



2024

**Interim Condensed Report
January to June 2024**

Report on the Six Months Ended June 30, 2024, and Interim Consolidated Financial Statements

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Santhera Announces Half-Year 2024 Financial Results and Provides Corporate Update

- Revenue from contracts with customers of CHF 14.1 million (H1-2023: CHF 3.9 million)
- Operating result of CHF -17.7 million (H1-2023: CHF -20.3 million) and net result of CHF -15.3 million (H1-2023: CHF -23.3 million)
- AGAMREE® (vamorolone) launched in Germany and Austria as first European markets; North America partner has launched in the U.S.
- Approval of AGAMREE in the UK for the treatment of Duchenne muscular dystrophy (DMD); new drug application (NDA) in DMD under regulatory priority review in China
- Cash and cash equivalents of CHF 16.5 million (June 30, 2024); bolstered by financing of up to CHF 69 million (closed in August 2024) to provide funding into 2026 when cash flow break-even is expected
- Business now fully focused on European commercialization and further geographic expansion of AGAMREE in DMD

Pratteln, Switzerland, September 12, 2024 – Santhera Pharmaceuticals (SIX: SANN) announces the Company’s financial results for the six months ended June 30, 2024, reports on progress with AGAMREE® (vamorolone) for the treatment of Duchenne muscular dystrophy (DMD) and provides updates on its corporate and financing initiatives.

“We are extremely encouraged by the strong early uptake of AGAMREE in Germany and Austria, which has exceeded our expectations. Our North American partner, Catalyst Pharmaceuticals, has also seen a successful launch in the U.S., further validating the potential of AGAMREE in treating DMD,” said **Dario Eklund, CEO of Santhera**. “While we are delaying the decision on a new indication for AGAMREE until at least the end of 2025 to allow Catalyst to conduct additional exploratory clinical work, this strategic pause gives us an exciting opportunity. We are reallocating resources and are intensifying our efforts in DMD by expanding our launch into the Nordics, Portugal, and Ireland, hereby retaining full control of all the markets in western Europe. Additionally, we have decided to invest in additional studies to further strengthen the evidence behind AGAMREE’s differentiated safety profile and drive continued growth in the DMD space.”

BUSINESS AND CORPORATE UPDATE

Half-year 2024 key events and post-period events

- AGAMREE approved in the UK for the treatment of DMD, following prior approvals in the U.S. and EU
- The UK MHRA, in accordance with EU regulators, acknowledged safety benefits of AGAMREE with regards to preserving bone health and maintaining growth compared to standard of care corticosteroids
- Launches of AGAMREE in Germany and Austria (by Santhera) and the U.S. (by Catalyst Pharmaceuticals) as first markets, experiencing strong market uptake
- Preparations for market entry are advancing across Europe, with pricing negotiations currently underway
- Expansion of self-commercialization reach (to include the Nordics, Ireland and Portugal) and new distribution agreements established, representing coverage of all of EU and some non-EU markets in Europe
- Priority review for AGAMREE NDA in DMD granted by China’s regulatory authority; early access program started by Sperogenix

AGAMREE approved across the U.S., EU and UK—NDA under priority review in China

On January 11, 2024, the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK approved AGAMREE for the treatment of DMD, following earlier approvals in the U.S. (by FDA on October 26, 2023) and the European Union (by the European Commission on December 18, 2023). AGAMREE became the first DMD treatment approved across these three territories. In the EU, AGAMREE is the first and only approved medication for treating all patients from age 4 years with DMD.

The European Medicines Agency (EMA) and the MHRA acknowledged clinically important safety benefits of AGAMREE with regards to maintaining normal bone metabolism, density and growth compared to standard of care corticosteroids, while demonstrating similar efficacy.

In March 2024, the National Medical Products Administration (NMPA) in China accepted the new drug application (NDA) filing for AGAMREE in DMD for patients aged 4 years and older, incorporating it into both the Priority Review Program and the Breakthrough Therapy Program. Subject to a positive review outcome, approval could be obtained by Q1-2025.

First launches in Germany and the U.S. met with strong market acceptance

The first market launch of AGAMREE (available as a 40 mg/ml oral suspension) for the treatment of DMD occurred on January 15, 2024, in Germany, where around 2,300 patients are affected by DMD. In the following month, AGAMREE became available in Austria. The reception in both markets has been very positive, evidenced by strong demand and proactive inquiries from patients and caretakers. Currently, after only a few months of availability, AGAMREE has been prescribed to around 300 patients in Germany and Austria.

In March 2024, Catalyst Pharmaceuticals, Inc. (NASDAQ: CPRX), executed the U.S. commercial launch of AGAMREE and reported yielding solid results and surpassing initial expectations by the end of June 2024. Catalyst Pharmaceuticals holds an exclusive license for AGAMREE for North America. Further, in July 2024, Catalyst entered into an exclusive license, supply, and commercialization agreement for AGAMREE with a partner in Canada, marking a pivotal strategic milestone in expanding the product's North American footprint.

