santhera
THEIR FUTURE - OUR FOCUS

2021

Interim Condensed Report
January to June 2021

Report on the Six Months Ended June 30, 2021, and Interim Condensed Consolidated Financial Statements

Contents

Santhera Announces First Half-Year 2021 Financial Results and Updates on Corporate Progress

- Cash and cash equivalents of CHF 8.0 million (as of June 30, 2021)
- Net revenue CHF 4.5 million (H1-2020: CHF 7.8 million)
- Net result for period of CHF -20.5 million (H1-2020: CHF -31.8 million)

Pratteln, Switzerland, October 15, 2021 – Santhera Pharmaceuticals (SIX: SANN) announces the Company's financial results for the first half-year ended June 30, 2021, and provides an update on corporate progress.

"Our achievements in the first half of 2021 have moved us significantly closer to accomplishing key goals. The highlights in the period under review were undoubtedly the positive results of the Phase 2b VISION-DMD study at 24 weeks with vamorolone compared to placebo in Duchenne muscular dystrophy, paving the way for an NDA submission in the U.S. We are equally excited about the favorable tolerability profile of vamorolone versus prednisone, potentially addressing the high medical need for steroid efficacy with a safety profile differentiated from steroids on some key clinically meaningful parameters. On the financing side, we successfully restructured the Company's balance sheet and secured adequate funding to take us to mid-2022 or beyond key upcoming milestones," said **Dario Eklund, Chief Executive Officer of Santhera**. "These successes are crucial for both patients who are in great need of a better tolerated steroid therapy suitable for chronic treatment and for Santhera as they lay the foundation for renewed future growth. We are grateful for the continued support of patients and their caregivers, health care staff and investors, which will allow us to move forward with our strategy and execute our plans and ambitions."

OPERATIONAL HIGHLIGHTS

Recent developments

- Statistically highly significant 24-week results across multiple endpoints with vamorolone in pivotal Phase 2b VISION-DMD study
- Long-term treatment data with vamorolone demonstrating maintenance of effect over 2.5 years
- Positive results with lonodelestat in Phase 1b cystic fibrosis (CF) trial
- Primary endpoint met in Phase 4 LEROS trial with Raxone® in Leber's hereditary optic neuropathy (LHON)
- Restructuring activities (announced in October 2020) completed
- Completion of 2017/22 convertible bond exchange offer and issuance of a new 2021/24 convertible bond
- Share capital increases implemented as a basis to enable additional financing to secure operations, fund prelaunch activities for vamorolone and support advancement of pipeline
- Completion of financing to provide up to CHF 42 million net of fees and expenses to fund operations and current debt obligations

Upcoming milestones

- Q4-2021: Completion of vamorolone 48-week VISION-DMD study providing additional safety data
- Q4-2021: Conclusion of Raxone PAMs (post-authorization measures)
- Q1-2022: NDA (new drug application) filing in the US for vamorolone in DMD
- Q2-2022: Regulatory submission in Europe for vamorolone in DMD

Vamorolone—nearing regulatory submission to the US FDA

In June 2021, Santhera and ReveraGen BioPharma announced positive 24-week results from the VISION-DMD study, a pivotal Phase 2b study comparing vamorolone (2 or 6 mg/kg/day) to placebo and prednisone (0.75 mg/kg/day) in the treatment of Duchenne muscular dystrophy (DMD). The results demonstrated robust efficacy as the study met its primary endpoint of superiority in change of time from supine positioning to standing (TTSTAND) velocity with vamorolone 6 mg/kg/day versus placebo (p=0.002) with a treatment difference of 0.06 rises/second [95% CI: 0.02–0.10] from baseline. Likewise, the study also demonstrated superiority of vamorolone versus placebo across multiple secondary endpoints and established the efficacy of vamorolone at 2 and 6 mg/kg/day. Vamorolone is the only steroid to have shown efficacy for two doses across a three-fold dose range, allowing physicians for the first time to tailor treatment to the individual.

Already in April 2021, Santhera and ReveraGen announced new clinical data of 2.5-year treatment outcome with vamorolone in patients with Duchenne muscular dystrophy (DMD). These Phase 2a long-term treatment data demonstrated a maintenance of treatment effect, equivalent to a delay of about two years in decline for time to stand (TTSTAND) velocity, and confirmed safety and tolerability benefits of vamorolone over the 2.5-year follow up period. In comparison to reports from clinical trials with other corticosteroids, long-term treatment with vamorolone resulted in fewer of the side effects that are typically observed with those drugs.

Based on clinical trial results, including long-term safety data up to 30 months, vamorolone at doses up to 6 mg/kg/day was generally well-tolerated. Vamorolone treatment has been shown to preserve height trajectory and had a significantly lower adverse impact on measures of bone health and behavior changes compared to prednisone.

On the basis of the positive 24-week efficacy results from the pivotal VISION-DMD study and the demonstration of long-term benefits of vamorolone, Santhera is preparing for submission of a New Drug Application (NDA) in the US in Q1-2022, for which fast track designation was granted by the FDA.

In Q4-2021, the 48-week data readout delivering supplementary safety and tolerability data for vamorolone is expected upon completion of the VISION-DMD study. During the second period of the study, where all participants receive vamorolone treatment on either of the two dose levels, additional longer-term tolerability data is captured. The 48-week data will support the submission of a marketing authorization application in Europe in Q2-2022.

In September 2021, the FDA awarded a USD 1.2 million grant to ReveraGen under their “Clinical Studies of Orphan Products Addressing Unmet Needs of Rare Diseases (R01)” grants program to initiate a clinical trial of vamorolone in adults and children with Becker muscular dystrophy (BMD), a progressive muscle wasting disease similar to DMD, but usually milder. The mechanisms of actions, which provide the basis of vamorolone’s efficacy as demonstrated in the pivotal VISION-DMD study in the more severe DMD, are hypothesized to be relevant to BMD too.

Santhera intends to commercialize vamorolone for the treatment of DMD through its own organization in the United States and main markets in Europe, and is seeking collaborations outside those regions for DMD and for additional indications worldwide. Santhera estimates the peak product sales potential for vamorolone in the indication DMD alone to be in excess of USD 500 million in the US and the largest five European countries combined.

Lonodelestat—positive results in early phase cystic fibrosis trial

In March 2021, Santhera announced positive results of a Phase 1b study with lonodelestat, a potent and selective peptide inhibitor of human neutrophil elastase (hNE) in development to treat cystic fibrosis (CF). Neutrophil elastase is an enzyme associated with tissue inflammation, leading to degradation of the lung tissue in cystic fibrosis and several other acute and chronic inflammatory conditions of the lung where neutrophils play a prominent role in the disease process. The double-blind, placebo-controlled multiple ascending dose Phase 1b study in patients with CF

established a safe dose regimen and provided promising data on the safety of lonodelestat. Furthermore, the study demonstrated that lonodelestat is well tolerated at 40 mg and 80 mg daily doses and achieves the desired effect of near complete inhibition of elastase without any drug/metabolite accumulation.

