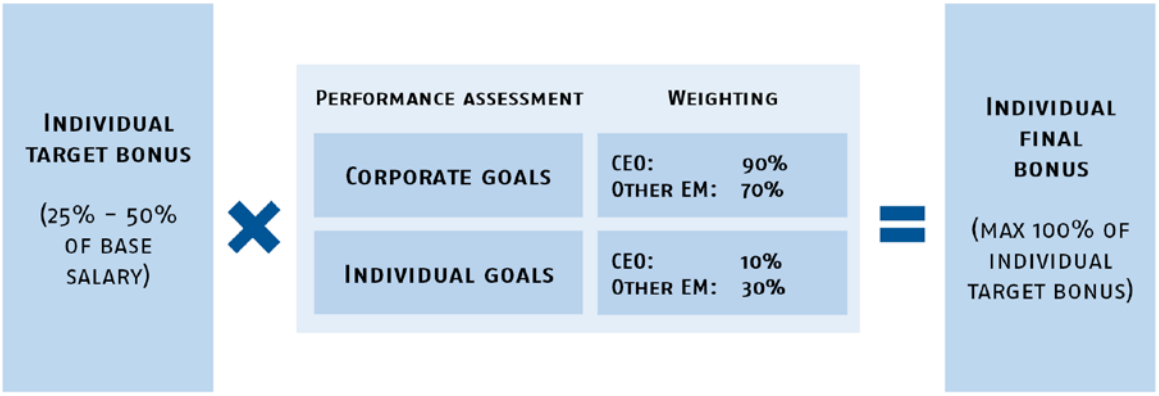
The annual cash bonus is based on the achievement of Company and individual goals and will be paid after the AGM until end of December of the same year, subject to the shareholders' approval. The target bonus, i.e. cash bonus to be paid if 100% of corporate and individual goals are met, is determined individually for

[4] Defined national and international peer group:
AC Immune, Alexion, Amgen, Basilea, Bayer, Cassiopea, Celgene, Cosmo, GSK, Jazz Pharmaceuticals, Lonza, Merck, Molecular Partners, Newron, Novartis, Pfizer, Roche, Sanofi, Siegfried, Shire, Straumann, Ypsomed, Vifor Pharma

each EM member as percentage of the base salary, ranging from 25% to 50%. The annual cash bonus is limited to a pay-out of maximum 100% of the target bonus.

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% and is unchanged with the new incumbent. The weighting of the achievement of corporate goals for the other Executives has been 70%.

Calculation of the individual annual bonus for EM members



Share Appreciation rights (SAR)

Under the Employee Share Appreciation Rights Plan (**ESARP**), members of the EM receive an annual individually allocated amount of Share Appreciation Rights (**SAR**) which is calculated as follows:

The Board defines for each EM function a certain percentage of the base salary 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, ranging from 100% to 120%.

The individual SAR amount is based on the achievement of corporate and individual goals and the same weightings apply as for the annual cash bonus. The percentage is limited to a percentage of maximum 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. 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.

For more information about the underlying Plan, see note 17 *"Equity Rights Plans"* in the consolidated financial statements.

Compensation awarded to the Board of Directors in 2019

Annual cash fees

At the AGM 2019, the shareholders approved a total cash compensation for the entire Board of a maximum of CHF 500,500. For the period between the 2019 and the AGM 2020, including social security contributions. The cash compensation of the Chairman of the Board is expected to amount to CHF 143,000, the cash compensation of the Vice Chairman of the Board to CHF 121,000 and the compensation of the other members of the Board to CHF 99,000 each. The former CEO of the Company, Thomas Meier, will not receive any additional compensation for his Board membership until the AGM 2020. The Chairman of the Audit Committee is expected to receive an additional amount of CHF 16,500; and the Chairman of the Compensation Committee an additional CHF 11,000. The members of the Audit Committee and of the Compensation Committee are expected to receive an additional amount of CHF 5,500 each.