Paid early access programs started in first countries—broader interest expressed

Santhera received a number of named patient requests from European as well as global markets and is exploring sustainable supply mechanisms with a selection of partners. Meanwhile, programs have started in Spain and China.

In June, Santhera started a paid-for named patient program (NPP) in Spain. Under a well-defined regulatory framework, with the approval of the national as well as regional regulatory bodies, this allows patients with serious or life-threatening conditions to access medicines, even before they are commercially available in the country.

In China, partner Sperogenix Therapeutics has launched a paid-for early access program (EAP) for AGAMREE for patients with DMD. In April 2024, the Hainan Medical Products Administration (HMPA) authorized the EAP for AGAMREE in China, where approved treatments are currently unavailable, based on local policies, AGAMREE's existing overseas approvals (U.S., EU, UK) and its demonstrated ability to address urgent clinical needs in DMD. The EAP started in the Bo'ao Lecheng Pilot Zone, located in Hainan Province, in mid-May, where strong interest has been received and approximately 70 patients are currently on active treatment with AGAMREE.

Pre-commercialization measures advancing across Europe—pricing negotiations ongoing

Santhera plans to make AGAMREE available to patients across Europe. After Germany and Austria, the build-up of a core commercial organization is well advanced in UK, France, Italy, Spain, and Benelux. Activities surrounding market access, stakeholder and key opinion leader engagement in the target countries advanced throughout the period under review. Across key European markets, Santhera is currently engaged in various national processes of health technology assessments (HTA), pricing negotiations, and reimbursement decisions. In Germany, considering that Santhera launched AGAMREE on January 15, 2024, the pricing negotiations are expected to be concluded by

January 15, 2025. Owing to the complex and lengthy nature of these evaluations, anticipated timelines for upcoming market entries are likely to be slightly later than previously indicated. The UK is expected to be concluded later this year, France and Spain by mid-2025 and Italy by late 2025. Meanwhile, mid-sized European countries will progress in parallel with the big five markets.

Self-marketing territory expanded—additional distribution agreements secured

Market uptake in the first launch countries has been strong and exceeded Santhera's expectations. On this basis, Santhera has decided to expand its self-marketing strategy for AGAMREE to include the Nordic countries (Denmark, Sweden, Finland, Norway, and Iceland), along with Portugal and Ireland, and the organizational build-up has started. This approach reflects confident economic projections, while ensuring that margins are kept in-house, and allows the Company to maximize value and revenue potential from Agamree in DMD.

For all other markets in Europe, Santhera has signed up **GENESIS Pharma** as its distribution partner. GENESIS Pharma, with domiciles in Greece and Cyprus, is a regional biopharma company specialized in the commercialization of innovative medicines targeting severe and rare diseases in Central and Eastern Europe. The company will market AGAMREE in DMD in Greece, Cyprus, Malta, Romania, Bulgaria, Slovenia, Croatia, Poland, Czech Republic, Hungary, Slovakia, Lithuania, Latvia, Estonia, Serbia, North Macedonia, Bosnia & Herzegovina, Montenegro, Albania, and Kosovo.

A supply and distribution agreement has also been signed with **Megapharm Ltd.** Megapharm is a leading specialty marketing and distribution company in Israel's healthcare sector and will market AGAMREE for the treatment of DMD in Israel and the Palestinian territories.

In addition, Santhera has entered into discussions with multiple potential partners for additional territories outside of Europe.

Clinical programs with AGAMREE

AGAMREE has been 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 AGAMREE, recent publications and presentations further characterized AGAMREE's differentiated profile mainly with regard to bone health.

Clinical studies with AGAMREE in *Duchenne muscular dystrophy (DMD)* were initiated to investigate its effects in a broader patient age group and additional clinical work was started to differentiate the safety profile over the next couple of years. The clinical development program for AGAMREE 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 AGAMREE outside this age range through inclusion of patients starting at an age of 2 years and up to 18 years. In addition, a Phase 1 study in healthy volunteers aims to confirm AGAMREE's mineralocorticoid antagonistic properties, a key mechanism in current standard therapies to slow cardiomyopathy progression, further distinguishing AGAMREE as the only corticosteroid that may offer early cardioprotective benefits alongside its proven efficacy in DMD.

Separately, a Phase 2 pilot study in *Becker muscular dystrophy (BMD)* is evaluating the safety, tolerability and exploratory clinical efficacy on motor function outcome.

Santhera is committed to fully realizing AGAMREE's potential in the treatment of DMD by investing in its market potential and refining its clinical development priorities for potential new indications. While the Company initially planned to provide more details on the development of a *second indication* in Q4 this year, Catalyst Pharmaceuticals, the partner in North America, will begin further clinical exploratory and development studies in 2025 to inform the strategy for future indications thereafter.

