santhera
THEIR FUTURE – OUR FOCUS

2023

Interim Condensed Report
January to June 2023

Report on the Six Months Ended June 30, 2023 and Interim Consolidated Financial Statements

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Santhera Announces Half-Year 2023 Financial Results and Provides Corporate Update

- Revenue from contracts with customers of CHF 3.9 million (H1-2022: CHF 6.3 million)
- Operating result of CHF -20.3 million (H1-2022: CHF -25.5 million) and net result of CHF -23.3 million (H1-2022: CHF -29.7 million)
- Review of vamorolone's regulatory filings (NDA, MAA) for Duchenne muscular dystrophy (DMD) treatment proceeding as planned, with potential approvals in Q4-2023 and first EU/U.S. launches planned for Q1-2024
- Strategic transactions completed in July 2023: North American (NA) license for vamorolone granted to Catalyst Pharmaceuticals and remaining Raxone/idebenone business divested to Chiesi Group
- Liquidity secured into 2025 through CHF 1.7 million in cash and cash equivalents (June 30, 2023), bolstered by USD 90 million upfront payment received in July 2023 from vamorolone NA licensing deal
- Business now fully focused on upcoming regulatory decisions and European commercialization of vamorolone in DMD

Pratteln, Switzerland, September 7, 2023 – Santhera Pharmaceuticals (SIX: SANN) announces the Company's financial results for the six months ended June 30, 2023, reports on the regulatory and clinical progress with its lead drug candidate vamorolone for the treatment of DMD, and provides updates on its corporate and financing initiatives.

"Upon reviewing the progress made in the year 2023 thus far, I am gratified to acknowledge a transformational phase in our business journey, marked by our successful navigation through various challenges. In our partnership with Catalyst for the outlicensing of vamorolone in DMD, we have teamed up with a company committed to expediting the delivery of this therapy to patients in North America. Furthermore, we have secured a solid financial footing which allows us to press ahead toward our goal of European commercialization," said **Dario Eklund, CEO of Santhera**. "The evaluation of our marketing authorization applications for vamorolone in DMD is proceeding as planned, and preparations for market entry, contingent upon approvals, are advancing on both sides of the Atlantic. I am immensely proud of our team's unwavering dedication to our shared objective: expeditiously delivering this potentially life-changing therapy to DMD patients."

BUSINESS AND CORPORATE UPDATE

Half-year 2023 key events and post-period events

- Review of marketing authorization applications in the U.S., EU and UK progressing according to plan with regulatory decisions expected in Q4-2023
- Exclusive license and collaboration agreement concluded with Catalyst Pharmaceuticals for vamorolone in North America in all indications
- Progress in establishing readiness for launch of vamorolone in the EU
- Financing secured for vamorolone launch preparations in Europe, with cash reach extended into 2025.
- Raxone®/idebenone business fully divested to Chiesi Group

Vamorolone on track for regulatory decisions in Q4-2023

USA. In January 2023, upon acceptance of the new drug application (NDA) for vamorolone, FDA established the target Prescription Drug User Fee Act (PDUFA) action date for its regulatory decision on the NDA as October 26, 2023. At the mid--cycle review meetings, the FDA indicated that no significant review or safety concerns were noted up to that point in its ongoing review and re-affirmed its earlier decision to forego an Advisory Committee Meeting. Subject to approval, Santhera's licensing partner Catalyst Pharmaceuticals, plans to launch vamorolone in the U.S. early in Q1-2024.

European Union. The European Commission (EC) is expected to decide on the EU marketing authorization submission for vamorolone in DMD in late 2023, subject to a prior positive opinion by the Committee for Medicinal Products for Human Use (CHMP). Potential launches of vamorolone in the first EU countries, with Germany taking the lead, are planned to start in Q1-2024.

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

North America license for vamorolone granted to Catalyst Pharmaceuticals

In June, Santhera announced the signing of an exclusive license and collaboration agreement for vamorolone in North America (NA) with Catalyst Pharmaceuticals, Inc. (NASDAQ: CPRX), a commercial-stage biopharmaceutical company focused on novel medicines for patients living with rare diseases. The agreement covers the development and commercialization of vamorolone in DMD in North America (NA) and rights to all potential future indications in NA. For indications in addition to DMD, Santhera and Catalyst will further discuss , decide upon and eventually undertake the joint clinical development of vamorolone for global indications, in which both parties would participate in the development process and funding.

Total consideration to Santhera is up to USD 231 million (including equity investment) plus royalty payments from product sales. After closing of the transaction in July 2023, Santhera received an upfront payment of USD 90 million (USD 75 million in cash and USD 15 million equity investment). Upon and subject to U.S. FDA approval of vamorolone in DMD, a decision expected on October 26, 2023 (PDUFA date), Santhera will receive an additional USD 36 million from Catalyst, of which Santhera will pay contractually agreed third-party regulatory milestone obligations (USD 26 million). Furthermore, Catalyst may pay Santhera sales-based milestones of up to USD 105 million as well as up to low-teen percentage royalties and will assume corresponding third-party royalty obligations of Santhera on vamorolone sales in all indications in NA.

Pre-commercialization measures advancing

In Europe, Santhera plans to commercialize vamorolone in key geographies (including Germany, France, UK, Italy, Spain, Austria, Benelux and Switzerland), and will seek partners for commercialization in all other countries. Activities surrounding market access, stakeholder and key opinion leader engagement in these countries are ongoing. In Germany, the first launch country, the build-up of a core organization is well underway. Elsewhere, the early access programs applied for in France and the UK could, if granted, allow treatment of the first DMD patients with vamorolone in Q4 of this year.

Santhera expects a decision from the European Medicines Agency (EMA) in late 2023 and, subject to approval, plans to launch vamorolone in DMD in Germany, followed by a gradual rollout across selected key markets from 2024. Within the next five years, the Company currently estimates to achieve annual sales in excess of EUR 150 million in Europe in DMD alone, the first indication for vamorolone.

Full divestment of Raxone®/idebenone business to Chiesi Group

In a post-period transaction closed on July 28, 2023, Chiesi Group acquired all assets and certain liabilities related to idebenone in all indications worldwide. This included Raxone in LHON, for which Chiesi already held exclusive license rights globally since 2019, except for North America and France. Under the terms of the agreement, Chiesi Group will assume the responsibility for the settlement agreed between Santhera and the French reimbursement authorities relating to Raxone in LHON amounting to EUR 25.3 million, significantly reducing near-term financial obligations and strengthening Santhera's balance sheet. Furthermore, the cessation of Raxone-related activities allows Santhera to streamline business processes, reducing operating costs and freeing up resources for the European vamorolone launch and strategic projects.

As an additional upside, Santhera retains contingent value for LHON in the U.S. and other indications worldwide. Santhera is eligible to participate in a potential marketing approval of Raxone in LHON in the U.S. through variable payments in the single-digit percentage range on net sales or milestone payments of up to USD 10 million. In the event that Chiesi chooses to pursue idebenone in non-ophthalmological indications, Santhera would be eligible for an additional milestone payment of USD 10 million related to the approval in the US for the first non-ophthalmological indication and variable payments in the high single-digit percentage range on net sales.

Clinical and early access programs with vamorolone

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

Clinical studies with vamorolone were initiated to investigate its effects in a broader patient age group in DMD and in patients with Becker muscular dystrophy (BMD). The clinical development program for vamorolone until now included patients 4 to <7 years old and, as part of the pediatric investigational plan (PIP) requested by EMA, a new Phase 2 study aims at collecting information on vamorolone outside this age range through inclusion of patients starting at an age of 2 years and up to 18 years. Separately, a second Phase 2 pilot study in BMD is evaluating the safety, tolerability and exploratory clinical efficacy on motor function outcomes of vamorolone compared to placebo in males aged ≥18 and <65 years.

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

Pursuing portfolio opportunities

Santhera intends to continue actively managing its portfolio of products as an additional source of future non-dilutive income streams and to optimize patient access and commercialization prospects. Having already out-licensed the product in North America to Catalyst and in China to Sperogenix, Santhera is seeking collaborations with a view of granting sublicensing rights to vamorolone in DMD and potentially in other indications in other jurisdictions. Likewise, the Company is looking to partner lonodelestat whose development is currently paused as it prioritizes its vamorolone strategy.