The results from the safety analyses and the confirmed effect on the hNE biomarker by lonodelestat are very encouraging for further development in CF and other inflammatory lung diseases. On this basis, Santhera will now be refining the further clinical development program to advance lonodelestat for the treatment of CF and potentially for other inflammatory pulmonary conditions, whether acute or chronic.

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

In June 2021, Santhera announced positive topline results from its long-term Phase 4 LEROS study with Raxone (idebenone) in the treatment of LHON. The primary endpoint, the proportion of eyes with clinically relevant benefit after 12 months treatment with Raxone versus untreated patients from an external natural history control group, was met with high statistical significance (p=0.002). The efficacy data confirm and extend previous findings which demonstrated that Raxone can prevent further vision loss and promote recovery of vision in LHON patients.

The study, which was designed with guidance and approval from the European Medicines Agency (EMA), was part of a post-authorization commitment. The strong evidence of efficacy is expected to support market access in countries where this is not yet the case, allowing patients who have no therapeutic alternative to benefit from treatment with Raxone.

Santhera holds the EU marketing authorization for Raxone (idebenone) and out-licensed rights to the product outside North America and France for the treatment of LHON to Chiesi Group. Santhera is still commercializing Raxone for LHON in France in a transitional phase and, as previously communicated, is supplying the product free of charge since August 2021 following its removal from the list of reimbursed products and while reimbursement discussions are ongoing. The Company is entitled to contingent variable near- to mid-term milestone payments from Chiesi Group of up to EUR 49 million subject to the achievement of certain commercial milestones for Raxone.

Corporate restructuring completed and organization realigned to future priorities

By the end of March 2021, Santhera completed an organizational restructuring which reduced costs and prioritized the Company's resources for vamorolone as a consequence of the termination of the Puldysa® program in late 2020. The result is a lower cost base and streamlined organization, focused on bringing vamorolone to patients. In doing so, the core team will leverage its know-how in the DMD space, regulatory experience with the EMA and FDA, strong relationships with key clinical experts and the patient community as well as its proven track record of successfully commercializing a rare disease product.

On the back of the positive VISION-DMD study results, paving the way for an NDA submission to the US FDA, the Company has defined operational and organizational measures to allow for a successful first launch of vamorolone in the US which is expected earliest at the beginning of 2023. Attraction of key talents with a focus on the US market for pre-commercialization activities will begin as soon as additional funding has become available.

Prioritization of the development pipeline

Given the resource limitations, and in parallel to the alignment of its organizational structure, Santhera has conducted a pipeline review and prioritization. Going forward, the Company will focus on its lead clinical-stage projects vamorolone in DMD and lonodelestat in CF and has decided to abandon the further development of omigapil. In parallel, Santhera is proactively pursuing collaborations with partners to assess and exploit the potential

of both clinical stage compounds in other disease areas, beyond DMD and CF, as well as for its undertakings in gene therapy for congenital muscular dystrophies (CMD).

Capital restructuring and share capital increases implemented to enable adequate funding to execute strategy

In the first half-year 2021, the Company implemented various measures to strengthen the capital structure of Santhera and to secure sufficient flexibility to continue operations and advance the pipeline as anticipated.

On May 4, Santhera announced completion of the exchange offer in respect of its CHF 60 Million Convertible Bonds due 2022 (SIX: SAN17) and the issuance of CHF 30,270,375 Senior Unsecured Convertible Bonds due 2024 (SIX: SAN21). The restructuring of the 2017/22 Bonds enabled Santhera to proceed with raising additional financing and was therefore crucial to preserve the Company as a going concern until after such subsequent financing.

Santhera's shareholders gave consent to various capital increases in the first half-year 2021. At the Extraordinary General Meeting (EGM) held on March 18, the Board of Directors (BoD) proposed to shareholders the authorization and issuance of the shares for the upsized financing from a fund managed by Highbridge Capital Management, LLC, and the restructuring of its CHF 60 million Senior Unsecured Convertible Bonds. At the Annual General Meeting (AGM) held on June 22, the BoD proposed various capital increases to Santhera's shareholders to give the Company sufficient flexibility to raise additional capital to fund ongoing development activities, increase pre-commercialization activities and expand the organization in view of a US market launch of vamorolone as early as the beginning of 2023, subject to approval by the US FDA. Santhera's shareholders approved all motions by the BoD at both the EGM and the AGM, allowing the Company to proceed with its strategy and plans as foreseen.

On September 20, 2021 the Company announced a financing of up to CHF 45 million gross or CHF 42 million net of fees and expenses to provide funding through to mid-2022 past the NDA filing planned for Q1-2022. The financing comprised CHF 20 million in equity, CHF 15 million in a new 2021/24 convertible bond to be used for settlement of the CHF 15 million nominal value outstanding on the 2017/22 convertible bond maturing February 2022, together with a CHF 10 million in new senior secured exchangeable notes. A first tranche of CHF 2 million may be drawn after closing, on October 14, 2021, subject to certain customary conditions. A further tranche of CHF 5 million may be drawn if and when the FDA supports an NDA for vamorolone in DMD in the United States upon which a USD 5 million milestone payment to licensor ReveraGen becomes due. The remaining tranche of CHF 3 million is available subject to investor consent. The maturity of the term loan will be May 2024.

However, considering the Company's current planned strategy for the next 12 months, additional funds will be required to fund operations and material uncertainties remain as to the Company's ability to continue as a going concern until June 30, 2022.

KEY FINANCIALS AS OF JUNE 30, 2021

- Cash and cash equivalents of CHF 8.0 million
- Net revenue CHF 4.5 million (H1-2020: CHF 7.8 million)
- Net result for period of CHF -20.5 million (H1-2020: CHF -31.8 million)

Financial liquidity as of June 30, 2021

As of June 30, 2021, the Company had cash and cash equivalents of CHF 8.0 million compared to CHF 12.4 million as of December 31, 2020. The decrease was primarily due to support of ongoing development and completion of organizational restructuring activities.

Net cash used in operating activities was CHF 18.6 million for the six months ended June 30, 2021, compared to CHF 19.8 million for the six months ended June 30, 2020.

Following financing activities, including the convertible bond 2017/22 exchange for 2021/2024 convertible bond overall net equity at June 30, 2021 increased to CHF 8.4 million from a deficit of CHF 6.4 million as at December 31, 2020.