FINANCIAL PERFORMANCE

Half-year results

- Revenue from contracts with customers of CHF 14.1 million (H1-2023: CHF 3.9 million)
- Operating result of CHF -17.7 million (H1-2023: CHF -20.3 million)
- Net result of CHF -15.3 million (H1-2023: CHF -23.3 million)
- Cash flow from operating activities of CHF -15.3 million (H1-2023: CHF -15.4 million)
- Cash and cash equivalents of CHF 16.5 million (Dec 31, 2023: CHF 30.4 million)

Subsequent events and financing outlook

- Close of financings with Highbridge and R-Bridge (August 12, 2024) provided initial receipt of CHF 58 million net of transaction costs with future sales milestones of up to USD 8 million
- Repayment of maturing listed convertible bonds (CHF 14 million including interest)
- Extension of CHF 7 million private convertible bond until August 2025
- Cash reach into 2026 when cash flow break-even is expected

Net Revenue

In the first half-year 2024, Santhera reported revenue from contracts with customers of CHF 14.1 million (H1-2023: CHF 3.9 million). Net sales amounted to CHF 6.5 million following the launch of AGAMREE in Germany and Austria (H1-2023: CHF 1.0 million arising from RAXONE which ceased following the disposal during H2-2023). Additionally, Santhera recognized CHF 7.7 million (H1-2023: CHF 3.0 million) from partners in China and North America reflecting milestones and product supply.

Cost of goods sold

Cost of goods sold amounted to CHF 5.2 million and increased on the prior year level (H1-2023: CHF 1.9 million), reflecting initiation of commercial supply and the amortization of intangible assets. Cost of goods for the six months includes non-cash intangible amortization of CHF 2.5 million (H1-2023 CHF 1.5 million), royalties payable of CHF 1.0 million (H1-2023 nil) as well as early-stage logistics and CMC set up expenses.

Operating expenses and result

Operating expenses of CHF 26.7 million (H1-2023: CHF 22.5 million) were 20% higher year-on-year, primarily due to an increase in activities to support the commercialization of AGAMREE.

Development expenses amounted to CHF 13.8 million (H1-2023: CHF 9.7 million). The increase of 40% arises from additional longer-term studies and CMC (chemistry, manufacturing, and controls) development activities to further enhance the commercial success of AGAMREE.

Marketing and sales expenses were CHF 4.7 million (H1-2023: CHF 4.3 million). This represents a slight increase due to higher activities for AGAMREE in Europe to support launches offset by reduction in expenses incurred in H1-2023 to support pre partnering US activities.

General and administrative expenses amounted to CHF 8.3 million (H1-2023: CHF 8.4 million), with activities focused in 2024 on supporting commercial growth.

The operating result amounted to a loss of CHF 17.7 million (H1-2023: loss of CHF 20.3 million).

Financial income and expenses

The financial income amounted to CHF 8.6 million (H1-2023: CHF 5.7 million). The increase was predominantly related to net positive changes in fair value of financial instruments, interest receivable and in (un)realized foreign exchange gains.

Financial expenses were CHF 6.0 million (H1-2023: CHF 8.8 million), primarily driven by interest payable and in (un)realized foreign exchange losses.

In summary, this resulted in a net financial income of CHF 2.7 million, compared with a net expense of CHF 3.1 million for H1-2023.

Net result

The net result in 2024 was a loss of CHF 15.3 million, compared to a net loss of CHF 23.3 million for H1-2023.

Cash balance and cash flows

As of June 30, 2024, the Company had cash and cash equivalents of CHF 16.5 million compared to CHF 30.4 million as of December 31, 2023, a decrease of CHF 13.9 million (H1-2023 an increase of CHF 0.3 million)

Net cash flow used in operating activities amounted to CHF 15.3 million (H1-2023: net cash outflow of CHF 15.4 million).

There was negligible cash flow from investing activities (H1-2023 income of CHF 5.7 million from proceeds of sale of shares).

Net cash flow used in/from financing activities was CHF -0.4 million (H1-2023: CHF 10.0 million). There were no financing inflows during the period due to the available cash balances, while additional finance was raised following the period end.

Assets and liabilities

Intangible assets decreased by CHF 2.5 million to CHF 71.5 million reflecting amortization in the period.

Total assets decreased by CHF 1.4 million to CHF 108.2 million as a result of a reduction in cash of CHF 13.9 million, offset by an increase in inventory and trade receivables following initial commercialization and milestones receivable.

Total liabilities increased by CHF 10.5 million to CHF 60.2 million mainly due to increase in trade payables relating to inventory purchases.

Shareholders' equity

Total consolidated equity as of June 30, 2024, amounted to CHF 48.1 million compared to CHF 59.9 million as of December 31, 2023.