FINANCIAL PERFORMANCE

Half-year results

- Revenue from contracts with customers of CHF 3.9 million (H1-2022: CHF 6.3 million)
- Operating result of CHF -20.3 million (H1-2022: CHF -25.5 million)
- Net result of CHF -23.3 million (H1-2022: CHF -29.7 million)
- Cash flow from operating activities of CHF -15.4 million (H1-2022: CHF -12.0 million)
- Cash and cash equivalents of CHF 1.7 million (Dec 31, 2022: CHF 1.4 million)

Subsequent events and financing outlook

- Agreement with Catalysts provided net upfront receipts of CHF 78.6 million
- Lower debt owing to full repayment of exchangeable notes to Highbridge Capital for CHF 29.0 million
- Divestment of Raxone/idebenone business reduces near-term liabilities by CHF 24.9 million
- Cash reach into 2025

Net revenue

In the first half-year 2023, Santhera reported revenue from contracts with customers of CHF 3.9 million (H1-2022: CHF 6.3 million). Net sales amounted to CHF 1.0 million (H1-2022: CHF -5.9 million, including non-recurring accruals of CHF 6.0 million associated with the French Raxone case). In the first half-year 2023, Santhera recognized revenue from out-licensing transactions in the amount of CHF 1.9 million (H1-2022: CHF 11.2 million), mainly consisting of a payment from Sperogenix for the granted license for vamorolone for China.

Operating expenses and result

Cost of goods sold remained at prior year level of CHF 1.9 million (H1-2022: CHF 1.9 million) and represents continuing supply of Raxone and amortization of intangibles. Operating expenses of CHF 22.5 million (H1-2022: CHF 30.0 million) were 25% lower year-on-year, primarily due to lower development expenses.

Development expenses amounted to CHF 9.7 million (H1-2022: CHF 16.9 million). The reduction was primarily due to lower third-party clinical and regulatory services for finalizing data analysis and the assembly of the regulatory dossiers for vamorolone in DMD to U.S., EU and UK authorities.

Marketing and sales expenses were CHF 4.3 million (H1-2022: CHF 5.9 million). On a comparable basis, i.e. excluding the nonrecurring accrual of CHF 2.1 million in relation to the French Raxone in the prior year, this represents a slight increase due to higher pre-commercialization activities for vamorolone.

General and administrative expenses amounted to CHF 8.4 million (H1-2022: CHF 7.1 million), for which the increase year-on-year reflects the addition of personnel in key functions in view of (the then ongoing) market readiness preparations for vamorolone in the U.S.

The operating result amounted to a loss of CHF 20.3 million which is 20% lower year-on-year (H1-2022: CHF -25.5 million).

Financial income and expenses

The financial income amounted to CHF 5.7 million (H1-2022: CHF 5.3 million) and was predominately related to the net positive change in fair value of financial instruments, as in the corresponding prior year period.

Financial expenses remained consistent year-on-year and amounted to CHF 8.8 million (H1-2022: CHF 8.9 million), primarily driven by interest payments and make-whole expenses.

In summary, this resulted in a net financial expense of CHF 3.1 million (H1-2022: CHF 3.6 million).

Net result

The net result in the first half-year 2023 was a loss of CHF 23.3 million, compared to a net loss of CHF 29.7 million for the corresponding period in the year 2022.

Cash balance and cash flows

As of June 30, 2023, the Company had cash and cash equivalents of CHF 1.7 million compared to CHF 1.4 million as of December 31, 2022.

Net cash outflow for operating activities was higher year-on-year and amounted to CHF 15.4 million (H1-2022: CHF 12.0 million). Net cash inflow from financing activities was higher year-on-year and amounted to CHF 10.0 million (H1-2022: CHF 3.5 million).

Shareholders' equity

Total consolidated net equity deficit as of June 30, 2023, amounted to CHF -42.8 million compared to a total equity deficit of CHF -43.7 million as of December 31, 2022, as a result of the net loss incurred for the period.

Settlement reached on pricing/reimbursement for Raxone in France – business sold to Chiesi Group

In February 2023, Santhera concluded the negotiations with the Comité économique des produits de santé (CEPS), securing a final pricing reimbursement, and resumed sales of Raxone in France from April 2023. Since the new reference price was lower than the price applied under the temporary pricing scheme since launch in 2015, this entailed a staggered reimbursement obligation of EUR 25.3 million (CHF 24.9 million), due 2024/25. For this purpose, Santhera had gradually accrued a total amount of CHF 24.9 million (as of December 31, 2022) in noncurrent provisions, recognized partially against net sales and as marketing and sales expenses.

During the six months ending June 30, 2023, Santhera committed to the sale of Raxone/idebenone upon settlement of the French case and the transaction closed on July 28, 2023. Accordingly, this is reflected in the accounting treatment of the corresponding assets and liabilities for disposal as of June 30, 2023. Under assets, intangible assets decreased by CHF 6.6 million mainly due to the reclassification of idebenone to asset held for sale. Under liabilities, noncurrent provisions in the amount of CHF 24.8 million, which Chiesi Group will cover, were reclassified to liability directly associated with assets held for sale.

Equity-linked financings and share capital

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

Bond instruments. In summary, Santhera has noncurrent convertible bonds outstanding in the total amount of CHF 19.2 million (June 30, 2023) and maturing in August 2024, reduced from CHF 21.2 million (December 31, 2022). Of the senior unsecured convertible bonds (2021/24 Bonds), nil were converted during the first half-year and an aggregate amount of CHF 13.5 million was outstanding at June 30, 2023. For the 2021/24 Private Bonds, in February 2023, Santhera and Highbridge agreed on a new conversion price of CHF 0.50 for a CHF 5 million tranche and to CHF 1.00 for the remaining outstanding tranche. The modification of the terms resulted in a gain in the amount of CHF 3.3 million, which has been recognized as financial income in the period.

Share capital and treasury stock. In February 2023, Santhera completed the ordinary capital increase resolved by its shareholders on November 29, 2022, by issuing 40 million shares. Thereof, 3 million shares were delivered in the context of the Highbridge financing and the remainder was kept in treasury. Additionally, during the period a further

0.5 million new shares were issued for financing transactions, share-based compensation. As of June 30, 2023, issued share capital consisted of 126,055,256 shares with a total nominal value of CHF 1,260,552.56, and the Company held 34,100,466 treasury shares with total nominal value of CHF 341,004.66 for future equity-based financings (nominal value CHF 0.01 per share).

At the Annual General Meeting (AGM) held on June 27, 2023, the shareholders approved a reverse share split in the ratio of 10:1. The reverse share split was completed on July 3, 2023. Additionally, shareholders also gave their consent to the creation of a capital range which authorizes the Board to increase or reduce the share capital within a certain range and over a period of up to five years. Furthermore, shareholders endorsed the replacement of the existing conditional capital for financing purposes and for employee participations by a corresponding new, increased conditional capital.

Amendments of Highbridge facility to satisfy near-term cash requirements

In February 2023, Santhera and Highbridge further amended the existing financing arrangement. Under the amended agreement, Highbridge agreed to provide up to CHF 22.2 million, thereof around CHF 2.2 million through the purchase of 3 million shares at CHF 0.75 per share and up to CHF 20 million through the existing financing arrangement, subject to conditions, to fund Santhera up to the PDUFA date in October 2023. An initial amount of CHF 5 million was drawn immediately and CHF 15 million were to become available in subsequent tranches, conditional on certain milestones and other conditions.

The Company had outstanding exchangeable instruments at nominal value as of June 30, 2023, of CHF 25.5 million, all amounts outstanding under exchangeable notes were settled during July 2023 post the closing of U.S. license transaction.

Financings post balance sheet date

Santhera closed two transactions in July 2023 which provided significant funding and markedly reduced near-term liabilities, thereby extending the Company's cash reach into 2025. Importantly, this enables the Company to advance its commercialization strategy in Europe where Santhera plans to make vamorolone available to patients in key geographies including Germany, France, UK, Italy, Spain, Austria, Benelux and Switzerland.

On July 19, 2023, Santhera announced the closing of the exclusive license agreement for vamorolone in North America (NA) with Catalyst Pharmaceuticals, Inc. (NASDAQ: CPRX), first announced on June 20, 2023. The net receipts from the upfront cash milestone and the equity investment amounted to CHF 78.6 million after transaction costs. Thereof, CHF 29.0 million has been used to fully repay current exchangeable notes to Highbridge Capital, significantly strengthening the Company's balance sheet. Also, due to the settlement of the exchangeable notes, the underlying 3.9 million shares (as of June 30, 2023, adjusted for the reverse share split) no longer require earmarking, thereby reducing potential future dilution compared to if the notes had been converted. Additionally, the first lien security and covenant obligations under the exchangeable note facility were removed. The remaining cash and cash equivalents of CHF 49.6 million, together with expected milestone payments from partners and initial revenue proceeds in Europe, are expected to fund Santhera's current operating plan into 2025.