Financial results for the six months ended June 30, 2021

For the six months ended June 30, 2021, the Company recorded a net loss of CHF 20.5 million, or CHF 0.92 per share, compared to a net loss of CHF 31.8 million or CHF 2.78 per share for the six months ended June 30, 2020.

Total revenue was CHF 4.5 million and CHF 7.8 million for the six months ended June 30, 2021, and June 30, 2020, respectively. The majority of this revenue reflects sales of Raxone for the treatment of LHON in France where Santhera continues to supply the product following the outlicensing and transfer to Chiesi Group in 2019. The decrease in revenues is mainly attributable to a CHF 2.0 million adjustment to defer revenues recorded in the first half-year 2021 due to uncertainties around pricing and reimbursement in France, as well as an agreement with the regulatory authorities in France to supply Raxone free of charge from August 2021 while reimbursement discussions are ongoing.

Development were CHF 13.6 million and CHF 17.7 million for the six months ended June 30, 2021, and June 30, 2020, respectively. The decrease in expenses was primarily due to lower contract research organization expenses and other third-party clinical trial expenses following the termination of the Puldysa Phase 3 SIDEROS study, offset by increased expenses to support the development of vamorolone to the recently announced 24-week, in addition to a reduction in staff costs following organizational restructuring.

Marketing and sales expenses were CHF 2.0 million and CHF 6.8 million for the six months ended June 30, 2021 and June 30, 2020 respectively. The decrease was primarily a result of the ceasing of Puldysa activities following the termination of the program announced in October 2020. Ongoing expenses relate to pre-commercialization activities for vamorolone and meeting ongoing obligations in relation to Raxone out-licensed to Chiesi Group.

General and administrative expenses were CHF 6.3 million and CHF 7.2 million for the six months ended June 30, 2021 and 2020 respectively, the decrease was primarily related to the organization restructuring announced in October 2020.

Interim Condensed Consolidated Financial Statements

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Interim Consolidated Balance Sheet

In CHF thousands	Notes	**June 30, 2021 (reviewed)**	Dec. 31, 2020 (audited)
Assets			
Tangible assets		1,604	1,902
Intangible assets		66,122	67,673
Financial assets long-term		521	552
Deferred tax assets		320	837
Noncurrent assets		**68,567**	**70,964**
Prepaid expenses		421	344
Inventories	5	437	481
Trade and other receivables		2,801	4,487
Cash and cash equivalents	6	7,991	12,411
Current assets		**11,650**	**17,723**
Total assets		**80,217**	**88,687**
Equity and liabilities			
Share capital	7	31,304	19,430
Capital reserves and share premium		502,468	480,005
Retained earnings		-521,418	-500,899
Employee benefit reserve		-1,177	-2,320
Treasury shares		-1,875	-1,580
Other components of equity		-949	-990
Total equity		**8,353**	**-6,354**
Convertible bonds	8	14,780	57,875
Noncurrent derivative financial instruments	8	4,973	-
Noncurrent lease liabilities		1,629	1,927
Pension liabilities		5,828	6,170
Total noncurrent liabilities		**27,210**	**65,972**
Trade and other payables		3,065	5,715
Accrued expenses		11,505	8,645
Income tax payable		37	60
Current provisions	9	294	2,034
Current contract liabilities		563	1,126
Current lease liabilities		748	769
Convertible Bonds	8	14,849	-
Current exchangeable notes	8	11,360	10,595
Current derivative financial instruments	8	2,233	125
Total current liabilities		**44,654**	**29,069**
Total liabilities		**71,864**	**95,041**
Total equity and liabilities		**80,217**	**88,687**

Interim Consolidated Income Statement (Reviewed)

For the half-year ended June 30, in CHF thousands	Notes	2021	2020
Net sales	10	2,853	6,133
Net sales to licensing partner	10	1,639	1,642
Revenue from contracts with customers		**4,492**	**7,775**
Cost of goods sold		-2,031	-2,114
Of which amortization intangible asset		*-1,519*	*-1,519*
Other operating income		-	357
Development	11	-13,592	-17,688
Marketing and sales	11	-2,008	-6,766
General and administrative	11	-6,307	-7,209
Other operating expenses	11	-31	-248
Operating expenses	**11**	**-21,938**	**-31,911**
Operating result		**-19,477**	**-25,893**
Financial income	12	13,957	547
Financial expenses	12	-14,346	-6,120
Result before taxes		**-19,866**	**-31,466**
Income taxes	13	-653	-361
Net result		**-20,519**	**-31,827**
Basic and diluted loss per share (in CHF)		-0.92	-2.78

Interim Consolidated Statement of Comprehensive Income (Reviewed)

For the half-year ended June 30, in CHF thousands	2021	2020
Net result	**-20,519**	**-31,827**
Items never to be reclassified subsequently to net income in subsequent periods:		
Net actuarial gains/(losses) from defined benefit plans	1,143	132
Items to be reclassified subsequently to net income in subsequent periods:		
Currency translation differences	41	-90
Other comprehensive result	**1,184**	**42**
Total comprehensive result	**-19,335**	**-31,785**

Interim Consolidated Statement of Cash Flows (Reviewed)

For the half-year ended June 30, in CHF thousands	Notes	2021	2020
Result before taxes		**-19,866**	**-31,466**
Depreciation of tangible assets		342	789
Amortization of intangible assets		1,551	1,567
Expenses for equity rights plans		1,152	1,749
Change in fair value of derivatives	8	-312	-339
Change in pension liabilities		-342	565
Use of current provisions	9	-589	-
Taxes paid		-159	-208
Change in net working capital		760	3,562
Total financial result	12	389	5,574
Interest received		-	1
Interest paid		-1,533	-1,589
Cash flow (used) in operating activities		**-18,607**	**-19,795**
Investments in tangible assets		-44	-24
Investments in intangible assets		-	-5
Change in investments in other financial assets long-term		-31	35
Change in restricted cash		-	1,500
Cash flow from investing activities		**-75**	**1,506**
Proceeds from sale of treasury shares		81	598
Purchase of treasury shares		-56	-633
Proceeds from convertible notes	8	17,000	6,983
Payment of lease liabilities		-392	-543
Transaction costs		-2,357	-
Cash flow from financing activities		**14,276**	**6,405**
Effects of exchange rate changes on cash and cash equivalents		-14	-121
Net increase/(decrease) in cash and cash equivalents		**-4,420**	**-12,005**
Cash and cash equivalents at January 1		12,411	31,358
Cash and cash equivalents at June 30		**7,991**	**19,353**

Interim Consolidated Statement of Changes in Equity (Reviewed)