Financing activities

As previously announced, additional funding was required to support ongoing activities and service debt obligations. In August, Santhera closed two financing agreements that provided the Company with gross funding totaling approximately CHF 69 million.

CHF 35 million received from Highbridge under a new term loan agreement

Santhera received CHF 35 million from a term loan financing from certain funds managed by Highbridge Capital Management, LLC (Highbridge). The loan has a four-year maturity with amortization in the amount of 15% per year, commencing after 24 months, and will pay a cash interest of 3-month SARON (floor of 2%) plus 9.75% per year. The transaction includes changes to the existing Highbridge private convertible bonds, extending CHF 7 million with a strike price of CHF 10 by 12 months to August 2025, and converting CHF 4 million, with a strike price of CHF 5 as well as issuing the new warrants to Highbridge.

USD 30 million received from R-Bridge for partial and capped royalty monetization

Upon closing of the royalty monetization financing agreement, R-Bridge paid an upfront of USD 30 million to Santhera and will make staged sales-related milestone payments that, if achieved, would result in total payments to Santhera of a further USD 8 million.

The royalty agreement with R-Bridge is partial and capped. Santhera is monetizing 75% of the future royalty income streams (net of any agreed payment obligations of Santhera to ReveraGen and Idorsia) from its licensing agreements for AGAMREE with Catalyst Pharmaceuticals, Inc. and with Sperogenix Therapeutics Ltd., in respect of net product sales occurring from July 1, 2024. Once the agreed threshold or duration of royalty payments is met, the North America and China royalty payments will revert back to Santhera. In addition, Santhera retained certain rights to buy back the royalty income stream.

Following closing of the financings, the proforma cash balance was CHF 72 million (August 13, 2024) after receipt of CHF 58 million net of transaction fees. After repayment of the maturing listed convertible bonds and interest in the amount of CHF 14 million, the remaining cash balance is expected to provide for a cash runway into 2026 and to expected cash flow break-even.

References:

Publications and applicable drug labeling to which this report makes reference to:

Labeling: United States Prescribing Information; European Union Summary of Product Characteristics

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Liu X et al (2020). *Proc Natl Acad Sci USA* 117:24285-24293

Heier CR et al (2019). *Life Science Alliance* DOI: 10.26508

Ward et al., *WMS 2022*, FP.27 - Poster 71. Link.

Hasham et al., *MDA 2022* Poster presentation. Link.

Half-year Report

The Santhera Half-year Report 2024 (English only) 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, 2024 (unaudited)	Dec 31, 2023 (audited)
Assets			
Tangible assets	5	2,811	582
Intangible assets		71,453	73,966
Financial assets long-term		342	424
Noncurrent assets		74,606	74,972
Prepaid expenses		692	321
Inventories		6,024	1,811
Trade and other receivables		10,433	2,155
Cash and cash equivalents	6	16,491	30,370
Current assets		33,640	34,657
Total assets		108,246	109,629
Equity and liabilities			
Share capital	7	1,262	1,262
Capital reserves and share premium		633,877	630,516
Retained deficit		(587,982)	(572,719)
Employee benefit reserve		1,019	1,018
Treasury shares		(92)	(131)
Translation differences		(27)	(3)
Total equity		48,057	59,943
Noncurrent warrant financial instruments	8	845	1,478
Noncurrent lease liabilities	5	2,436	35
Pension liabilities		3,858	3,858
Noncurrent liabilities		7,139	5,371
Trade and other payables		14,915	5,616
Accrued expenses		10,241	9,572
Income tax payable		265	182
Current lease liabilities		271	571
Current convertible bonds	8	23,665	20,943
Current derivative financial instruments	8	2,838	5,255
Current warrant financial instruments	8	820	2,035
Current provisions	10	35	141
Current liabilities		53,050	44,315
Total liabilities		60,189	49,686
Total equity and liabilities		108,246	109,629

Interim Consolidated Income Statement

<i>In CHF thousands (except per share data)</i>	Notes	Six months ended (unaudited)	
		Jun 30, 2024	Jun 30, 2023
Net sales	11	6,464	969
Revenue from out-licensing transactions	11	6,361	1,921
Net sales to licensing partner	11	1,289	1,049
Revenue from contracts with customers		14,114	3,939
Cost of goods sold		(5,215)	(1,928)
<i>Of which amortization of intangible asset</i>		<i>(2,487)</i>	<i>(1,519)</i>
Other operating income		67	141
Development	12	(13,771)	(9,748)
Marketing and sales	12	(4,660)	(4,257)
General and administrative	12	(8,265)	(8,351)
Other operating expenses	12	(11)	(101)
Operating expenses		(26,707)	(22,457)
Operating result		(17,741)	(20,305)
Financial income	13	8,638	5,694
Financial expense	13	(5,986)	(8,809)
Result before taxes		(15,089)	(23,420)
Income tax (expense)/benefit	14	(174)	84
Net result		(15,263)	(23,336)
Basic and diluted loss per share	16	(1.35)	(2.09)