On July 28, 2023, Santhera divested its idebenone intangible asset (marketed as Raxone for LHON) for all indications worldwide to Chiesi Farmaceutici S.p.A., an international research focused healthcare group (Chiesi Group). Under the terms of the agreement, Chiesi Group will assume the responsibility for the settlement agreed between Santhera and the French reimbursement authorities relating to Raxone in LHON amounting to EUR 25.3 million, significantly reducing near-term financial obligations and strengthening Santhera's balance sheet. Furthermore, the cessation of Raxone-related activities allows Santhera to streamline business processes, thereby reducing operating costs and freeing up resources to be deployed for the European vamorolone launch and strategic projects.

Funding outlook

As previously noted, the July transactions of the US license, completion of Raxone transfer and repayment of exchangeable debt provide together with anticipated future revenue from vamorolone provide for a cash runway into 2025.

Santhera will keep under review the need to provide further financing to support market growth and pipeline development and has treasury shares, conditional and authorized capitals which are available for future placement or issue, subject to market conditions.

References:
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[5] Liu X, et al (2020). Proc Natl Acad Sci USA 117:24285-24293

Half-year Report

The Santhera Half-year Report 2023 is available for download on the Company's website at www.santhera.com/financial-reports.

Interim Consolidated Financial Statements

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Interim Consolidated Balance Sheet

In CHF thousands	Notes	**Jun 30, 2023** (unaudited)	**Dec 31, 2022** (audited)
Assets			
Tangible assets		782	1,008
Intangible assets	11	51,088	59,206
Financial assets long-term		441	444
Deferred tax assets		20	3
Noncurrent assets		**52,331**	**60,661**
Prepaid expenses		449	513
Inventories	11	-	108
Trade and other receivables		1,971	1,091
Cash and cash equivalents	5	1,674	1,353
Current assets		**4,094**	**3,065**
Assets of disposal group held for sale	11	6,650	-
Total assets		**63,075**	**63,726**
Equity and liabilities			
Share capital	6	1,261	753
Capital reserves and share premium		604,730	581,116
Retained deficit		(650,837)	(627,501)
Employee benefit reserve		2,944	2,722
Treasury shares		(341)	(94)
Translation differences		(519)	(682)
Total equity		**(42,762)**	**(43,686)**
Noncurrent convertible bonds	7.2	19,210	21,080
Noncurrent derivative financial instruments	7	4,813	4,335
Noncurrent warrant financial instruments	7	2,424	5,171
Noncurrent lease liabilities		310	607
Noncurrent provisions	9, 11	-	24,961
Pension liabilities		1,701	1,844
Noncurrent liabilities		**28,458**	**57,998**
Trade and other payables		8,730	7,583
Accrued expenses		14,366	10,852
Income tax payable		392	553
Current lease liabilities		620	623
Current Exchangeable Notes	7.1	21,367	22,127
Current derivative financial instruments	7	3,703	5,440
Current warrant financial instruments	7	2,867	2,225
Current provisions	10	557	11
Current liabilities		**52,602**	**49,414**
Liability directly associated with the assets of disposal group held for sale	9, 11	24,777	-
Total liabilities		**105,837**	**107,412**
Total equity and liabilities		**63,075**	**63,726**

Interim Consolidated Income Statement

In CHF thousands (except per share data)	Notes	**Six months ended** (unaudited) **Jun 30, 2023**	**Jun 30, 2022**
Net sales	12	969	(5,873)
Revenue from out-licensing transactions	12	1,921	11,190
Net sales to licensing partner	12	1,049	933
Revenue from contracts with customers		**3,939**	**6,250**
Cost of goods sold		(1,928)	(1,875)
Of which amortization of intangible asset		*(1,519)*	*(1,519)*
Other operating income		141	79
Development	13	(9,748)	(16,870)
Marketing and sales	13	(4,257)	(5,917)
General and administrative	13	(8,351)	(7,133)
Other operating expenses	13	(101)	(70)
Operating expenses		**(22,457)**	**(29,990)**
Operating result		**(20,305)**	**(25,536)**
Financial income	14	5,694	5,291
Financial expense	14	(8,809)	(8,887)
Result before taxes		**(23,420)**	**(29,132)**
Income tax (expense)/benefit	15	84	(592)
Net result		**(23,336)**	**(29,724)**
Basic and diluted loss per share	17	(2.09)	(5.16)

Interim Consolidated Statement of Comprehensive Income

In CHF thousands	**Six months ended** (unaudited)	
	Jun 30, 2023	**Jun 30, 2022**
Net result	**(23,336)**	**(29,724)**
Items that will not be reclassified to profit or loss in subsequent periods:		
Net actuarial gains/(losses) from defined benefit plans	222	5,376
Items that may be reclassified to profit or loss in subsequent periods:		
Currency translation differences	163	21
Other comprehensive result	**385**	**5,397**
Total comprehensive result	**(22,951)**	**(24,327)**

Interim Consolidated Statement of Cash Flows

In CHF thousands	Notes	**Six months ended** (unaudited)	
		Jun 30, 2023	**Jun 30, 2022**
Result before taxes		**(23,420)**	**(29,132)**
Depreciation of tangible assets		306	297
Amortization of intangible assets		1,519	1,519
Share-based compensation	16	1,900	1,451
Change in fair value of financial instruments, net		(4,649)	(4,968)
Loss on modification of convertible bonds	7.2	254	-
Change in pension liabilities		78	106
Change in current provisions	10	546	-
Change in noncurrent provisions	9	(184)	8,137
Taxes paid		(137)	(58)
Change in net working capital		3,723	2,550
Total financial result		4,748	8,559
Interest paid		(42)	(418)
Net cash flow from/(used in) operating activities		**(15,358)**	**(11,957)**
Proceeds from sale of financial assets		5,679	-
Change in financial assets long-term		3	-
Net cash flow from/(used in) investing activities		**5,682**	**-**
Proceeds from shares sold through a private placement	6	2,250	-
Proceeds from sale of treasury shares	6	624	-
Proceeds from exercise of warrants financial instruments	7.1	200	-
Proceeds from Exchangeable Notes	7.1	7,500	18,000
Repayment of convertible bonds	7.2	-	(13,935)
Financing transaction costs		(102)	(5)
Cost of issuance of capital		(145)	(207)
Payment of lease liabilities		(348)	(365)
Net cash flow from/(used in) financing activities		**9,979**	**3,488**
Effects of exchange rate changes on cash and cash equivalents		18	(42)
Net increase/(decrease) in cash and cash equivalents		**321**	**(8,511)**
Cash and cash equivalents at January 1		1,353	21,208
Cash and cash equivalents at June 30		**1,674**	**12,697**

Interim Consolidated Statement of Changes in Equity

In CHF thousands	Notes	Share capital	Capital reserves and share premium	Retained earnings/(deficit)	Employee benefit reserve	Treasury shares	Translation differences	**Total**
Balance, January 1, 2022		**54,608**	**509,513**	**(556,425)**	**(437)**	**(5,020)**	**(911)**	**1,328**
Net result		-	-	(29,724)	-	-	-	**(29,724)**
Other comprehensive income		-	-	-	5,376	-	21	**5,397**
Total comprehensive result		**-**	**-**	**(29,724)**	**5,376**	**-**	**21**	**(24,327)**
Share-based compensation	16	-	1,451	-	-	-	-	**1,451**
Shares issued	6	19,118	-	-	-	(19,108)	-	**10**
Delivery of Shares on conversion of Exchangeable Notes into Shares	7.1	-	437	-	-	1,712	-	**2,149**
Delivery of Shares on conversion of convertible bonds into Shares	7.2	-	2,592	-	-	2,193	-	**4,785**
Delivery of Shares on settlement of convertible bonds interest expense	7.2	-	229	-	-	659	-	**888**
Delivery of Shares for financing transactions		-	-	-	-	78	-	**78**
Cost of issuance of capital		-	(207)	-	-	-	-	**(207)**
Balance, June 30, 2022 (unaudited)		**73,726**	**514,015**	**(586,149)**	**4,939**	**(19,486)**	**(890)**	**(13,845)**
Balance, January 1, 2023		**753**	**581,116**	**(627,501)**	**2,722**	**(94)**	**(682)**	**(43,686)**
Net result		-	-	(23,336)	-	-	-	**(23,336)**
Other comprehensive income		-	-	-	222	-	163	**385**
Total comprehensive result		**-**	**-**	**(23,336)**	**222**	**-**	**163**	**(22,951)**
Share-based compensation	16	-	1,900	-	-	-	-	**1,900**
Shares issued	6	508	-	-	-	(508)	-	**-**
Shares sold through a private placement	6	-	2,220	-	-	30	-	**2,250**
Delivery of Shares on conversion of Exchangeable Notes into Shares	7.1	-	12,290	-	-	148	-	**12,438**
Delivery of Shares on conversion of convertible bonds into Shares	7.2	-	217	-	-	4	-	**221**
Delivery of Shares on settlement of convertible bonds interest expense	7.2	-	910	-	-	10	-	**920**
Delivery of Shares for financing transactions	7.1	-	4,945	-	-	55	-	**5,000**
Delivery of Shares for exercise of share-based compensation		-	388	-	-	5	-	**393**
Delivery of Shares for exercise of warrants financial instruments	7.1	-	420	-	-	4	-	**424**
Sale of treasury shares		-	469	-	-	5	-	**474**
Cost of issuance of capital		-	(145)	-	-	-	-	**(145)**
Balance, June 30, 2023 (unaudited)		**1,261**	**604,730**	**(650,837)**	**2,944**	**(341)**	**(519)**	**(42,762)**

Notes to the Interim Consolidated Financial Statements

1 General Information

Santhera Pharmaceuticals Holding AG (herein 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 interim consolidated financial statements were approved for publication by the Board of Directors (**Board**) on September 6, 2023.