In CHF thousands	Notes	Share capital	Capital reserves and share premium	Retained earnings	Employee benefit reserve	Treasury shares	Trans-lation differ-ences	**Total**
Balance at January 1, 2020		**11,165**	**448,084**	**-433,240**	**-3,160**	**-745**	**-857**	**21,247**
Net result		-	-	-31,827	-	-	-	**-31,827**
Other comprehensive income		-	-	-	132	-	-90	**42**
Total comprehensive result for the period		**-**	**-**	**-31,827**	**132**	**-**	**-90**	**-31,785**
Share-based payment transactions	14	-	1,749	-	-	-	-	**1,749**
Capital increase from conversions of loans	8	1,945	7,484	-	-	-1,036	-	**8,393**
Capital increase	7	75	566	-	-	-	-	**641**
Change in treasury shares		-	-191	-	-	156	-	**-35**
Balance at June 30, 2020		**13,185**	**457,692**	**-465,067**	**-3,028**	**-1,625**	**-947**	**210**
Balance at January 1, 2021		**19,430**	**480,005**	**-500,899**	**-2,320**	**-1,580**	**-990**	**-6,354**
Net result		-		-20,519	-	-	-	**-20,519**
Other comprehensive income		-		-	1,143	-	41	**1,184**
Total comprehensive result for the period		**-**		**-20,519**	**1,143**	**-**	**41**	**-19,335**
Share-based payment transactions	14	-	1,152	-	-		-	**1,152**
Capital increase for financing transactions	8	11,874	-	-	-	-11,695	-	**179**
Delivery of shares upon conversions of notes		-	14,154	-	-	6,394	-	**20,458**
Delivery of shares on conversion of convertible bonds and settlement of make whole and interest		-	7,954	-	-	4,249	-	**12,203**
Delivery of shares for financing facility		-	-	-	-	233	-	**233**
Cost of issuance of capital		-	-545	-	-	-	-	**-545**
Change in treasury shares		-	-252	-	-	524	-	**272**
Balance at June 30, 2021		**31,304**	**502,468**	**-521,418**	**-1,177**	**-1,875**	**-949**	**8,353**

Notes to the Interim Condensed Consolidated Financial Statements (Reviewed)

1 General Information

Santhera Pharmaceuticals Holding AG (the **Company**, together with its subsidiaries **Santhera** or **Group**) is a 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 rare indications with high unmet medical needs.

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

The consolidated interim financial statements were approved for publication by the Board of Directors (**Board**) on October 15, 2021.

2 Summary of Significant Accounting Policies

The accounting policies used in the preparation of the interim condensed consolidated financial statements are consistent with those used in the preparation of the Group's annual consolidated financial statements for the year ended December 31, 2020, except for the changes in accounting policies as noted further below.

Basis of preparation

These interim condensed consolidated interim financial statements were prepared in accordance with IAS 34, Interim Financial Reporting, of the International Financial Reporting Standards (**IFRS**) and should be read in conjunction with the Group's annual consolidated financial statements for the year ended December 31, 2020.

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

Material uncertainties and ability to continue operations

The interim condensed consolidated financial statements have been prepared under the going concern assumption despite several material uncertainties present as at June 30, 2021 that may be contrary to this assumption.

Following the announcement of the discontinuation of development of Puldysa (Idebenone) in patients with Duchenne muscular dystrophy (DMD) in October 2020 and the subsequent organizational restructuring, the Company required additional funds in order to reach the next inflection point, the topline results of the pivotal Phase 2b study with vamorolone.

In February 2021, the Company increased its financing facility by CHF 12 million that provided liquidity through the third quarter of 2021. As of June 30, 2021, CHF 3 million was remaining under this facility and was fully drawn during August 2021.

In May 2021, the Company closed an exchange of its 2017/22 convertible bond, resulting in 75% being exchanged for a new 2021/2024 convertible bond with new terms, thereby reducing the overall debt obligation by CHF 15 million. Because 25% of the 2017/22 convertible bond was not exchanged, of the original nominal value of CHF 60

million of the 2017/22 convertible bond, a nominal value of CHF 15 million (or a carrying amount of CHF 14.9 million) remains unchanged with a maturity date in February 2022. The new 2021/24 bond was issued with a nominal value of CHF 30 million maturing August 2024 and, as of June 30, 2021, bonds with a nominal value of CHF 10 million have been converted resulting in a remaining obligation of CHF 20 million at nominal value (carrying amount of CHF 14.8 million).

On June 1, 2021, the Company announced positive topline results from the pivotal Phase 2b study with vamorolone, and on June 22, 2021, shareholders endorsed capital increases that would support a future financing transaction, with approved increases in ordinary capital and associated authorized and conditional increases available until September 22, 2021.

On September 20, 2021 the Company announced a financing of up to CHF 45 million gross or CHF 42 million net of fees and expenses to provide funding through to mid-2022 (see also subsequent events). The financing comprised CHF 20 million in equity, CHF 15 million in a new 2021/24 convertible bond to be used for settlement of the CHF 15 million nominal value outstanding on the 2017/22 convertible bond maturing February 2022, together with a CHF 10 million in new senior secured exchangeable notes. A first tranche of CHF 2 million may be drawn after closing, on October 14, 2021 subject to certain customary conditions. A further tranche of CHF 5 million may be drawn if and when the FDA supports an NDA for vamorolone in DMD in the United States upon which a USD 5 million milestone payment to licensor ReveraGen becomes due. The remaining tranche of CHF 3 million are available subject to investor consent. The maturity of the term loan will be May 2024.

Following the positive 24-week results from the VISION-DMD study, a pivotal Phase 2b study comparing vamorolone (2 or 6 mg/kg/day) to placebo and prednisone (0.75 mg/kg/day) in the treatment of Duchenne muscular dystrophy (DMD) was announced in June 2021. The results of the 48-week data readout delivering supplementary safety and tolerability data for vamorolone is expected upon completion of the VISION-DMD study during the fourth quarter of 2021. The 48-week data is intended to support the submission of a marketing authorization application in Europe in Q2-2022. The outcome of the 48-week period, if negative, may delay or otherwise adversely affect the anticipated regulatory submissions (FDA and EMA) planned for 2022.

As of June 30, 2021, the Company had cash and cash equivalents in the amount of CHF 8.0 million. However, considering the Company's current planned strategy for the next 12 months, additional funds will be required to fund operations and material uncertainties remain as to the Company's ability to continue as a going concern until June 30, 2022. Executing the Company's strategy significantly depends on the following:

- The results of the 48-week data readout delivering supplementary safety and tolerability data for vamorolone expected during the fourth quarter of 2021 and the NDA filing with the FDA expected in Q1 2022.
- Funding, in addition to the funding described above (arranged in September 2021), in order to ensure the execution of the Company's planned strategy through June 30, 2022 and beyond.
- Continued revenue from Raxone, as well as no material adverse events as it relates to the reimbursement status of Raxone in France.
- Ability to initiate cost savings or to delay costs (e.g., stop or delay certain development activities).
- Ability to settle current debt obligations.