Interim Consolidated Statement of Comprehensive Income

In CHF thousands

	Six months ended (unaudited)	
	Jun 30, 2024	Jun 30, 2023
Net result	(15,263)	(23,336)
<i>Items that will not be reclassified to profit or loss in subsequent periods:</i>		
Net actuarial gains/(losses) from defined benefit plans	1	222
<i>Items that may be reclassified to profit or loss in subsequent periods:</i>		
Currency translation differences	(24)	163
Other comprehensive result	(23)	385
Total comprehensive result	(15,286)	(22,951)

Interim Consolidated Statement of Cash Flows

<i>In CHF thousands</i>	Notes	Six months ended (unaudited)	
		Jun 30, 2024	Jun 30, 2023
Result before taxes		(15,089)	(23,420)
Depreciation of tangible assets		286	306
Amortization of intangible assets		2,487	1,519
Share-based compensation	15	2,590	1,900
Change in fair value of financial instruments, net		(4,263)	(4,649)
Loss on modification of convertible bonds	8	-	254
Change in pension liabilities		-	78
Change in current provisions	10	(106)	546
Change in noncurrent provisions		-	(184)
Income taxes paid		(91)	(137)
Change in net working capital		(1,887)	3,723
Total financial result		1,042	4,748
Interest received		480	-
Interest paid		(732)	(42)
Net cash flow from/(used in) operating activities		(15,283)	(15,358)
Proceeds from sale of financial assets		-	5,679
Investment in tangible assets		(72)	-
Change in financial assets long-term		82	3
Net cash flow from/(used in) investing activities		10	5,682
Proceeds from shares sold through a private placement		-	2,250
Proceeds from sale of treasury shares		-	624
Proceeds from exercise of warrants financial instruments		-	200
Proceeds from Exchangeable Notes		-	7,500
Financing transaction costs		-	(102)
Cost of issuance of capital		-	(145)
Payment of lease liabilities		(358)	(348)
Net cash flow from/(used in) financing activities		(358)	9,979
Effects of exchange rate changes on cash and cash equivalents		1,752	18
Net increase/(decrease) in cash and cash equivalents		(13,879)	321
Cash and cash equivalents at January 1		30,370	1,353
Cash and cash equivalents at June 30		16,491	1,674

Interim Consolidated Statement of Changes in Equity

<i>In CHF thousands</i>	Notes	Share capital	Capital reserves and share premium	Retained earnings/(deficit)	Employee benefit reserve	Treasury shares	Translation differences	Total
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	15	-	1,900	-	-	-	-	1,900
Shares issued	7	508	-	-	-	(508)	-	-
Shares sold through a private placement	7	-	2,220	-	-	30	-	2,250
Delivery of Shares on conversion of Exchangeable Notes into Shares	8	-	12,290	-	-	148	-	12,438
Delivery of Shares on conversion of convertible bonds into Shares	8	-	217	-	-	4	-	221
Delivery of Shares on settlement of convertible bonds interest expense	8	-	910	-	-	10	-	920
Delivery of Shares for financing transactions	8	-	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	8	-	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)
Balance, January 1, 2024		1,262	630,516	(572,719)	1,018	(131)	(3)	59,943
Net result		-	-	(15,263)	-	-	-	(15,263)
Other comprehensive income		-	-	-	1	-	(24)	(23)
Total comprehensive result		-	-	(15,263)	1	-	(24)	(15,286)
Share-based compensation		-	2,590	-	-	-	-	2,590
Delivery of Shares for exercise of share-based compensation		-	771	-	-	39	-	810
Balance, June 30, 2024 (unaudited)		1,262	633,877	(587,982)	1,019	(92)	(27)	48,057

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 11, 2024.

2 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, 2023.

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, 2023.

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 2024 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.

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, 2024	Jun 30, 2023	Jun 30, 2024	Dec 31, 2023
1 Euro (EUR)	0.9614	0.9856	0.9624	0.9281
1 US dollar (USD)	0.8894	0.9116	0.8997	0.8401
1 British pound (GBP)	1.1253	1.1242	1.1369	1.0672

5 Tangible Assets

During the six months to June 30, 2024 the Company recognized right-of-use assets and corresponding lease liabilities of CHF 2.4 million as part of adopting IFRS 16 for new lease agreements. This represents a non-cash financing activity and therefore is not reflected in the cash flow statement.