2 Summary of Material Accounting Policies

2.1 Basis of presentation

The Company's interim consolidated financial statements are prepared in accordance with International Financial Reporting Standards (**IFRS**), IAS 34 *Interim Financial Reporting*. Accordingly, the interim financial information does not include all the information and notes required under IFRS for annual consolidated financial statements. Therefore, such information should be read in conjunction with the Group's audited consolidated financial statements for the year ended December 31, 2022.

Except as described in 2.2 below, the accounting policies applied in these unaudited interim consolidated financial statements are consistent with those applied in the audited consolidated financial statements for the year ended December 31, 2022.

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

2.2 Changes in accounting policies

In 2023 the Group adopted various amendments to existing standards and interpretations. Adoption of these amendments had no material impact on the Group's overall results and financial position.

2.3 Financial liabilities

Financial liabilities at fair value through profit or loss

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

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

- the host contract is not an asset in the scope of IFRS 9 *Financial Instruments*
- the host contract is not itself carried at fair value through profit or loss

- the terms of the embedded derivative would meet the definition of a derivative if they were contained in a separate contract
- the economic characteristics and risks of the embedded derivative are not closely related to the economic characteristics and risks of the host

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

Other financial liabilities measured at amortized cost

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

3 Seasonality

The Group's operating result is not subject to significant seasonal variations.

4 Principal Currencies Translation Rates

	average rates for six months ended		period-end rates	
	Jun 30, 2023	**Jun 30, 2022**	**Jun 30, 2023**	**Dec 31, 2022**
1 Euro (**EUR**)	0.9856	1.0250	0.9767	0.9839
1 US dollar (**USD**)	0.9116	0.9696	0.9011	0.9233
1 British pound (**GBP**)	1.1242	1.1949	1.1367	1.1108
1 Canadian dollar (**CAD**)	0.6766	0.7565	0.6797	0.6814

5 Cash and Cash Equivalents

In CHF thousands	**Jun 30, 2023**	**Dec 31, 2022**
Cash at banks and on hand		
in CHF	1,566	1,096
in EUR	82	130
in USD	21	48
in GBP	-	6
in CAD	5	18
other currencies	-	55
Total cash and cash equivalents	**1,674**	**1,353**

6 Share Capital

6.1 Ordinary share capital

As announced on February 28, 2023, through a private placement to Highbridge Capital Management LLC, the Company issued 3 million Shares at CHF 0.75 per Share for total proceeds of CHF 2.2 million.

At the Annual General Meeting (**AGM**) held on June 27, 2023, the shareholders approved a reverse share split in the ratio of 10:1. The reverse share split was completed on July 3, 2023. All share data presented in these interim consolidated financial statements do not reflect the effects of the reverse share split, unless otherwise indicated. The new shares issued following the reverse stock split have a new International Securities Identification Number (**ISIN**) while the existing shares held prior to the reverse stock split have been canceled. At the AGM, shareholders also gave their consent to the creation of a capital band which authorizes the Board to increase or reduce the share capital within a certain range and over a period of up to five years.

During the six months ending June 30, 2023, a total of 50,734,746 new Shares were issued for financing transactions, share-based compensation, and for treasury shares. As of June 30, 2023, issued share capital totals CHF 1,260,552.56, consisting of 126,055,256 Shares with a nominal value of CHF 0.01 each. As of December 31, 2022, issued share capital totaled CHF 753,205.10, consisting of 75,320,510 Shares with a nominal value of CHF 0.01 each.

6.2 Treasury shares

During the six months ending June 30, 2023, a total of 50,734,746 new Shares were issued to be held as treasury shares intended to be used for financing transactions and share-based compensation, and of which 26,072,297 treasury shares were used for the same.

As of June 30, 2023, the Company holds 34,100,466 treasury shares with a nominal value of CHF 0.01 each for a total value of CHF 341,004.66. As of December 31, 2022, the Company held 9,438,017 treasury shares with a nominal value of CHF 0.01 each for a total value of CHF 94,380.17.

6.3 Authorized shares

At the Extraordinary General Meeting (**EGM**) held on November 29, 2022, the shareholders approved an increase to authorized shares by CHF 100,000.00 (and its extension until November 28, 2024). Accordingly, during the six months ending June 30, 2023, authorized shares increased by 10,000,000 at a nominal value of CHF 0.01. As of June 30, 2023, authorized share capital totals CHF 468,606.87 consisting of 46,860,687 shares with a nominal value of CHF 0.01 each. As of December 31, 2022, authorized share capital totaled CHF 368,606.87, consisting of 36,860,687 shares with a nominal value of CHF 0.01 each.

6.4 Conditional shares

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

At the AGM held on June 27, 2023, the shareholders endorsed the replacement of the existing conditional capital for financing purposes and for employee participations by corresponding new, increased conditional capital.

Article 3b conditional shares

As of June 30, 2023, Article 3b conditional capital totals CHF 50,345.83, consisting of 5,034,583 shares with a nominal value of CHF 0.01 each. As of December 31, 2022, Article 3b conditional capital totaled CHF 50,345.83 consisting of 5,034,583 shares with a nominal value of CHF 0.01 each.

Article 3c conditional shares

As of June 30, 2023, Article 3c conditional capital totals CHF 298,886.87, consisting of 29,888,687 shares with a nominal value of CHF 0.01 each. As of December 31, 2022, Article 3c conditional capital totaled CHF 301,566.22, consisting of 30,156,622 shares with a nominal value of CHF 0.01 each.

7 Financial Liabilities

7.1 Equity-linked financing arrangements

Exchangeable Notes – Highbridge Capital Management

In July 2020, the Company and its subsidiary Santhera Pharmaceuticals (Schweiz) AG (**Santhera Schweiz**), entered into a subscription agreement with a fund managed by Highbridge Capital Management LLC (any such entity, **Highbridge**), providing for the issuance of senior secured Exchangeable Notes (**Exchangeable Notes**), subject to certain conditions and available in tranches, and exchangeable for Shares. The Exchangeable Notes are guaranteed by the Company and certain of its subsidiaries and secured by a comprehensive security package, including security over all shares of Santhera Schweiz and other subsidiaries of the Company, as well as over the Group's material intellectual property and other assets. In 2021, 2022, and 2023, amendments to the subscription agreement have been made to increase the commitment principal from the original total.

The Highbridge Exchangeable Notes are considered hybrid contracts containing a host that is a financial liability and different embedded derivatives. Since the economic characteristics and risks of the host and the embedded derivatives are not closely related, the embedded derivatives are separated from the host. The compound embedded derivative includes different features like interest rate choices, a compound interest rate calculation based on the interest rate choice, discounts based on Share prices, a floor for Share prices and different exchange rights. There is an interdependence between the mentioned features, which is why they are recognized as one compound embedded derivative with their fair value. The Exchangeable Notes are recognized as financial liabilities measured at amortized cost using the effective interest method and the embedded derivatives are recognized as financial liabilities measured at fair value through profit or loss for the periods presented.

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

In September 2022, Santhera and Highbridge agreed to amend the June Amendment, to allow for the immediate drawdown of a CHF 10 million tranche and amend certain provisions (**September Amendment**). The new Exchangeable Notes can be exchanged by Highbridge for Shares at a discount to VWAP, subject to a reduced floor price. As part of this new money financing and further commitments, Santhera agreed on a new conversion price of CHF 1.20 for the remaining outstanding private convertible bond issued to Highbridge in 2021 (see Note 7.2 "2021/24 Private Bonds" for more information) and a new exercise price of CHF 0.80 per Share for the existing warrants held by Highbridge (see "Warrants – Highbridge" below for more information). A further tranche of CHF 10 million available for drawdown is conditional on management achieving certain milestones and other conditions.