Share Appreciation Rights (SAR)

At the AGM 2019, the shareholders approved a total maximum amount of CHF 500,500 to be granted in SAR for the period until the AGM 2020. In accordance with the Board Share Appreciation Rights Plan (**BSARP 2017**), 78,944 SARs were granted to the Board members (excluding Thomas Meier, as he does not receive a separate compensation for his Board mandate until the AGM 2020) as of May 29, 2019. The exercise price was the closing price of Santhera's share on May 29, 2019 and amounted to CHF 14.50 (2018: CHF 18.90).

Total Compensation

Function	Compensation (CHF)	Number	Total (CHF)
Chairman of the Board (**COB**)	286,000	1	286,000
Vice Chairman of the Board (**VC**)	242,000	1	242,000
Member of the Board	198,000	2*	396,000
Chairman of the AC	33,000	1	33,000
Member of the AC	11,000	1	11,000
Chairman of the CC	22,000	1	22,000
Member of the CC	11,000	1	11,000
Total			**1,001,000**

* Five Board members excluding Chairman, Vice Chairman and Santhera's CEO who has not and will not receive a separate compensation as member of the Board until the AGM 2020. The function of Vice Chairman will be abolished from the 2020 AGM onward.

Disclosure of compensation of members of the Board for the financial years 2019 and 2018 (audited)

In CHF	Annual cash fees	Stock options[1] SAR	Social security[1, 2]	Total compensation	Number of stock options/SAR granted
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**
2018					
Elmar Schnee	148,500	137,499	10,312	296,311	18,591
Martin Gertsch	127,315	127,315	19,651	274,281	17,214
Philipp Gutzwiller	96,759	96,762	14,935	208,456	13,083
Thomas Meier[3]	0	0	0	0	0
Patrick Vink	101,852	101,850	15,721	219,423	13,771
Total	**474,426**	**463,426**	**60,619**	**998,471**	**62,659**

[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 stock options is CHF 0 until stock options are exercised. Such stock option values are theoretical values and do not reflect income tax values and do also take into consideration certain vesting provisions.

[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. For all SARs held by Board members as of December 31, 2019, the social security contribution is CHF 0 since the SARS are not in-the-money. The total value of social security payments on options exercised by members of the Board during 2019 is CHF 0 (2018: CHF 0).

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

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

At the AGM 2019, the shareholders approved a maximum total amount of fixed compensation for the Board of CHF 500,500 for the period from the AGM 2019 to the AGM 2020. In addition, the shareholders approved the allocation of SAR with a fair market value of a maximum of CHF 500,500.

The table below represents the approved maximum compensation for the Board, the actual amounts paid in 2019 and those still payable until AGM 2020.

	Approved AGM 2019 - AGM 2020	Paid/payable AGM 2019 - AGM 2020
Board fees (CHF)	500,500	499,799
SAR[1] (CHF)	500,500	498,183
Total (CHF)	**1,001,000**	997,982
SAR (number)	n/a	78,944

[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 on the first trading day immediately following the AGM 2019 (CHF 5.8703).

Compensation awarded to the members of the Executive Management in 2019

Comparison of the approved and paid EM fixed compensation

At the AGM 2018, shareholders approved a maximum total compensation for the EM for 2019 as follows: CHF 3,200,000 for the fixed compensation in cash.

In CHF	Approved 2019	Paid 2019
Base salary	3,200,000	2,145,181

Annual cash bonus

The annual cash bonus for 2019 is based on the achievement of Company and individual goals and will be paid, subject to the shareholders' approval. The Company goals included the achievement of sales targets, the successful completion of a financing, the submission of a Marketing Authorization Application dossier for DMD to the EMA and certain preparatory business development activities for the implementation of the company's strategy. Sales targets were overachieved and a Marketing Authorization Application has been submitted timely. The achievement of all other goals ranged between 62.5% and 87.5% leading to the corporate target achievement was determined by the Board to amount to 86.7%.

The proposal to the shareholders at the AGM 2020 is for a maximum cash bonus payment of CHF 705,000 (of which a maximum of CHF 155,000 for social security contributions) and which shall be subject to Santhera meeting important milestones in the months to come which are relevant for the future development of the Company.

SAR entitlement in CHF

The annual SAR entitlement for 2019 is based on the achievement of Company and individual goals as described in section above "Annual cash bonus".