6 Cash and Cash Equivalents

<i>In CHF thousands</i>	Jun 30, 2024	Dec 31, 2023
Cash at banks and on hand		
in CHF	378	1,275
in EUR	5,582	787
in USD	10,514	28,303
other currencies	17	5
Total cash and cash equivalents	16,491	30,370

7 Share Capital

7.1 Ordinary share capital

As of June 30, 2024, and as of December 31, 2023, issued share capital totaled CHF 1,262,037.60, consisting of 12,620,376 shares with a nominal value of CHF 0.10 each.

7.2 Treasury shares

During the six months ending June 30, 2024, a total of 386,979 treasury shares were issued in respect of share-based compensation.

As of June 30, 2024, the Company holds 918,814 treasury shares with a nominal value of CHF 0.10 each for a total value of CHF 91,818.40. As of December 31, 2023, the Company held 1,305,167 treasury shares with a nominal value of CHF 0.10 each for a total value of CHF 130,516.70.

7.3 Capital band

As of June 30, 2024, the Company held a capital band between CHF 630,000.00 (lower limit) and CHF 1,860,000.00 (upper limit). Within the range of the capital band, the Board of Directors is authorized to increase the share capital in any amount once or several times until June 26, 2028.

7.4 Conditional shares

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

Article 3b conditional shares

As of June 30, 2024 and as of December 31, 2023, Article 3b conditional capital totaled CHF 54,245 consisting of 542,450 shares with a nominal value of CHF 0.10 each.

Article 3c conditional shares

As of June 30, 2024, Article 3c conditional capital totals CHF 550,000, consisting of 5,500,000 shares with a nominal value of CHF 0.10 each. As of December 31, 2023, Article 3c conditional capital totaled CHF 550,000 consisting of 5,500,000 shares with a nominal value of CHF 0.10 each.

8 Financial Liabilities

8.1 Equity-linked financing arrangements

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, 2024, and June 30, 2023:

<i>In CHF thousands</i>	Exchangeable Notes Highbridge	Exchangeable Notes Highbridge derivatives	Exchangeable Notes Highbridge Warrants	Warrants
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)	(2,573)
Balance, June 30, 2023	21,367	3,702	1,804	2,828

(continued)

Repayment of Exchangeable Notes	(25,475)	-	-	-
Non-cash changes:				
Derecognition of financial instruments on Exercise	-	-	-	(1,591)
Derecognition of financial instruments at Settlement	-	(4,224)	(1,060)	-
Effective interest/amortized cost/fair value adjustments	4,108	522	504	1,028
Balance, December 31, 2023	-	-	1,248	2,265

Non-cash changes:				
Effective interest/amortized cost/fair value adjustments	-	-	(614)	(1,234)
Balance, June 30, 2024	-	-	634	1,031

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:

<i>Financial instruments</i>	Jun 30, 2024	Dec 31, 2023
Equity-linked financing arrangements – warrants:		
Granted in September 2021	79%	82%
Granted in January 2023	46%	85%
Granted in February 2023	71%	82%

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.

<i>In CHF thousands</i>		Jun 30, 2024	Dec 31, 2023
<i>Financial instruments</i>	Increase/decrease in volatility assumption	Effect on result before taxes	Effect on result before taxes
Equity-linked financing arrangements – warrants			
Change in volatility	+5%	290	(214)
	-5%	(137)	208

8.2 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.

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.

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.

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. 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.

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, 2024, and December 31, 2023:

<i>In CHF thousands</i>					Jun 30, 2024		Dec 31, 2023	
	Offering	Currency	Interest	Maturity	Nominal value	Carrying value	Nominal value	Carrying value
2021/24 Bonds								
(ISIN: CH0563348744)	Public	CHF	7.5%	2024	13,547	13,409	13,547	12,755
2021/24 Private Bonds								
	Private	CHF	7.5%	2024	10,999	10,256	10,999	8,188
Total convertible bonds					24,546	23,665	24,546	20,943

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, 2024, and June 30, 2023:

<i>In CHF thousands</i>	2021/24 Bonds	2021/24 Bonds derivatives	2021/24 Private Bonds	2021/24 Private Bonds derivatives	2021/24 Private Bonds warrants
Balance, December 31, 2022	11,613	830	9,467	3,505	1,335
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
Nominal value of bonds converted into Shares	-	-	(773)	-	-
Derecognition of financial instruments on conversion of bonds into Shares	-	-	-	(664)	-
Derecognition of financial instruments on exercise	-	-	-	-	(671)
Effective interest/amortized cost/fair value adjustments	597	(150)	1,909	1,256	11
Balance, December 31, 2023	12,755	67	8,188	5,188	0
Effective interest/amortized cost/fair value adjustments	654	(67)	2,068	(2,350)	-
Balance, June 30, 2024	13,409	0	10,256	2,838	-

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:

<i>Financial instruments</i>	Jun 30, 2024	Dec 31, 2023
Derivatives:		
2021/24 Bonds	52%	80%
2021/24 Private Bonds	52%	80%