For the year ended December 31, 2022, net proceeds from Exchangeable Notes totaled CHF 33 million. As of December 31, 2022, the carrying value of the Exchangeable Notes totaled CHF 22.1 million and the fair value of the embedded derivatives totaled CHF 5.4 million. At December 31, 2022 CHF 5.0 million remained available under the “September Amendment”.

In February 2023, Santhera and Highbridge agreed to amend the June Amendment and the September Amendment (**February Amendment**). Highbridge agreed to the disbursement of up to CHF 20 million, of which CHF 5 million becomes available for immediate drawdown, and CHF 15 million in subsequent tranches, conditional on certain milestones and other conditions. All outstanding Exchangeable Notes can be exchanged by Highbridge for Shares at a discount to VWAP, subject to the then current floor price. In addition, Santhera agreed on a new conversion price of CHF 0.50 for CHF 5 million of the private convertible bond and to CHF 1.00 for the remaining outstanding private convertible bond (see Note 7.2 “2021/24 Private Bonds” for more information), and a new exercise price of CHF 0.50 per Share for the existing warrants held by Highbridge (see “Warrants – Highbridge” below for more information). As consideration for the incremental capital of up to CHF 20 million, Santhera issued to Highbridge two million warrants, each of which is exercisable for one Share at an exercise price of CHF 0.50 at any time upon issuance until September 20, 2026 (see “Warrants – Highbridge” below for more information).

For the six months ended June 30, 2023, net proceeds from Exchangeable Notes totals CHF 7.5 million. As of June 30, 2023, the carrying value of the Exchangeable Notes totals CHF 21.4 million and the fair value of the embedded derivatives totals CHF 3.7 million.

Warrants – Highbridge

In connection with the Highbridge Exchangeable Notes amendments of 2021, warrants were granted in two tranches equal to 15% of the total aggregate amount of the remaining existing facility, and new money tranches. In May 2021, a total of 984,769 warrants with a fair value of CHF 1.58 per warrant were granted. Each of the May warrants is exercisable at any time from the date of grant until March 15, 2026, for one Share at an exercise price of CHF 2.74. In September 2021, an additional 1,000,000 warrants with a fair value of CHF 1.05 per warrant were granted. Each of the September warrants is exercisable at any time until September 22, 2026, for one Share at an exercise price of CHF 2.00. In connection with the Highbridge Exchangeable Notes amendments agreed to in September 2022 (described above), a new exercise price of CHF 0.80 per Share was agreed for all the existing warrants held by Highbridge as of the September Amendment date. Subsequently, the February Amendment (as described above) amended the exercise price of the existing and outstanding warrants held by Highbridge to CHF 0.50 per Share as of the February Amendment date. As consideration for the incremental capital of up to CHF 20 million available per the February Amendment, Santhera issued to Highbridge two million warrants, each of which is exercisable for one Share at an exercise price of CHF 0.50 at any time upon issuance until September 20, 2026. The warrants are initially and subsequently recognized at fair value through profit or loss and are classified as financial liabilities until exercised by the holder.

The combined fair value of the warrants granted to Highbridge are initially recognized as prepaid financing transaction costs. Once the Exchangeable Notes are issued, the prepaid financing transaction cost is expensed on a pro rata basis. As of December 31, 2022, prepaid financing transaction costs totaled CHF 0.3 million. As of June 30, 2023, prepaid financing transaction costs is nil.

As of December 31, 2022, the combined fair value of the warrants totaled CHF 1.8 million and nil had been exercised in 2022. As of June 30, 2023, the combined fair value of the warrants totals CHF 1.8 million and 400,000 have been exercised during the six month period ending June 30, 2023. Refer to Note 7.3 for a summary of total warrants issued and outstanding at June 30, 2023.

Warrants – equity raise

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

As of December 31, 2022, the warrants granted in the September 2021 equity raise had a combined fair value of CHF 4.3 million and nil had been exercised in 2022. As of June 30, 2023, the combined fair value of the warrants totals CHF 2.1 million and nil has been exercised during six month period ending June 30, 2023. Refer to Note 7.3 for a summary of total warrants issued and outstanding at June 30, 2023.

Warrants – Idorsia

As announced on January 10, 2023, Santhera entered into a share exchange agreement with Idorsia Ltd (SIX: IDIA), a biopharmaceutical company headquartered in Allschwil, Switzerland (**Idorsia**), pursuant to which Idorsia transferred 346,500 of its registered shares to Santhera. As consideration, Santhera delivered 5,529,016 Shares, valued at CHF 0.9043 to Idorsia and issued 2,211,607 warrants to Idorsia, each of which is exercisable for one Share at an exercise price of CHF 0.9043 at any time until January 9, 2025. The purpose of such a share exchange was to obtain short-term liquidity by selling the Idorsia shares. During the six months ended June 30, 2023, all these Idorsia shares have been sold generating net proceeds of CHF 5.7 million. The warrants are initially and subsequently recognized at fair value through profit or loss and are classified as financial liabilities until exercised by the holder.

As of June 30, 2023, the fair value of the warrants totals CHF 0.7 million and nil has been exercised during six month period ending June 30, 2023. Refer to Note 7.3 for a summary of total warrants issued and outstanding at June 30, 2023.

Movement schedule of the financial liabilities arising from equity-linked financing arrangements

The table below summarizes the changes in financial liabilities arising from equity-linked financing arrangements and their financial instruments during the six months ending June 30, 2023, and June 30, 2022:

In CHF thousands	Exchangeable Notes Highbridge	Exchangeable Notes Highbridge derivatives	Warrants Highbridge	Warrants equity raise	Warrants Idorsia
Balance, December 31, 2021	**1,488**	**402**	**1,202**	**4,181**	**-**
Proceeds from Exchangeable Notes	18,000	-	-	-	-
Non-cash changes:					
Initial recognition of financial instruments at fair value	(5,693)	5,693	-	-	-
Nominal value of Exchangeable Notes converted into Shares	(1,500)	-	-	-	-
Derecognition of financial instruments on conversion of Exchangeable Notes into Shares	-	(1,497)	-	-	-
Effective interest/amortized cost/fair value adjustments	1,862	(669)	(616)	(2,154)	-
Balance, June 30, 2022	**14,157**	**3,929**	**586**	**2,027**	**-**

(continued)	Exchangeable Notes Highbridge	Exchangeable Notes Highbridge derivatives	Warrants Highbridge	Warrants equity raise	Warrants Idorsia
Proceeds from Exchangeable Notes	15,000	-	-	-	-
Non-cash changes:					-
Initial recognition of financial instruments at fair value	(3,080)	3,080	-		-
Nominal value of Exchangeable Notes converted into Shares	(12,825)	-	-		-
Issuance of notes against non-cash settlement	7,000	-	-		-
Derecognition of financial instruments on conversion of Exchangeable Notes into Shares	-	(1,054)	-		-
Effective interest/amortized cost/fair value adjustments	1,875	(515)	1,180	2,268	-
Balance, December 31, 2022	**22,127**	**5,440**	**1,766**	**4,295**	**-**
Proceeds from Exchangeable Notes	7,500	-	-	-	-
Non-cash changes:					
Initial recognition of financial instruments at fair value	(1,933)	1,213	720	-	1,106
Nominal value of Exchangeable Notes converted into Shares	(9,700)	-	-	-	-
Derecognition of financial instruments on conversion of Exchangeable Notes into Shares	-	(1,633)	-	-	-
Derecognition of financial instruments on exercise	-	-	(224)	-	-
Effective interest/amortized cost/fair value adjustments	3,373	(1,318)	(458)	(2,175)	(398)
Balance, June 30, 2023	**21,367**	**3,702**	**1,804**	**2,120**	**708**

Equity-linked financial instruments valuation and sensitivity analysis

The equity-linked financing arrangements' financial instruments includes the embedded derivatives and warrants. The financial instruments valuations are based on Level 3 unobservable input parameters applying a simulation-based approach. The implied volatility, a significant valuation input, is determined by reference to the annualized daily trading volatility of Santhera's Shares for a historical lookback period equal to the expected remaining life of the conversion right as of the valuation date. By construction, the compound financial instrument issued to Highbridge is assumed will be exercised before maturity. For valuation purposes, it is therefore assumed that the expected exercise date is between the investing date and the maturity date.