The proposal to the shareholders at the AGM 2020 is for a maximum SAR entitlement of CHF 930,000.

To calculate the number of SAR to be allocated, the total SAR amount would be divided by the fair market value of the SAR on the date of their grant (one business day after the AGM). The fair market value is calculated based on the share price on the trading day at the grant day, then applying the Hull-White model (excluding employer's social security contribution).

It was decided to cap the distributable group-wide SAR allocation numbers at 7.1% of the outstanding share capital to account for the shareholder dilution, the currently low share price, and the upside potential. Therefore, across the Company, the calculation of SARs will be adapted pro rata to ensure that the 7.1% threshold is not exceeded. Last year, the distributed SARs were representing 7.1% of the outstanding share capital.

Disclosure of compensation of members of the Executive Management for the years 2019 and 2018 (audited)

In CHF	Base salary	Allowances	Cash bonus[1]	SAR[1,3,6]	Social security and pension[3,4]	Total compen-sation	Number of SAR granted[5]
2019							
Dario Eklund	41,667	3,782	18,340	1,000,006[2]	83,638	1,147,433	184,248
Other 4 members of EM[7]	**1,696,710**	**0**	**523,798**	**510,113[1]**	**548,919**	**3,279,540**	**175,273**
Total	**1,738,377**	**3,782**	**542,138**	**1,510,119**	**632,557**	**4,426,973**	**359,521**
2018							
Thomas Meier	400,000	0	121,500	291,600	147,749	960,849	
Other 5 members of EM	**1,557,504**	**0**	**306,148**	**893,968**	**517,851**	**3,275,471**	
Total	**1,957,504**	**0**	**427,648**	**1,185,568**	**665,600**	**4,236,320**	

1 2019 information as proposal for approval by the AGM 2020.

2 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, 2019 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.

3 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.

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

5 Since the financial year 2018, the grant date for SAR is one business day after the AGM of a particular year. Therefore, number of SAR granted in the financial year 2019 represents the annual grant for the year 2018. Number of SAR granted in the financial year 2018, representing the annual grant for the year 2017, have been disclosed in the year 2017.

6 The distributable group-wide SAR allocation numbers will be capped at 7.1% of the outstanding share capital to account for the shareholder dilution, the currently low share price and the upside potential.

7 The compensation information includes the compensation and number of SAR granted for Thomas Meier until November 30, 2019, and the cash bonus 2019 for Thomas Meier for approval by the AGM 2020.

Changes in the Executive Management in 2019

Chief Executive Officer (CEO): Dario Eklund was appointed CEO of the Company effective December 1, 2019. Thomas Meier resigned as the CEO of the Company effective November 30, 2019. Since December 1, 2019, Thomas Meier does not serve as a member of the Executive Management team and continues, in addition to his Board membership, to advise the new CEO on a request basis until latest December 31, 2020. Thomas Meier will not be eligible to receive SAR for 2019 and 2020 and a cash bonus for the year 2020. Unvested Options/SAR granted will continue to vest according to the normal vesting schedule and according to the conditions of the ESARP (for Options/SARs granted until 1.12.2019).

Chief Financial Officer (CFO): Christoph Rentsch left the Company effective December 31, 2019. Unvested option/SAR granted will continue to vest according to the normal vesting schedule and according to the conditions of the ESARP (for options/SARs granted until 31.12.2019).

The designated successor, Andrew Smith, has been announced on January 24, 2020 and is appointed as CFO and member of the Executive Management Team effective April 1, 2020.

Event	Date	Number of Executives
Thomas Meier CEO step down	December 1, 2019	4
Dario Eklund assumes CEO position	December 1, 2019	5
Christoph Rentsch leaves Company	December 31, 2019	4

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 2019, 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 (2018: CHF 0) for such payments in 2019.

Disclosure of compensation of former Board members for the years 2019 and 2018 (audited)

In CHF	Total payment
2019	
n/a	0
Total	**0**
2018	
n/a	0
Total	**0**

With regard to the former EM members, Santhera made payments of CHF 41,225 in 2019 (2018: CHF 0).