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:

<i>In CHF thousands</i>		Jun 30, 2024	Dec 31, 2023
<i>Financial instruments</i>	Increase/decrease in volatility assumption	Effect on result before taxes	Effect on result before taxes
2021/24 Bonds – derivatives			
	+5%	-	(22)
Change in volatility	-5%	-	20
2021/24 Private Bonds – derivatives			
	+5%	(33)	(22)
Change in volatility	-5%	29	29

8.3 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, 2024, and December 31, 2023:

Warrants granted	Expiry date	Exercise price (CHF)	Outstanding Dec 31, 2023	Exercised	Expired/ Forfeited	Outstanding Jun 30, 2024
458,504	Sep 22, 2026	20.00	458,504	-	-	458,504
221,161	Jan 9, 2025	9.043	221,161	-	-	221,161
200,000	Sep 20, 2026	5.00	191,502	-	-	191,502
879,665			871,167	-	-	871,167

9 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, 2024, and December 31, 2023. During the six months ended June 30, 2024, there have been no transfers between the different hierarchy levels.

In CHF thousands

	Jun 30, 2024				
	Carrying value	Level 1	Level 2	Level 3	Total
Exchangeable Notes					
2021/24 Bonds	13,409	13,574			13,574
2021/24 Private Bonds	10,256		8,183		8,183
Total financial liabilities at amortized cost	23,665	13,574	8,183		21,757
Derivative financial instruments	2,838	-	-	2,838	2,838
Warrant financial instruments	1,665	-	-	1,665	1,665
Total financial liabilities at fair value through profit or loss	4,503	-	-	4,503	4,503

In CHF thousands

	Dec 31, 2023				
	Carrying value	Level 1	Level 2	Level 3	Total
2021/24 Bonds	12,755	13,496	-	-	13,496
2021/24 Private Bonds	8,188	-	5,855	-	5,855
Total financial liabilities at amortized cost	20,943	13,496	5,855	-	19,351
Derivative financial instruments	5,255	-	-	5,255	5,255
Warrant financial instruments	3,513	-	-	3,513	3,513
Total financial liabilities at fair value through profit or loss	8,768	-	-	8,768	8,768

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)

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 AGAMREE 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, 2023	141
Utilizations	(106)
Balance, June 30, 2024	35

11 Segment and Geographic Information

11.1 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 AGAMREE and RAXONE for the treatment of DMD and LHON respectively and revenues from licensing agreements. Geographic revenue information is based on location of the customer.

11.2 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, 2024				Jun 30, 2023			
	Europe	North America	Asia	Total	Europe	North America	Asia	Total
Net sales	6,464	-	-	6,464	969	-	-	969
Revenue from out-licensing transactions	99	910	5,352	6,361	-	-	1,921	1,921
Net sales to licensing partner	-	1,240	49	1,289	1,049	-	-	1,049
Total revenue from contracts with customers	6,563	2,150	6,641	14,114	2,018	-	1,921	3,939

During the six months ending June 30, 2024, AGAMREE direct sales are to Germany and Austria, with the majority of sales generated in Germany following launches within the period. During the six months ending June 30, 2023, RAXONE direct sales were to Italy, France, and Switzerland, with the majority of sales generated in Italy.

11.3 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.

<i>In CHF thousands</i>	Jun 30, 2024	Dec 31, 2023
Switzerland	74,240	74,519
Netherlands	24	29
Total	74,264	74,548

12 Operating Expenses by Nature

<i>In CHF thousands</i>	Six months ended	
	Jun 30, 2024	Jun 30, 2023
External development expenses	9,944	5,104
Patent and license expenses	85	146
Marketing and sales expenses	2,057	3,148
Employee expenses	8,223	9,313
Share-based compensation	2,590	1,900
General and administrative expenses	2,752	1,955
Depreciation and amortization	286	306
Facility related and lease expenses	209	141
Other	561	444
Total operating expenses	26,707	22,457

13 Financial Income/(Expense)

13.1 Financial income

<i>In CHF thousands</i>	Six months ended	
	Jun 30, 2024	Jun 30, 2023
Interest income	480	-
Change in fair value of financial instruments, net	4,263	4,649
Realized and unrealized foreign exchange gains, net	3,895	366
Gain on sale of financial assets	-	679
Total financial income	8,638	5,694

13.2 Financial expense*In CHF thousands*

	Six months ended	
	Jun 30, 2024	Jun 30, 2023
Interest and make-whole expenses	(4,019)	(8,001)
Loss on modification of 2021/24 Private Bonds	-	(254)
Interest expense on lease liabilities	(12)	(16)
Financing transaction costs	-	(102)
Realized and unrealized foreign exchange losses, net	(1,955)	(436)
Total financial expense	(5,986)	(8,809)

14 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, 2024, and June 30, 2023. Movements in deferred taxes relate to temporary differences on inventory.