Shareholders should note that whilst the management and the Board of Directors continue to apply best efforts to evaluate available options, there is no guarantee that the financing may be fully utilized or other sources would generate sufficient funds to finance operations through June 30, 2022. This material uncertainty may cast significant doubt 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 June 30, 2022. Hence, the consolidated financial statements have been prepared on a going concern basis.

Financial liabilities

The Company classifies its financial liabilities into two categories: Financial liabilities at fair value through profit or loss. This category includes derivatives with negative replacement values. They are initially recognized at their fair value. Any subsequent change in fair value is recognized in the income statement in the period the changes occur. Derivatives may be embedded in other contractual arrangements. The Company accounts for an embedded derivative separately from the host contract when:

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

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

Other liabilities measured at amortized costs

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

Changes in accounting policies

The adopted accounting policies are consistent with those of the previous accounting period.

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

3 Seasonality

The operating result is not subject to significant seasonal variations during the financial year.

4 Exchange Rates of Principal Currencies

	Income statement in CHF		**Balance sheet in CHF**	
	average rates for half-year ended		as of period end	
	June 30, 2021	June 30, 2020	**June 30, 2021**	Dec. 31, 2020
1 Euro (**EUR**)	**1.0945**	**1.0639**	**1.1000**	1.0822
1 US dollar (**USD**)	**0.9091**	**0.9660**	**0.9095**	0.8812
1 British pound (**GBP**)	**1.2564**	**1.2179**	**1.2647**	1.2036
1 Canadian dollar (**CAD**)	**0.7230**	**0.7085**	**0.7409**	0.6911

5 Inventories

This position consists mainly of active pharmaceutical ingredients and semi-finished products which are kept by Santhera as stock for market supply, development and inventory risk management purposes (security stock) for Raxone.

6 Cash and Cash Equivalents

6.1 Cash and cash equivalents

In CHF thousands	**June 30, 2021**	Dec. 31, 2020
Cash at banks and on hand		
in CHF	6,855	11,183
in EUR	873	913
in USD	121	74
in GBP	44	130
In CAD	30	48
other currencies	68	63
Total at period end	**7,991**	**12,411**

7 Share Capital

7.1 Ordinary share capital

During the reporting period ending June 30, 2021, 11,873,816 Shares were issued out of the authorized and conditional share capital for financing arrangements in connection with financing facilities (see note 8 “Financial Liabilities”). As a result, as of June 30, 2021, the issued nominal share capital amounted to CHF 31,303,512, divided into 31,303,512 Shares at a nominal value of CHF 1 each.

7.2 Authorized share capital

In the six months to June 2021, the aggregate amount of 9,155,184 Shares was issued out of the authorized share capital and 2,718,732 from conditional capital in connection with financing arrangements. On the occasion of the Annual General Meeting (**AGM**) on June 22, 2021, Santhera’s shareholders approved the increase of the authorized share capital of the Company. The Board is authorized to increase the share capital at any time until June 21, 2023, through the issuance of up to 14,381,755 Shares with a nominal value of CHF 1 each.

7.3 Conditional share capital

As of June 30, 2021, the Company had conditional share capital pursuant to which the share capital may be increased by

(i) a maximum amount of CHF 5,537,052 (2020: CHF 687,552) through the issuance of up to 5,537,052 (2020: 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 13 “Equity Rights Plans”).

(ii) a maximum amount of CHF 6,304,703 (2020: CHF 2,500,000) by issuing up to 6,304,703 (2020: 2,500,000) Shares through the exercise of warrants/options and/or notes granted in connection with bonds or similar debt instruments linked with option and/or conversion rights granted by the Company.

8 Financial Liabilities

8.1 Financial current and noncurrent liabilities – Convertible bonds

On February 17, 2017, Santhera issued senior unsecured 2017/22 convertible bonds in the nominal amount of CHF 60 million. The bonds, listed on the SIX, are interest bearing (5%) with a maximum term of 5 years and are convertible into registered Shares of Santhera with a nominal value of CHF 1 each. The initial conversion price was fixed at CHF 86.4006 and was reset in accordance with the terms of the bond in February 2018 to CHF 64.80. In addition, Santhera may call the convertible bonds at any time on or after the second anniversary of the issue date at par, plus accrued interest, if any, if the volume weighted average price (**VWAP**) of the Shares is at least 160% of the conversion price. The convertible bonds are measured at amortized costs applying the effective interest method. As of June 30, 2021, the remaining aggregate principal amount of the 2017/22 Bonds was CHF 15.2 million. To the extent that the Company does not repurchase or redeem these 2017/22 Bonds, such 2017/22 Bonds continue to be outstanding and will become due for redemption on February 17, 2022. The fair value of the 2017/22 bond (Level 1) at June 30, 2021 amounts to CHF 12.8 million (December 31, 2020: CHF 18 million).

On March 25, 2021 Santhera announced an exchange offer for the 2017/22 convertible bonds due in 2022. The holders of the 2017/22 bonds who accepted the exchange offer received, for each of their 2017/22 bonds, one new bond issued in 2021 with a maturity in 2024 (2021/24 convertible bonds) and 26 shares on exchange. The 2021/24 convertible bonds were offered as consideration for the 2017/21 convertible bonds. Santhera did therefore not receive any cash proceeds for the issue of 2021/24 bonds.

The nominal amount of the new convertible bond is CHF 30.3 million. The bonds, listed on the SIX, are interest bearing (7.5%) with a maximum term of 39 months and are convertible into registered Shares of Santhera with a nominal value of CHF 1 each. The initial conversion price is fixed at CHF 3.0029. In addition, Santhera may call the convertible bonds at any time on or after the second anniversary of the issue date at par, plus accrued interest, if any, if the VWAP of the Shares is at least 150% of the conversion price. The convertible bonds are measured at amortized costs applying the effective interest method. As of June 30, 2021, 2021/24 Bonds with an aggregate nominal value of CHF 10.7 million had been converted and the remaining outstanding aggregate principal amount of the 2021/24 Bonds was CHF 19.7 million. The fair value of the bond (Level 1) at June 30, 2021, amounts to CHF 21.3 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 June 30, 2021, was 81%. At June 30, 2021, the value of the embedded derivative was CHF 5.0 million. The change in the fair value was recognized in the financial result and amounted in 2021 to CHF 0.3 million.

The Convertible bonds are accounted for at amortized costs. The following table shows the amounts of the convertible bonds as of June 30, 2021 and December 31, 2020.