Disclosure of compensation of former EM members for the years 2019 and 2018 (audited)

In CHF	Total payment
2019	
Thomas Meier	41,225
Total	**41,225**
2018	
n/a	0
Total	**0**

Shareholdings of Members of the Board and Executive Management

Disclosure of shareholdings in the Company of Board members for the years 2019 and 2018 (audited)

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**

December 31, 2018	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	2,244	20,833
Martin Gertsch	38,109	3,891	2,390	2,079	19,289
Philipp Gutzwiller	7,100	0	0	1,581	14,659
Thomas Meier[1]	0	0	0	0	0
Patrick Vink	1,000	0	0	1,662	18,225
Total	**58,209**	**3,891**	**2,390**	**7,566**	**73,006**

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

Disclosure of shareholdings in the Company of Executive Management members for the years 2019 and 2018 (audited)

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**

December 31, 2018	Number of shares	Number of stock options (vested)	Number of stock options (unvested)	Number of SAR (vested)	Number of SAR (unvested)
Thomas Meier	79,402	9,563	5,312	11,107	33,054
Günther Metz	0	16,560	2,560	6,641	21,396
Christoph Rentsch	0	14,750	7,250	8,229	26,670
Kristina Sjöblom Nygren	0	0	0	0	36,937
Giovanni Stropoli[1]	250	14,033	0	6,718	0
Oliver Strub	0	8,621	2,620	6,857	21,872
Total	**79,652**	**63,527**	**17,742**	**39,552**	**139,929**

[1] Giovanni Stropoli forfeited all his unvested Options/SAR on September 30, 2019, the effective date of his resignation.

Outlook for Board compensation

At the AGM 2020, the existing members are proposed to be re-elected as members of the Board. Among those proposed is Thomas Meier who shall for the first time receive a separate compensation as a Board member in the proposed total amount of CHF 198,000 (50% in the form of cash fees, including social security contributions, and 50% in the form of SAR for the period from AGM 2020 to the AGM 2021. It is further proposed, that Thomas Meier chairs the newly to be formed Scientific Committee, for which he shall receive a proposed compensation of CHF 22,000 for the period from AGM 2020 to the AGM 2021. The Vice Chairman role of the Board is proposed to be eliminated.

The Board will continue with the Audit Committee (**AC**), Compensation Committee (**CC**) and has approved the charter of the Scientific Committee (**SC**). Both 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)
Chairman of the Board (**COB**)	286,000	1	286,000
Member of the Board	198,000	4	792,000
Chairman of the AC	33,000	1	33,000
Member of the AC	11,000	1	11,000
Chairman of the CC	22,000	1	22,000
Member of the CC	11,000	1	11,000
Chairman of the SC	22,000	1	22,000
Member of the SC	11,000	1	11,000
Total			**1,188,000**

The total compensation of CHF 1,188,000 would be made 50% in the form of cash fees (including social security contributions) and 50% in the form of SAR. Therefore, the Board will propose a maximum total amount of 1,188,000 to the AGM 2020.

To calculate the number of SAR to be allocated, the total SAR amount of approximately CHF 552,500 (CHF 594,000 minus approximately CHF 41,500 for social security deductions) would be divided by the fair market value of the SAR on the date of their grant. The fair market value is calculated based on the share price on the trading day at the grant day, then applying the Hull-White model (excluding employer's social security contribution).

Outlook for EM compensation

The AGM 2019 has already approved the fix compensation for 2020 in the amount of CHF 3,000,000.

For the fix compensation for 2021, the Board will propose an amount of CHF 3,000,000 to the AGM 2020 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.