In CHF thousands

	Six months ended	
	Jun 30, 2024	Jun 30, 2023
Current income taxes	174	(17)
Deferred taxes	-	(67)
Total income tax expense / (benefit)	174	(84)

15 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, 2024, and June 30, 2023:

In CHF thousands (except no. of grants)

	Six months ended			
	Jun 30, 2024		Jun 30, 2023	
	Number granted	Fair value	Number granted	Fair value
Restricted Stock Units (RSUs)	40,429	443	81,317	317
Share Appreciation Rights (SARs)	2,104	16	253,605	1,471
Performance Stock Units (PSUs)	4,269	34	531,895	2,505

The fair value of equity rights granted is measured on the grant date. For the six months ended June 30, 2024, 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, 2023, except for the volatility,

exercise price (equal to the Share prices at grant), which was based on an exercise base value of CHF 10.50 (2023: CHF 8.40).

The RSUs granted during the six months ended June 30, 2024, vest between June 19, 2024, and one day before the AGM 2025.

The PSUs granted during the six months ended June 30, 2024, vest between March 2024 and February 2027, with the achievement of pre-defined performance targets.

The stock options granted during the six months ended June 30, 2023, vest annually over a three-year period and have an exercise price of CHF 10.50

For the six months ended June 30, 2024, and June 30, 2023, non-cash share-based compensation expense recognized in the interim consolidated income statement, for all equity rights plans totaled CHF 2.6 million and CHF 1.9 million, respectively.

16 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.

<i>In CHF thousands (except per share data)</i>	Six months ended	
	Jun 30, 2024	Jun 30, 2023
Net result attributable to shareholders	(15,263)	(23,336)
Weighted average number of shares issued and outstanding	11,335,864	11,159,999
Basic and diluted net result per share	(1.35)	(2.09)

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.

17 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, 2024, and June 30, 2023:

<i>In CHF thousands</i>	Six months ended	
	Jun 30, 2024	Jun 30, 2023
Executive Management:		
Short-term employee benefits	1,405	1,498
Post-employment benefits	338	131
Share-based compensation	398	998
Board of Directors	341	517
Total compensation expense	2,482	3,144

Detailed remuneration disclosures are provided in the Group's audited consolidated financial statements for the year ended December 31, 2023.

18 Subsequent Events

On August 13, 2024, Santhera closed two financing agreements that provided the Company with gross funding totaling approximately CHF 69 million, as further described below. Together with existing cash resources, this will support the Company's growth initiatives, repayment of maturing convertible bonds and liquidity through to the first half of 2026, at which point Santhera expects to be cash flow break-even.

Santhera received CHF 35 million from a term loan financing from certain funds managed by Highbridge Capital Management, LLC (Highbridge) with a four-year maturity and an interest rate of 3-month SARON plus 9.75%. The transaction includes changes to the existing Highbridge private convertible bonds, extending CHF 7 million with a strike price of CHF 10 by 12 months to August 2025, and converting CHF 4 million, with a strike price of CHF 5 as well as issuing the new warrants to Highbridge.

In addition, Santhera closed a royalty monetization financing agreement, R-Bridge paid an upfront of USD 30 million to Santhera and will make staged sales-related milestone payments that, if achieved, would result in total payments to Santhera of a further USD 8 million. The royalty agreement with R-Bridge is partial and capped. Santhera is monetizing 75% of the future royalty income streams (net of any agreed payment obligations of Santhera to ReveraGen and Idorsia) from its licensing agreements for AGAMREE with Catalyst Pharmaceuticals, Inc. and with Sperogenix Therapeutics Ltd., in respect of net product sales occurring from July 1, 2024. Once the agreed threshold or duration of royalty payments is met, the North America and China royalty payments will revert back to Santhera. In addition, Santhera retained certain rights to buy back the royalty income stream.

On closing CHF 58 million was received being CHF 69 million gross net of future milestones (as described above) and transaction fees. On August 18, 2024, listed 2021/24 convertible bonds amounting to CHF 14 million were redeemed on maturity.

On September 10, 2024, Santhera announce the signing of an exclusive distribution agreement with GENESIS Pharma for AGAMREE for the treatment of Duchenne muscular dystrophy (DMD) in 20 markets in Central and Eastern Europe.

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 from ReveraGen for all indications worldwide to AGAMREE® (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. AGAMREE for the treatment of DMD is approved in the U.S. by the Food and Drug Administration (FDA), in the EU by the European Medicines Agency (EMA), and in the UK by the 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. For further information, please visit www.santhera.com.

AGAMREE® 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.

Contact

Eva Kalias
Head Investor Relations & Communications
Phone +41 61 906 89 26
eva.kalias@santhera.com

Santhera Pharmaceuticals Holding AG

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