In CHF thousands	Maturity date	Nominal amount		Carrying amount	
		Jun 30, 2021	Dec 31, 2020	Jun 30, 2021	Dec 31, 2020
2017/2022 convertible bonds	February 17, 2022	15,155	60,000	14,849	57,875
2021/2024 convertible bonds	August 17, 2024	19,568	-	14,780	-
Total		**34,723**	**60,000**	**29,629**	**57,875**

Changes in financial liabilities from convertible bonds and their derivative financial instruments

In CHF thousands	Current Convertible bonds 2017/22	Noncurrent Convertible bonds 2022/24	Noncurrent derivative financial instruments
December 31, 2019	**56,154**	**-**	617
Change in fair value of derivative financial instruments	-	-	-339
Effective interest/amortized cost calculation/amortization of transaction cost	843	-	
June 30,2020	**56,997**	**-**	**278**
Change in fair value of derivative financial instruments	-	-	-278
Effective interest/amortized cost calculation	878	-	-
December 31, 2020	**57,875**	**-**	**-**
Redemption on exchange	-44,845	-	-
Issue on exchange	-	30,270	-
Initial recognition of derivative financial instruments	-	-7,693	7,693
Nominal value of convertible bonds converted into shares	-	-10,702	-
Derecognition of derivative financial instruments on conversion into shares	-	-	-2,408
Effective interest/amortized cost calculation on converted bonds/change in fair value	-	2,720	-312
Effective interest/amortized cost calculation	1,819	185	-
June 30, 2021	**14,849**	**14,780**	**4,973**

8.2 Financial current liabilities – Equity-linked financing arrangements with Highbridge

In July 2020, the Company and certain of the Company's subsidiaries entered into a subscription agreement with a fund managed by Highbridge Capital Management LLC (any such entity, "Highbridge"), providing for the issuance of an aggregate principal amount of originally up to CHF 20.0 million in senior secured exchangeable notes with a principal amount of CHF 5,000 each (the "Exchangeable Notes"), issued by Santhera Pharmaceuticals (Schweiz) AG ("Santhera Schweiz"), subject to certain conditions and in tranches, and exchangeable for Shares. As consideration for the commitment and utilization of the original financing, Highbridge received 300,000 Shares.

Under the Exchangeable Notes, Santhera Schweiz agreed to pay a fixed interest, which the Company could pay in cash at a rate of 12% per annum or in Exchangeable Notes at a rate of 13% per annum. Subject to certain restrictions, Highbridge could elect to exchange Exchangeable Notes for Shares at any time, at an exchange price of 90% of the VWAP of the Shares on the exchange date, subject to a floor price. The Exchangeable Notes would have become due for redemption at their principal value on January 13, 2022, if not exchanged or redeemed prior to that date. The Exchangeable Notes were guaranteed by the Company and certain subsidiaries of the Company and secured by a comprehensive security package, including security over all shares in Santhera Schweiz and other subsidiaries of the Company as well as over the Group's material intellectual property and other assets of the Group. Of the original aggregate principal amount of up to CHF 20 million, Exchangeable Notes in the aggregate principal amount of CHF 7.5 million were issued and fully exchanged by October 2020. The unused amount of up to CHF 12.5 million could no longer be drawn down by Santhera Schweiz following the termination of the development program with regard to Puldysa announced in October 2020.

In November 2020, the Company, Santhera Schweiz and Highbridge agreed to replace the commitment with respect to such amount by a commitment with respect to new Exchangeable Notes in the aggregate principal amount of up to CHF 10 million (the "Further Notes") and changed some of their terms, including a lowering of the floor price. Santhera Schweiz has issued Further Notes in the full aggregate principal amount of CHF 10 million to Highbridge; such Further Notes have been fully exchanged. The Further Notes were secured in the same way as the Exchangeable Notes.

On December 2, 2020, Santhera entered into a subscription agreement to issue exchangeable notes in four tranches in an aggregate principal amount of up to CHF 10 million to Highbridge. Each note is convertible at the discretion of its holder into a number of shares. In February, 2021 Santhera and Highbridge agree on an amendment of the original agreement which increases the principal amount to CHF 22 million. During the first half of the year, Santhera received CHF 17 million of the total amount whereas a nominal amount of CHF 14.25 million has been fully converted into shares of Santhera Pharmaceuticals Holding, a nominal amount of CHF 2.75 million (without accrued interest) of the tranche is outstanding as of June 30, 2021.

During 2021, the Company has amended different equity-linked financing agreements in order to receive additional liquidity in support of the Company's ongoing development pipeline. Commitment fees for the amendments to Highbridge facilities, warrants, equal to 15% of the total aggregate amount of the remaining existing facility and new money tranches, were issued and are exercisable into Santhera Shares at the discretion of Highbridge. A total of 984,769 warrants with a fair value of CHF 1.58 per warrant, were issued and represent transaction costs. The warrants are classified as financial liabilities at initial recognition and subsequently as the fixed-for-fixed criteria is not fulfilled.

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

The embedded financial derivatives, are valued by an independent consultant at period end at fair value, applying a simulation-based valuation approach. They are classifying as Level 3 financial instruments in the fair value hierarchy. Some input parameters may not be observable in the market and may be derived from market prices or rates or estimated based on assumptions. One of the significant unobservable inputs is the volatility, which is derived from the Company's historical stock price. The period of volatility data used is measured according to the

remaining life of the exchangeable note. The observed volatility as of June 30, 2021 amounts to 102%. There are also assumptions made based on the expected remaining lifetime and in connection with that the expected exercise date which is October 5, 2021. By construction, the compound financial instrument issued to Highbridge will be exercised early, before maturity. For valuation purposes, it was therefore assumed that the expected exercise date is between the investing date and the maturity date.

As of June 30, 2021, the carrying amount of the host for notes issued but not yet converted amounted to CHF 1.4 million is included in the balance sheet under current exchangeable notes and the separated embedded derivative is included with a fair value of CHF 0.7 million in current derivative financial instruments.

Sensitivity

For Level 3 financial liability, the sensitivity analysis below represents the potential absolute change in fair value for each category. The favorable and unfavorable effects on the result before taxes, resulting from using reasonably alternative assumptions for the valuation of the Exchangeable Notes to Highbridge and the Convertible Note have been calculated by recalibrating the modes using unobservable inputs based on an average volatility of 5%.

	June 30, 2021	
	Increase/decrease in volatility assumption	Effect on result before taxes on CHF thousand
Change in volatility for Highbridge	+5%	-664
	-5% (or more)	688
Change in volatility the 2021/24 convertible bond	+5%	-3,914
	-5% (or more)	3,719

The analysis as of June 30, 2021, shows that an increase in volatility leads to an increase of the fair value of the conversion right which is in line with general option theory.