Ernst & Young Ltd
Aeschengraben 9
P.O. Box
CH-4002 Basle

Phone +41 58 286 86 86
Fax +41 58 286 86 00
www.ey.com/ch

To the General Meeting of
Santhera Pharmaceuticals Holding Ltd, Pratteln

Basle, March 23, 2020

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, 2019. 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 86 to 97 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, 2019 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/ Karina Gawron
Licensed audit expert

Corporate Governance Report

Contents

General Information

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

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

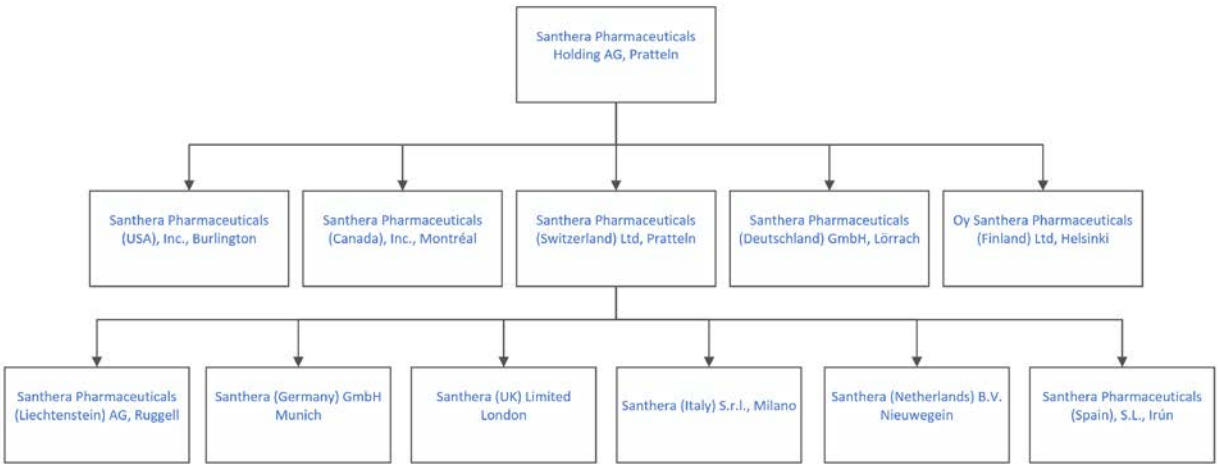
Group Structure and Shareholders (DCG 1)

Group structure (DCG 1.1)

Listed company

Name	Santhera Pharmaceuticals Holding AG (**Company**, together with its affiliates, **Santhera**)
Legal domicile	Hohenrainstrasse 24, 4133 Pratteln, Switzerland
Register number	CHE-105.388.338
Listing	SIX Swiss Exchange
Symbol	SANN
Security ID	2714864
ISIN	CH0027148649
Market capitalization	CHF 127 million (December 30, 2019)
Website	www.santhera.com
Duration of Company	Not limited
Subsidiaries	See following section as well as note 3.2 *"Investments in shareholdings"* to the statutory financial statements of the Company.

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



Company	Share Capital	Domicile	Activities
Santhera Pharmaceuticals (Schweiz) AG	CHF 125,000	Pratteln, CH	Headquarters; development of pharmaceutical drugs, administrative functions
Santhera Pharmaceuticals (Liechtenstein) AG	CHF 50,000	Ruggell, LI	Logistics/distribution
Santhera (Germany) GmbH	EUR 50,000	München, DE	Medical information
Santhera (Netherlands) B.V.	EUR 50,000	Nieuwegein, NL	Medical information
Santhera (UK) Limited	GBP 50,000	London, GB	Medical information
Santhera (Italy) S.r.l.	EUR 50,000	Milano, IT	Medical information
Santhera Pharmaceuticals (Spain), S.L.U	EUR 50,000	Irún, ES	Medical information
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).

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			
	Amount in CHF	As % of ordinary capital	Amount in CHF	As % of ordinary capital	Expiry	Section in Articles
Ordinary capital	11,164,563	100.0	11,165,063	100.0		3
Authorized capital	3,000,000	26.9	3,000,000	26.9	May 27, 2021	3a
Conditional capital for warrants/option rights granted in connection with debt instruments	2,500,000	22.4	2,500,000	22.4	For conversion rights: 10 years from issue date. For options: 7 years from issue date.	3c
Conditional capital for ESOP/BSOP/EIP	687,552	6.2	687,052	6.2		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 20 "Equity Rights Plans" to the consolidated financial statements.