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

Financial instruments	**Jun 30, 2023**	**Dec 31, 2022**
Equity-linked financing arrangements – derivatives	126%	104%
Equity-linked financing arrangements – warrants:		
Granted in May 2021	81%	76%
Granted in September 2021	79%	72%
Granted in January 2023	87%	-
Granted in February 2023	79%	-

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

In CHF thousands		**Jun 30, 2023**	**Dec 31, 2022**
Financial instruments	Increase/decrease in volatility assumption	Effect on result before taxes	Effect on result before taxes
Equity-linked financing arrangements – derivatives			
Change in volatility	+5%	(46)	86
	-5%	44	(83)
Equity-linked financing arrangements – warrants			
Change in volatility	+5%	(26)	(29)
	-5%	24	22

7.2 Financing arrangements – convertible bonds

2021/24 Bonds

On May 4, 2021, Santhera issued senior unsecured convertible bonds with a maturity date of August 17, 2024 in the nominal value of CHF 30.3 million (**2021/24 Bonds**). The bonds, listed on the SIX, have interest bearing (7.5%) with a maximum term of 39 months, and are convertible into Shares with a nominal value of CHF 1 each. The initial conversion price is fixed at CHF 3.0029. In addition, Santhera could call the 2021/24 Bonds at any time on or after the second anniversary of the issue date at par, plus accrued interest, if any, if the VWAP of the Shares is at least 150% of the conversion price.

The 2021/24 Bonds were offered as consideration for the previously issued 2017/22 Bonds (which have since been fully repaid with effective date February 17, 2022, and delisted from the SIX Swiss Exchange). Accordingly, Santhera did not receive any cash proceeds upon issuance of the 2021/24 Bonds.

During the year ended December 31, 2022, in connection with the Highbridge Exchangeable Notes September Amendment (described in Note 7.1 "Exchangeable Notes – Highbridge Capital Management"), approximately CHF 5.2 million of the CHF 10 million drawdown was used to repurchase the remaining outstanding 2021/24 Public Bonds issued to Highbridge. The repurchase of CHF 6.0 million of bonds at a discount, resulted in a realized gain of CHF 1.5 million, which is recognized in the consolidated income statement for the year ended December 31, 2022.

During the year ended December 31, 2022, nil 2021/24 Bonds were converted into Shares. As of December 31, 2022, the 2021/24 Bonds had a remaining aggregate nominal value of CHF 13.5 million and a carrying value of CHF 11.6 million, and the fair value of the derivatives totals CHF 0.8 million. As of June 30, 2023, the 2021/24 Bonds have a remaining aggregate nominal value of CHF 13.5 million and a carrying value of CHF 12.2 million, and the fair value of the derivatives totals CHF 0.2 million.

2021/24 Private Bonds

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

The proceeds from issuance of the 2021/24 Private Bonds were used for the repayment of the outstanding 2017/22 Bonds publicly issued in 2017 and due on February 17, 2022. The remaining 2017/22 Bonds have since been fully repaid with effective date February 17, 2022, and delisted from the SIX Swiss Exchange.

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

During the year ended December 31, 2022, in connection with the Highbridge Exchangeable Notes September Amendment (described in Note 7.1 “Exchangeable Notes – Highbridge Capital Management”), as part of the new money financing and further commitments, Santhera agreed on a new conversion price of CHF 1.20 for the remaining outstanding 2021/24 Private Bonds and a new exercise price of CHF 0.80 per Share for the existing warrants held by Highbridge.

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

In February 2023, Santhera and Highbridge agreed on a new conversion price of CHF 0.50 for CHF 5 million of the 2021/24 Private Bonds and to CHF 1.00 for the remaining outstanding 2021/24 Private Bonds (see Note 7.1 “*Exchangeable Notes – Highbridge Capital Management*” for more information). The modification of the terms resulted in a loss in the amount of CHF 0.3 million, which has been recognized as financial expense in the interim consolidated income statement for the six months ending June 30, 2023.

During the six months ended June 30, 2023, 2021/24 Private Bonds with a total aggregate nominal value of CHF 0.2 million were converted into Shares. Nil warrants were exercised and converted into Shares. As of June 30, 2023, the 2021/24 Private Bonds have an aggregate nominal value of CHF 11.8 million and a carrying value of CHF 7.1 million. As of June 30, 2023, the fair value of the derivatives totals CHF 4.6 million and the fair value of the warrants totals CHF 0.7 million.

Nominal values and carrying values of the convertible bonds

The following table summarizes the nominal and carrying values of the convertible bonds as of June 30, 2023, and December 31, 2022:

In CHF thousands					**Jun 30, 2023**		**Dec 31, 2022**	
	Offering	Currency	Interest	Maturity	Nominal value	Carrying value	Nominal value	Carrying value
2021/24 Bonds (ISIN: CH0563348744)	Public	CHF	7.5%	2024	13,547	12,158	13,547	11,613
2021/24 Private Bonds	Private	CHF	7.5%	2024	11,772	7,052	11,971	9,467
Total convertible bonds					**25,319**	**19,210**	**25,518**	**21,080**
Less current portion of convertible bonds with short-term maturities						-		-
Noncurrent portion of convertible bonds with long-term maturities						19,210		21,080

Movement schedule of the financial liabilities arising from convertible bond issuances

The table below summarizes the changes in financial liabilities arising from convertible bond issuances and their financial instruments during the six months ending June 30, 2023, and June 30, 2022:

In CHF thousands	2017/22 Bonds	2021/24 Bonds	2021/24 Bonds derivatives	2021/24 Private Bonds	2021/24 Private Bonds derivatives	2021/24 Private Bonds warrants
Balance, December 31, 2021	**13,880**	**15,387**	**1,126**	**10,409**	**2,557**	**990**
Repayment of bonds	(13,935)	-	-	-	-	-
Nominal value of bonds converted into Shares	(10)	-	-	(3,031)	-	-
Derecognition of financial instruments on conversion of bonds into Shares	-	-	-	-	(1,117)	-
Effective interest/amortized cost/fair value adjustments	65	656	(774)	1,478	209	(510)
Balance, June 30, 2022	**-**	**16,043**	**352**	**8,856**	**1,649**	**480**
Repurchase of bonds	-	(6,014)	(45)	-	-	-
Nominal value of bonds converted into Shares	-	-	-	-	-	-
Derecognition of financial instruments on conversion of bonds into Shares	-	-	-	-	-	-
Effective interest/amortized cost/fair value adjustments	-	1,584	523	611	1,856	855
Balance, December 31, 2022	-	**11,613**	**830**	**9,467**	**3,505**	**1,335**

(continued)	2017/22 Bonds	2021/24 Bonds	2021/24 Bonds derivatives	2021/24 Private Bonds	2021/24 Private Bonds derivatives	2021/24 Private Bonds warrants
Adjustment for modification of bonds	-	-	-	(3,340)	3,594	-
Nominal value of bonds converted into Shares	-	-	-	(199)	-	-
Derecognition of financial instruments on conversion of bonds into Shares	-	-	-	-	(165)	-
Effective interest/amortized cost/fair value adjustments	-	545	(613)	1,124	(2,338)	(675)
Balance, June 30, 2023	**-**	**12,158**	**217**	**7,052**	**4,596**	**660**

Convertible bonds financial instruments valuation and sensitivity analysis

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

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

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

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

Financial instruments	**Jun 30, 2023**	**Dec 31, 2022**
Derivatives:		
2021/24 Bonds	96%	88%
2021/24 Private Bonds	96%	88%
Warrants:		
2021/24 Private Bonds	79%	72%

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

In CHF thousands		**Jun 30, 2023**	**Dec 31, 2022**
Financial instruments	Increase/decrease in volatility assumption	Effect on result before taxes	Effect on result before taxes
2021/24 Bonds – derivatives			
Change in volatility	+5%	29	(45)
	-5%	(34)	67
2021/24 Private Bonds – derivatives			
Change in volatility	+5%	13	(7)
	-5%	(81)	2
2021/24 Private Bonds – warrants			
Change in volatility	+5%	(30)	(45)
	-5%	30	45

7.3 Summary of warrants issued and outstanding

The table below summarizes the changes in warrants granted and outstanding in connection with financing arrangements, pre-reverse share split, as of June 30, 2023, and December 31, 2022:

Warrants granted	Expiry date	Exercise price (CHF)	**Outstanding Dec 31,2022**	Exercised	Expired/ Forfeited	**Outstanding Jun 30,2023**
984,769	Mar 15, 2026	0.50	984,769	(400,000)	-	584,769
4,250,000	Sep 22, 2026	0.50	4,250,000	-	-	4,250,000
4,585,039	Sep 22, 2026	2.00	4,585,039	-	-	4,585,039
2,211,607	Jan 9, 2025	0.90	-	-	-	2,211,607
2,000,000	Sep 20, 2026	0.50	-	-	-	2,000,000
14,031,415			**9,819,808**	**(400,000)**	**-**	**13,631,415**

8 Fair Value of Financial Liabilities Arising from Financing Activities

The table below summarizes the fair value hierarchy of financial liabilities measured at amortized cost and measured at fair value through profit or loss as of June 30, 2023, and December 31, 2022. During the six months ended June 30, 2023, there have been no transfers between the different hierarchy levels.