8.3 Financial current liabilities – Equity-linked financing Idorsia Exchangeable Note

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

The exchangeable notes issued to Idorsia represent compound financial instruments, including a host contract which classifies as a financial liability and different embedded derivatives that have been valued as one compound derivative. The financial liability is initially recognized under current exchangeable notes with an amount of CHF 9.9 million (December 31, 2020: CHF 9.9 million net of transaction costs and amortized to the nominal amount using the effective interest method. The carrying amount of the liability at the balance sheet date is CHF 10 million (December 31, 2020: CHF 10 million). The value of the embedded derivatives is solely based on entity specific information and is insignificant.

Changes in current financial liabilities from convertible notes and their derivative financial instruments:

In CHF thousands	Convertible notes IRIS	Convertible notes Highbridge	Convertible notes Idorsia	Current derivative IRIS	Current derivative Highbridge	Current derivative Warrant
December 31, 2019	**-**	**-**	**-**	-	**-**	**-**
Proceeds from convertible notes	6,983	-	-	-	-	-
Initial recognition of derivative financial instruments	-	-	-	2,579	-	-
Derecognition of derivative financial instruments on warrants exercise	240	-	-	-240	-	-
Nominal value of convertible notes converted into shares	-6,900	-	-		-	-
Derecognition of derivative financial instruments on conversion of notes	-	-	-	-1,492	-	-
Change in fair value of derivative financial instruments	-	-	-	12	-	-
Effective interest/amortized cost calculation/amortization of transaction cost	777	-	-		-	-
June 30,2020	**1,100**	**-**	**-**	**859**	**-**	**-**
Proceeds from convertible notes	3,850	13,726	-	-	-	-
Initial recognition financial instruments	-	-	9,930	-	3,416	-
Nominal value of convertible notes converted into shares	-5,100	-13,844	-	-	-3,583	-
Derecognition of derivative financial instruments on conversion of notes	-	-	-	-739	-321	-
Derecognition of derivative financial instruments on warrants exercise	120	-	-	-120	-	-
Effective interest/amortized cost calculation/ fair value adjustments	30	760	23	-	613	-
December 31. 2020	**-**	**642**	**9,953**	**-**	**125**	**-**
Proceeds from convertible notes	-	17,000	-	-	-	-
Initial recognition of derivative financial instruments	-	-7,111	-	-	5,496	1,556
Nominal value of convertible notes converted into shares	-	-15,000	-	-	-4,944	-
Effective interest/amortized cost calculation/fair value adjustments	-	5,842	35	-	-	-
June 30, 2021	**-**	**1,372**	**9,988**	**-**	**677**	**1,556**

9 Current Provisions

Short-term provisions related to the organizational restructuring commenced in October 2020.

In CHF thousands	
Balance December 31, 2020	2,034
Utilization of provision	-1,151
Reversal of provision	-589
Balance June 30, 2021	**294**

10 Segment and Geographic Information

10.1 Segment information

Santhera operates in one business segment, namely 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, assess the reporting data and allocate resources as one segment on an aggregated consolidated level according to operating expenses by function. Santhera generates revenue from sales of Raxone for the treatment of LHON (Leber's hereditary optic neuropathy) and sales to licensing partner. Geographic revenue information is based on location of the customer.

10.2 Geographic information

Revenue from contracts with customers

Half-year ended June 30, in CHF thousands	**2021**	2020
Net sales		
EU	2,853	6,133
Net sales to licensing partner		
EU	1,639	1,642
Total	**4,492**	**7,775**

The decrease in revenues in the EU is mainly attributable to a CHF 2.0 million adjustment to net sales recorded in the first half-year 2021 due to increased uncertainties around pricing reimbursement in France, as well as an agreement with the authorities in France to supply Raxone free of charge from August 2021 following the removal of Raxone from the list of reimbursed drugs. Reimbursement discussions are ongoing and timing of resolution is expected to be during 2022. Refer to section *French social security – Reimbursement Status of Raxone in France* of note 17 of the Annual Report 2020 for further information on this matter.

Noncurrent assets (excluding financial instruments and deferred tax assets)

In CHF thousands	**June 30, 2021**	Dec. 31, 2020
Switzerland	67,640	69,444
North America	85	131
Total	**67,725**	**69,575**

11 Operating Expenses by Nature

Half-year ended June 30, in CHF thousands	**2021**	2020
External development expenses	-8,946	-10,989
Patent and license expenses	-263	-266
Marketing expenses	-277	-1,692
Employee expenses	-7,739	-15,201
Of which non-cash-relevant expenses for share-based payments	*-1,152*	*-1,749*
General and administrative expenses	-3,806	-2,562
Depreciation and amortization	-333	-851
Facility related and lease expenses	-126	-102
Other operating expenses	-448	-248
Total operating expenses	**-21,938**	**-31,911**

12 Financial Income/Expenses

Financial income

Half-year ended June 30, in CHF thousands	**2021**	2020
Interests on cash and cash equivalents	-	1
Change in fair value of financial derivative instruments	312	339
Realized and unrealized foreign exchange gains	206	207
Recognized gain on exchange of 2017/22 Convertible Bond	13,439	-
Total	**13,957**	**547**

Financial expenses

Half-year ended June 30, in CHF thousands	**2021**	2020
Interest and make whole expenses	-10,927	-2,381
Interest expenses on lease liabilities	-32	-51
Initial recognition of financial derivative instruments	-	-2,591
Transaction cost financial instruments	-3,167	-777
Realized and unrealized foreign exchange losses	-220	-320
Total	**-14,346**	**-6,120**

13 Income Taxes

Half-year ended June 30, in CHF thousands	**2021**	2020
Current income taxes	-85	-208
Deferred taxes	-568	-153
Total	**-653**	-361

Movements on deferred taxes relate to temporary differences on inventory.

14 Equity Rights Plans

Santhera has established long-term equity incentive 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. New grants currently include a combination of performance share units (PSUs), restricted stock units (RSUs) and stock options. From 2016 to 2020, the Company issued stock appreciation rights (SARs), and until 2016, the Company issued stock options.

Grants made during the period under long-term equity incentive plans were as follows:

	Number	Total fair value at time of grant TCHF
Restricted stock units (A) (RSUs)	200,000	400
Restricted stock units (B) (RSUs)	156,250	313
Performance stock units (PSUs)	2,148,225	3,954
Stock options	385,225	686

The fair value of equity rights granted is determined at each grant date. For the calculation of the fair value of each grant during the reporting period in 2021, the similar range of valuation parameters as disclosed in the financial statements as of December 31, 2020, was applied, except for the exercise prices (equal to the Share prices at grant) which were between CHF 2.73 and CHF 2.85 and performance criteria that did not apply to previously granted SARS

The (A) RSUs comprise three equal tranches with annual vesting on the anniversary of grant and remain restricted until June 21, 2024. The (B) RSUs granted June 23, 2021 vest by April 27, 2022 All PSUs vest between April 1, 2024 and June 23, 2024, with staggered vesting and subject to the achievement of pre-defined performance targets, one of such targets being the achievement of a Share price exceeding CHF 9.00 by the vesting date. Options vest annually over a three-year period at an exercise price of CHF 2.73.