Changes in share capital (DCG 2.3)

For changes in capital that occurred in 2017 and 2018, see the Company's Annual Report 2018, which can be downloaded at http://www.santhera.com/assets/files/financial_reports/2018-Santhera-Annual-Report_final.pdf. For changes that took place in 2019, 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, 2019, 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 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 of CHF 2,500,000, allowing for an issue of a maximum of 2,500,000 Shares with a nominal value of CHF 1 each.

Options, warrants

See the statutory financial statements of the Company and note 20 "*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[4]
Elmar Schnee[1]	1959	CH	2017	●		○	
Martin Gertsch	1965	CH	2006	⊙[5]	●		
Philipp Gutzwiller[1]	1968	CH	2017	○	○		
Thomas Meier[1, 2]	1962	DE	2017	○			●
Patrick Vink[1, 3]	1963	NL	2017	○		●	○

● = Chairman ⊙ = Vice 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.

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

4 The Board has established the charter of the Scientific Committee on March 12, 2020; the SC will formally start its work once the Board has constituted itself after the AGM.

5 The function of Vice Chairman will be abolished from the 2020 AGM onward.

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 Cardiorentis 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 Santhera's Vice Chairman[5] of the Board and Chairman of the Audit Committee since 2017. He had been Santhera's Chairman of the Board from 2006 to 2017. 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 ESBATech 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 of Evolva SA and the University Center of Dentistry (both 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 a non-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 has no other activities and vested interests.

Patrick Vink

Patrick Vink, born 1963, Dutch citizen, is Member of Santhera's Board and Chairman of the Compensation Committee since 2017. He is both a non-executive and an independent Board Member. Patrick Vink has an MD from Leiden University and an MBA from Rotterdam School of Management and University of Rochester.

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

[5] The function of Vice Chairman will be abolished from the 2020 AGM onward.

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 Pharmaceutics (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 25 "*Related Party Transactions*" to the consolidated financial statements.

Other activities and vested interests (DCG 3.2)

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

Permitted mandates in other companies (DCG 3.3)

See table in section on DCG 4.3.

Elections and terms of office (DCG 3.4)

According to the Company's Articles, the Board consists of no more than eight members. 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 2020 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).

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 teleconference 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 86).

Scientific Committee

The charter of Scientific Committee (**SC**) has been approved by the Board on March 12, 2020. After the AGM, when constituting itself, the SC will formally start to work. The Purpose of the SC is to assist the Board in its oversight of the Company's research and development strategy. Both CEO and Chief Medical Officer/Head of Development are to participate in such meetings. The SC shall report 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 2019

Corporate Body	In person meetings	Tele-conferences	Circular resolutions	Average duration
Board of Directors	5	9	1	~3¼ hrs
Audit Committee	3	1	0	~2 hrs
Compensation Committee	0	5	0	~1 hr

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 advisors to its meetings.

In the year under review, the Board discussed the Company's strategy, major projects and risks. The BoD resolved to out-license its LHON Business to Chiesi and to focus its operations on Duchenne muscular dystrophy (**DMD**). It consummated a share placement, started a collaboration with the Biozentrum, University of Basel, in Gene Therapy research and submitted a conditional marketing authorization application with the EMA for Puldysa in DMD. It continued the development of POL6014 in cystic fibrosis and announced the presentation of positive 18-month data by ReveraGen with vamorolone in DMD.

Among the key risks identified were the financial situation of the Company, the regulatory risk in the EU and the US 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 have been and are being implemented.

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. In addition, the Company had a consultant conduct select internal audits during the review period.

Executive Management (DCG 4 and 3.6)

The Executive Management consisted of five Executives.

Executive	Function	Nationality	Year of Birth
Dario Eklund	Chief Executive Officer[6]	AT/FI	1968
Thomas Meier	Chief Executive Officer[7], Board Member and Delegate of the Board[8]	DE	1962
Günther Metz	Head Business Development, EVP	DE	1958
Kristina Sjöblom Nygren	Chief Medical Officer & Head Development, EVP	SE	1961
Christoph Rentsch	Chief Financial Officer, EVP[9]	CH	1959
Oliver Strub	General Counsel & Secretary to the Board, EVP	CH	1963

On January 24, 2020, the Company announced the appointment of Andrew Smith as CFO and member of the Executive Management

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 of the Region Central Europe, the Head Region Western Europe, the Head Santhera US, the Head Group HR, and Head Technical Development & Operations - 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.