In CHF thousands	**Jun 30, 2023**				
	Carrying value	Level 1	Level 2	Level 3	Total
Exchangeable Notes	21,367	-	21,367	-	**21,367**
2021/24 Bonds	12,158	12,508	-	-	**12,508**
2021/24 Private Bonds	7,052	-	6,461	-	**6,461**
Total financial liabilities at amortized cost	**40,577**	**12,508**	**27,828**	**-**	**40,336**
Derivative financial instruments	8,516	-	-	8,516	**8,516**
Warrant financial instruments	5,291	-	-	5,291	**5,291**
Total financial liabilities at fair value through profit or loss	**13,807**	**-**	**-**	**13,807**	**13,807**

In CHF thousands	Dec 31, 2022				
	Carrying value	Level 1	Level 2	Level 3	Total
Exchangeable Notes	22,127	-	22,127	-	**22,127**
2021/24 Bonds	11,613	10,900	-	-	**10,900**
2021/24 Private Bonds	9,467	-	6,860	-	**6,860**
Total financial liabilities at amortized cost	**43,207**	**10,900**	**28,987**	**-**	**39,887**
Derivative financial instruments	9,775	-	-	9,775	**9,775**
Warrant financial instruments	7,396	-	-	7,396	**7,396**
Total financial liabilities at fair value through profit or loss	**17,171**	**-**	**-**	**17,171**	**17,171**

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

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

9 Noncurrent Provisions

Noncurrent provisions relate to the French Social Security pricing reimbursement for sales of Raxone for Leber's hereditary optic neuropathy (**LHON**) in France. Since obtaining the marketing authorization for Raxone in 2014, Raxone had been reimbursed by the French Social Security under a so-called autorisation temporaire d'utilisation (**ATU**) and a so-called post-autorisation temporaire d'utilisation (**post-ATU**) financing scheme (dispositif pérenne).

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

In 2021, based on additional data from post approval studies in LHON, Santhera submitted an updated dossier to the Commission de la Transparence (**CdT**) to determine the medical value of Raxone. In January 2002, the CdT ruled inter alia that the service médical rendu (**SMR**) was "moderate" (and no longer "insufficient"). The améliorisation du service medical rendu (**ASMR**) was determined to be IV (while earlier no ASMR was given). Also, the CdT's opinion stated that the drug which might be used to assess the SMR, ASMR and the place of Raxone in the therapeutic strategy in France was Lumevoq, a gene therapy for the treatment of LHON patients under an early access program.

After having received the CdT's ruling, Santhera started to negotiate a price for Raxone with the CEPS. Such price would not only apply to future sales of Raxone, but also form the basis to calculate a refund for past sales. At the pricing stage, the price of the comparator(s) listed in the CdT's opinion should be referred to by the CEPS as a basis for negotiation. Even though the CdT had concluded that the comparator drug was Lumevoq, the CEPS argued that the price of another drug also still under an ATU could not be taken into consideration as a comparator. Given the difficulties in identifying a single drug as the comparator drug, Santhera suggested to the CEPS the concept of applying a basket approach with possible comparator drugs and using the pricing of such comparator drugs as a reference price.

When Raxone was officially taken off the list of reimbursed products, in August 2021, Santhera agreed with the French authorities to provide Raxone free of charge to existing and newly diagnosed LHON patients in France. Such free of charge delivery was not a formal settlement with the French authorities, rather it was primarily initiated to ensure the continued supply of Raxone to LHON patients in France.

As of December 31, 2022, the Company had recognized an aggregate of CHF 24.9 million in noncurrent provisions.

In February 2023, Santhera concluded the negotiations with the CEPS securing a final pricing reimbursement. The newly agreed price for Raxone in France is lower than the price applied under the temporary pricing scheme, leading to a settlement payment of approximately EUR 25.4 million (CHF 24.9 million), with 30% due in mid-2024 and the remainder one year later. No additional provisions have been recognized during the six months ending June 30, 2023, the change at June 30, 2023 compared to December 31, 2022 is due to foreign currency revaluation.

In March 2023, Raxone was included on the list of reimbursed products in France, allowing Santhera to resume sales in April 2023.

As introduced in Note 11, in April 2023, following the settlement of the France pricing reimbursement and the listing of Raxone on the list of reimbursed products in France, management initiated an active program to locate a buyer for the sale of the idebenone intangible asset. On July 28, 2023, Santhera divested the idebenone business worldwide and for all indications to Chiesi Farmaceutici S.p.A., an international research focused healthcare group (**Chiesi Group**). Under the terms of the agreement, Chiesi Group will assume the responsibility for the settlement agreed between Santhera and the French reimbursement authorities relating to Raxone in LHON. At June 30, 2023, the carrying value of the noncurrent provision in the amount of CHF 24.7 million is reclassified as liability directly associated with the assets of disposal group held for sale in the consolidated balance sheet.

10 Current Provisions

Current provisions mainly consist of restructuring liabilities for employee-related costs. In June 2023, the Group initiated a restructuring plan in response to the out-licensing of intangible asset vamorolone in North America. The changes in restructuring liabilities for the six months ended June 30, 2022, are as follows:

In CHF thousands	
Balance, December 31, 2022	11
Additions	546
Utilizations	-
Reversals	-
Balance, June 30, 2023	**557**

11 Disposal Group Held for Sale

During the six months ending June 30, 2023, management committed to the sale of the idebenone intangible asset (current marketed product Raxone for LHON) and its associated inventory and liability (the liability is described in more detail in Note 9), together in a single transaction. For this reason, on reclassification to asset held for sale, the intangible assets primarily decreased by CHF 6.6 million compared to December 31, 2022. The associated inventory and liability have also been reclassified as part of the disposal group. On July 28, 2023, the full divestment of the disposal group held for sale was completed. The disposal is consistent with the Group's strategic realignment to focus its activities on the vamorolone development in order to advance operational preparations for a potential launch of vamorolone in the U.S. and/or the EU as early as Q4-2023, subject to obtaining approvals from the U.S. Food and Drug Administration and European Medicines Agency.

At June 30, 2023, the disposal group is stated at carrying value and comprised of the following assets and liability.

In CHF thousands	**Jun 30, 2023**
Idebenone intangible asset, net	6,581
Inventory	69
Assets held for sale	**6,650**
Liability directly associated with assets held for sale	24,777
Liability held for sale	**24,777**

There are no gains or losses relating to the disposal group held for sale arising at the time of reclassification that have been recognized in the interim consolidated income statement for the six months ending June 30, 2023.

12 Segment and Geographic Information

12.1 Segment information

The Group operates as 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. The Group has generated revenue from sales of Raxone for the treatment of LHON and revenues from licensing agreements. Geographic revenue information is based on location of the customer.

12.2 Geographic information – revenues

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

In CHF thousands	Six months ended					
	Jun 30, 2023			**Jun 30, 2022**		
	Europe	Asia	**Total**	Europe	Asia	**Total**
Net sales	969	-	**969**	(5,873)	-	**(5,873)**
Revenue from out-licensing transactions	-	1,921	**1,921**	-	11,190	**11,190**
Net sales to licensing partner	1,049	-	**1,049**	933	-	**933**
Total revenue from contracts with customers	**2,018**	**1,921**	**3,939**	**(4,940)**	**11,190**	**6,250**

During the six months ending June 30, 2023, Raxone direct sales are to Italy, France, and Switzerland, with the majority of sales generated in Italy. During the six months ending June 30, 2022, Raxone direct sales were to Italy, France, and Switzerland, with the majority of sales generated in Italy.