The non-cash-relevant expenses for all long-term equity incentive plans in the reporting period 2021 amounted to CHF 1.2 million (2020: CHF 1.7 million).

15 Loss per Share

Basic and diluted loss per share is calculated by dividing the net profit/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.

6 months ended June 30,	2021	2020
Net result attributable to shareholders (in TCHF)	-20,519	-31,827
Weighted average number of shares issued and outstanding	22,244	11,448
Basic and diluted net result per share (in CHF)	**-0.92**	**-2.78**

16 Related Party Transactions

On June 23, 2021 a total of 200,000 (A) and 156,250 (B), restricted stock units (RSUs), were granted to members of the Board. The (A) RSUs comprise three equal tranches with annual vesting on the anniversary of grant and remain restricted until June 21, 2024. The (B) RSUs granted June 23, 2021 vest by April 27, 2022

Performance share units (PSUs) totaling 995,000 were granted to members of the Executive Management. All such PSUs vest between April 1, 2024 and June 23, 2024, with staggered vesting and subject to the achievement of pre-defined performance targets, one of such targets being the achievement of a Share price exceeding CHF 9.00 by the vesting date.

On June 23, 2021 stock options 145,000 were granted to members of the Executive Management. Options vest annually over a three-year period at an exercise price of CHF 2.73.

In the same period in 2020, a total of 165,332 SAR were granted to members of the Board and 283,127 SAR to members of the Executive Management.

17 Subsequent Events

On September 1, 2021 the Company settled the CHF 10 million exchangeable note with Idorsia with a cash payment of CHF 3.5 million together with the issue of 3,594,759 shares at an issue price of CHF 1.81 or CHF 6.5 million in aggregate.

On September 20, 2021 the Company announced a strengthening of its capital structure via an oversubscribed equity financing of CHF 20 million, a placement of private convertible bonds of CHF 15 million and upsizing of an existing financing arrangement of up to CHF 10 million. In aggregate, the financing amounted to up to CHF 45 million gross or CHF 42 million net after fees and expenses. The new funding secures current operations to mid-2022, past the NDA filing planned for Q1-2022, and allows for the repayment of the convertible bond maturing in February 2022. In relation to this financing capital increases were made on September 22 and 24, 2021, a total of 12,670,077 shares were issued in the private placement, with gross proceeds of CHF 20.2 million. In addition, a total of 8,835,039 warrants were issued to investors participating in the private placement. In addition, Santhera issued 5,440,000 shares out of the existing authorized capital as treasury shares in order to settle share delivery and provide treasury shares for use in future drawdowns of finance facility. Following the increase completed on September 24, 2021, the number of shares amounted to 54,607,810 including 5,440,000 treasury shares.

In September 2021, the FDA awarded a USD 1.2 million grant to ReveraGen under their “Clinical Studies of Orphan Products Addressing Unmet Needs of Rare Diseases (R01)” grants program to initiate a clinical trial of vamorolone in adults and children with Becker muscular dystrophy (BMD), a progressive muscle wasting disease similar to DMD, but usually milder. The mechanisms of actions, which provide the basis of vamorolone’s efficacy as demonstrated in the pivotal VISION-DMD study in the more severe DMD, are hypothesized to be relevant to BMD too.

Building a better working world

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To the Board of Directors of
Santhera Pharmaceuticals Holding AG, Pratteln

Basle, October 15, 2021

Report on the review of interim condensed consolidated financial statements

Introduction

We have reviewed the interim condensed consolidated financial statements (consolidated balance sheet, consolidated income statement, consolidated statement of comprehensive income, consolidated statement of cash flows, consolidated statement of changes in equity and notes, pages 9 to 26) of Santhera Pharmaceuticals Holding AG for the period from January 1, 2021 to June 30, 2021. The Board of Directors is responsible for the preparation and presentation of these interim condensed consolidated financial statements in accordance with International Financial Reporting Standard IAS 34 “Interim Financial Reporting”. Our responsibility is to express a conclusion on these interim condensed consolidated financial statements based on our review.

Scope of Review

We conducted our review in accordance with International Standard on Review Engagements 2410 “Review of Interim Financial Information Performed by the Independent Auditor of the Entity”. A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim condensed consolidated financial statements are not prepared, in all material respects, in accordance with International Financial Reporting Standard IAS 34 “Interim Financial Reporting”.

Material Uncertainty Related to Going Concern

We draw attention to note 2 of the interim condensed consolidated financial statements that outlines that the Group’s ability to continue operations as planned depends on various matters. This indicates that a material uncertainty exists that may cast significant doubt about the Group’s ability to continue as a going concern. Our review conclusion is not modified in respect of this matter.

Ernst & Young Ltd

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

/s/ Diana Vejina
ACCA

About Santhera

Santhera Pharmaceuticals (SIX: SANN) is a Swiss specialty pharmaceutical company focused on the development and commercialization of innovative medicines for rare neuromuscular and pulmonary diseases with high unmet medical need. Santhera has an exclusive license for all indications worldwide to vamorolone, a first-in-class dissociative steroid with novel mode of action, which was investigated in a pivotal study in patients with DMD as an alternative to standard corticosteroids. The clinical stage pipeline also includes lonodelestat (POL6014) to treat cystic fibrosis (CF) and other neutrophilic pulmonary diseases as well as an exploratory gene therapy approach targeting congenital muscular dystrophies. Santhera out-licensed rights to its first approved product, Raxone® (idebenone), outside North America and France for the treatment of Leber's hereditary optic neuropathy (LHON) to Chiesi Group. For further information, please visit www.santhera.com.

Trademarks

Raxone® is a trademark of Santhera Pharmaceuticals.

Forward-Looking Statements

This Interim Report expressly or implicitly contains certain forward-looking statements concerning Santhera Pharmaceuticals Holding AG and its business. Such statements involve certain known and unknown risks, uncertainties and other factors, which could cause the actual results, financial condition, performance or achievements of Santhera Pharmaceuticals Holding AG to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. There can be no guarantee that any of the development projects described will succeed or that any new products or indications will be brought to market. Similarly, there can be no guarantee that Santhera Pharmaceuticals Holding AG or any future product or indication will achieve any particular level of revenue. In particular, management's expectations could be affected by, among other things, uncertainties involved in the development of new pharmaceutical products, including unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the Company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing and other political pressures. Santhera Pharmaceuticals Holding AG is providing the information in this Interim Report as of the date of the publication, and does not undertake any obligation to update any forward-looking statements contained herein as a result of new information, future events or otherwise.

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