6 From December 1, 2019
7 Until December 1, 2019
8 Until December 1, 2019
9 Until December 31, 2019

Dario Eklund

Dario Eklund, born 1968, Finnish and Austrian citizen, is Santhera's CEO since December 1, 2019. He has an MSc in Economics 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, 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.

Thomas Meier

See section on "*Board of Directors"* (DCG 3).

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).

Christoph Rentsch

Christoph Rentsch, born 1959, Swiss citizen, joined Santhera as Chief Financial Officer (CFO) on July 1, 2015 and left the Company on December 31, 2019.

He holds a Master in Economics and Business Administration from the University of Applied Sciences, Basel.

Mr. Rentsch started his career in investment banking at Credit Suisse. Subsequently, he worked in various senior management functions for the Alusuisse-Lonza Group both in Switzerland and in the USA. He joined F. Hoffmann La Roche in 1994 and became Head of Group Funding and Capital Markets. For almost 10 years he was responsible for all of Roche's finance transactions on group level. In 2003, Mr. Rentsch became partner of Caperis Ltd, an investment management and life science advisory firm, before joining then still privately held Polyphor as CFO, where he supported the Company in key stages of its development.

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.

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.

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, 2019, 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	2019	2018
Audit services	413	325
Audit-related services	33	524

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 2020

The 2020 Annual General Meeting will be held on April 22, 2020 where a personal attendance will be impossible. See also www.santhera.com/investors-and-media/corporate-calendar.

Contact

Eva Kalias, Head External Communications
Phone +41 61 906 89 26
eva.kalias@santhera.com

Addresses

Santhera Pharmaceuticals Holding AG (Headquarters)
Santhera Pharmaceuticals (Schweiz) AG
Hohenrainstrasse 24
4133 Pratteln
Switzerland
Phone +41 61 906 89 50
Fax +41 61 906 89 51
office@santhera.com
www.santhera.com

Santhera (Germany) GmbH
Arnulfstrasse 199
80634 Munich
Germany
Phone +49 89 189 85 100
Fax +49 89 189 85 102

Santhera (UK) Ltd.
26-28 Hammersmith Grove
2nd Floor
London W6 7HA
United Kingdom
Phone +44 20 3434 5740

Santhera (Netherlands) B.V.
Ratelaar 40
3434 EW Nieuwegein
The Netherlands
Phone +31 30 820 1029

Santhera Pharmaceuticals (Spain) S.L.U.
Pol. Ind. Arretxe, Edificio Ugalde
Lamisingo Iturria 1, oficina 210
20305 Irun - Gipuzkoa
Spain
Phone +34 943 149 520

Santhera (Italy) S.r.l.
Via Rosellini 12
20124 Milano
Italy
Phone +39 02 69 311 926
Fax +39 02 60 73 6164

Santhera Pharmaceuticals (USA), Inc.
25 Corporate Drive, Suite 250
Burlington, MA 01803
USA
Phone +1 781 365 0301
Fax +1 781 365 0230

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 is building a Duchenne muscular dystrophy (DMD) product portfolio to treat patients irrespective of causative mutations, disease stage or age. A marketing authorization application for Puldysa® (idebenone) is currently under review by the European Medicines Agency. Santhera has an option to license vamorolone, a first-in-class anti-inflammatory drug candidate with novel mode of action, currently investigated in a pivotal study in patients with DMD to replace standard corticosteroids. The clinical stage pipeline also includes POL6014 to treat cystic fibrosis (CF) and other neutrophilic pulmonary diseases, as well as omigapil and 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® and Puldysa® are trademarks 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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let’s go further…

Santhera Pharmaceuticals Holding AG
Hohenrainstrasse 24
4133 Pratteln
Switzerland
Phone +41 61 906 89 50
Fax +41 61 906 89 51
www.santhera.com