12.3 Geographic information – noncurrent assets

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

In CHF thousands	**Jun 30, 2023**	**Dec 31, 2022**
Switzerland	51,786	60,116
United States and Canada	48	55
Total	**51,834**	**60,171**

13 Operating Expenses by Nature

In CHF thousands	Six months ended	
	Jun 30, 2023	**Jun 30, 2022**
External development expenses	5,104	13,540
Patent and license expenses	146	202
Marketing and sales expenses	3,146	2,547
Employee expenses	9,313	7,220
Share-based compensation	1,900	1,451
General and administrative expenses	1,955	3,747
Depreciation and amortization	306	297
Facility related and lease expenses	141	150
Other	446	836
Total operating expenses	**22,457**	**29,990**

14 Financial Income/(Expense)

14.1 Financial income

In CHF thousands	Six months ended	
	Jun 30, 2023	**Jun 30, 2022**
Change in fair value of financial instruments, net	4,649	4,968
Realized and unrealized foreign exchange gains, net	366	323
Gain on sale of financial assets	679	-
Total financial income	**5,694**	**5,291**

14.2 Financial expense

In CHF thousands	Six months ended	
	Jun 30, 2023	**Jun 30, 2022**
Interest and make-whole expenses	(8,001)	(8,332)
Loss on modification of 2021/24 Private Bonds	(254)	-
Interest expense on lease liabilities	(16)	(22)
Financing transaction costs	(102)	(5)
Realized and unrealized foreign exchange losses, net	(436)	(528)
Total financial expense	**(8,809)**	**(8,887)**

15 Income Tax Expense

To determine income tax expense or benefit, various internal and external factors are considered, which may have favorable or unfavorable effects on the future effective tax rate. These factors include, but are not limited to, changes in tax laws, regulations and/or rates, changing interpretations of existing tax laws or regulations, results of tax audits, and changes in the overall level of pre-tax results. The table below summarizes the provision for income taxes for the six months ended June 30, 2023, and June 30, 2022. Movements in deferred taxes relate to temporary differences on inventory.

In CHF thousands	Six months ended	
	Jun 30, 2023	**Jun 30, 2022**
Current income taxes	(17)	514
Deferred taxes	(67)	78
Total income tax expense / (benefit)	**(84)**	**592**

16 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. The table below summarizes the equity rights plans' instruments granted during the six months ended June 30, 2023, and June 30, 2022:

In CHF thousands (except no. of grants)	Six months ended			
	Jun 30, 2023		**Jun 30, 2022**	
	Number granted	Fair value	Number granted	Fair value
Restricted Stock Units (RSUs)	813,167	317	-	-
Share Appreciation Rights (SARs)	2,536,050	1,471	-	-
Performance Stock Units (PSUs)	5,318,950	2,505	71,250	56
Stock Options	-	-	71,250	66

As introduced in Note 6, at the AGM held on June 27, 2023, the shareholders approved a reverse share split in the ratio of 10:1. The reverse share split was completed on July 3, 2023. The information presented in this note does not reflect the post-split effect.

The fair value of equity rights granted is measured on the grant date. For the six months ended June 30, 2023, the fair value measurement range of valuation parameters remained relatively similar with those disclosed in the Group's audited consolidated financial statements for the year ended December 31, 2022, except for the volatility, exercise price (equal to the Share prices at grant), which was based on an exercise base value of CHF 0.84 (2022: CHF 1.45 and CHF 1.48).

The RSUs granted during the six months ended June 30, 2023, vest between June 26, 2023, and one day before the AGM 2024.

The SARs granted during the six months ended June 30, 2023, vest between July 12, 2024, and June 27, 2026, with staggered vesting.

The PSUs granted during the six months ended June 30, 2023, vest between February 29, 2024, and June 27, 2026 (2022: February 13, 2025, and March 31, 2025), with staggered vesting and subject to the achievement of pre-defined performance targets. One of such performance targets dependent on satisfying a market condition of a Share price exceeding CHF 0.84 by the vesting date.

The stock options granted during the six months ended June 30, 2022, vest annually over a three-year period and have an exercise price of CHF 2.73.

For the six months ended June 30, 2023, and June 30, 2022, non-cash share-based compensation expense recognized in the interim consolidated income statement, for all equity rights plans totaled CHF 1.9 million and CHF 1.5 million, respectively.

17 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.

In CHF thousands (except per share data)	Six months ended	
	Jun 30, 2023	**Jun 30, 2022**
Net result attributable to shareholders	(23,336)	(29,724)
Weighted average number of shares issued and outstanding	11,159,999	5,672,000
Basic and diluted net result per share	**(2.09)**	**(5.16)**

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

As introduced in Note 6, at the AGM held on June 27, 2023, the shareholders approved a reverse share split in the ratio of 10:1. The reverse share split was completed on July 3, 2023. The weighted average number of shares issued and outstanding reflects the post-split effect for the periods presented.

18 Transactions with Related Parties

The Company's related parties include members of the Executive Management and Board. The table below summarizes the Executive Management and Board compensation expense for the six months ended June 30, 2023, and June 30, 2022:

In CHF thousands	Six months ended	
	Jun 30, 2023	**Jun 30, 2022**
Executive Management:		
Short-term employee benefits	1,498	1,426
Post-employment benefits	131	146
Share-based compensation	998	346
Board of Directors	517	453
Total compensation expense	**3,144**	**2,371**

Detailed remuneration disclosures are provided in the Group's audited consolidated financial statements for the year ended December 31, 2022.

19 Subsequent Events

License agreement for vamorolone in North America

On July 19, 2023, the Company announced the closing of the exclusive license agreement for vamorolone in North America (**NA**) with Catalyst Pharmaceuticals, Inc. (NASDAQ: CPRX) (**Catalyst**), first announced on June 20, 2023. The license agreement grants Catalyst development and commercialization rights in NA for vamorolone in DMD and all potential future indications for a total consideration to Santhera of up to USD 231 million plus royalty payments from product sales.

Upon closing of the agreement, Santhera received a USD 75 million upfront cash milestone payment from Catalyst and an additional USD 15 million through the sale of treasury shares to Catalyst. Upon and subject to U.S. FDA approval of vamorolone in DMD, a decision expected by October 26, 2023 (PDUFA date), Santhera will receive another USD 10 million from Catalyst. Furthermore, Santhera is eligible to receive sales-based milestones of up to USD 105 million as well as royalties on sales. Catalyst will also pay USD 26 million of Santhera's third-party obligations at FDA approval, and royalty obligations on vamorolone sales in all indications in NA.

The net receipts from the upfront cash milestone and the equity investment amounted to CHF 78.6 million after transaction costs. Thereof, CHF 29 million was used to fully repay current Exchangeable Notes to Highbridge Capital, significantly strengthening the Company's balance sheet. The remaining cash and cash equivalents of CHF 49.6 million, together with expected milestone and revenue income, extend Santhera's cash reach into 2025.

As a result of settlement of the Exchangeable Notes, the first lien security and covenant obligations under the Exchangeable Notes facility were removed.

Disposal of remaining Raxone/idebenone business

On July 28, 2023, Santhera divested its idebenone intangible asset (marketed as Raxone for LHON) for all indications worldwide to Chiesi Farmaceutici S.p.A., an international research focused healthcare group (Chiesi Group). The transaction replaced the existing license agreement between the two companies entered into in 2019.

Under the terms of the agreement, Chiesi Group acquired all assets and certain liabilities related to idebenone in all indications worldwide, including Raxone in LHON, for which Chiesi already held exclusive license rights globally since 2019, except for North America and France. As consideration, Chiesi Group will assume the responsibility for the settlement agreed between Santhera and the French reimbursement authorities relating to Raxone in LHON amounting to EUR 25.4 million, significantly reducing near-term financial obligations and strengthening Santhera's balance sheet. In addition, Santhera is eligible to participate in a potential marketing approval of Raxone in LHON in the U.S. through variable payments in the single-digit percentage range on net sales or milestone payments of up to USD 10 million. In the event that Chiesi chooses to pursue idebenone in non-ophthalmological indications, Santhera would be eligible for an additional milestone payment of USD 10 million related to the approval in the U.S. for the first non-ophthalmological indication and variable payments in the high single-digit percentage range on net sales.

About Santhera

Santhera Pharmaceuticals (SIX: SANN) is a Swiss specialty pharmaceutical company focused on the development and commercialization of innovative medicines for rare neuromuscular and pulmonary diseases with high unmet medical need. The Company has an exclusive license for all indications worldwide to vamorolone, a dissociative steroid with novel mode of action, which was investigated in a pivotal study in patients with Duchenne muscular dystrophy (DMD) as an alternative to standard corticosteroids. For vamorolone in the treatment of DMD, Santhera has a new drug application (NDA) under review by the U.S. FDA, a marketing authorization application (MAA) under review by the European Medicines Agency (EMA) and an MAA submitted to the UK Medicines and Healthcare products Regulatory Agency (MHRA). Santhera has out-licensed rights to vamorolone for North America to Catalyst Pharmaceuticals and for China to Sperogenix Therapeutics. The clinical stage pipeline also includes lonodelestat to treat cystic fibrosis (CF) and other neutrophilic pulmonary diseases. For further information, please visit www.santhera.com.

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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