

Ad hoc announcement pursuant to Art. 53 LR

A conference call will be held today at 14:30 CEST / 13:30 BST / 08:30 EDT. Details are at the end of this news release.

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 Ionodelestat 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:

- [1] Guglieri M et al (2022). JAMA Neurol. Published online August 29, 2022. doi:10.1001/jamaneurol.2022.2480. [Link](#).
- [2] Mah JK et al (2022). JAMA Netw Open. 2022;5(1):e2144178. doi:10.1001/jamanetworkopen.2021.44178. [Link](#).
- [3] Guglieri, et al (2022) JAMA. doi:10.1001/jama.2022.4315
- [4] Heier CR et al (2019). Life Science Alliance DOI: 10.26508
- [5] Liu X, et al (2020). Proc Natl Acad Sci USA 117:24285-24293

2023 Half-year Financial Information

Interim condensed consolidated income statement (for the six months ended June 30, in CHF thousands, except per share data)	H1-2023 (unaudited)	H1-2022 (unaudited)
Net sales	969	(5,873)
Revenue from out-licensing transactions	1,921	11,190
Net sales to licensing partner	1,049	933
Revenue from contracts with customers	3,939	6,250
Cost of goods sold	(1,928)	(1,875)
<i>of which amortization intangible assets</i>	<i>(1,519)</i>	<i>(1,519)</i>
Development	(9,748)	(16,870)
Marketing and sales	(4,257)	(5,917)
General and administrative, other	(8,452)	(7,203)
Operating expenses	(22,457)	(29,990)
Operating result	(20,305)	(25,536)
Financial result, net	(3,115)	(3,596)
Income tax (expense)/benefit	84	(592)
Net result	(23,336)	(29,724)
Basic and diluted loss per share (in CHF)	(2.09)	(5.16)

Interim condensed consolidated balance sheet (in CHF thousands)	Jun 30, 2023 (unaudited)	Dec 31, 2022 (audited)
Cash and cash equivalents	1,674	1,353
Other current assets	2,420	1,712
Noncurrent assets	52,331	60,661
Assets of disposal group held for sale	6,650	-
Total assets	63,075	63,726
Equity	(42,762)	(43,686)
Noncurrent liabilities	28,458	57,998
Current liabilities	52,602	49,414
Liability directly associated with assets of disposal group held for sale	24,777	-
Total equity and liabilities	63,075	63,726

Interim condensed consolidated cash flow statement (for six months ended June 30, in CHF thousands)	H1-2023 (unaudited)	H1-2022 (unaudited)
Net cash flow from/(used in) operating activities	(15,358)	(11,957)
Net cash flow from/(used in) investing activities	5,682	-
Net cash flow from/(used in) financing activities	9,979	3,488
Cash and cash equivalents at January 1	1,353	21,208
Cash and cash equivalents at June 30	1,674	12,697
Net increase/(decrease) in cash and cash equivalents	321	(8,511)

Share capital (number of shares with par value of CHF 0.01, before reverse split)	Jun 30, 2023 (unaudited)	Dec 31, 2022 (audited)
Ordinary shares issued	126,055,256	75,320,510
Treasury shares	34,100,466	9,438,017
Conditional capital for equity rights	5,034,583	5,034,583
Conditional capital for convertible rights	29,888,687	30,156,622
Authorized capital	46,860,687	36,860,687

Half-year Report

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

Conference Call

Santhera will host a conference call on September 7, 2023, at 14:30 CEST / 13:30 BST / 08:30 EDT. CEO Dario Eklund, CFO Andrew Smith and CMO Shabir Hasham, MD, will discuss the 2023 half-year results and comment on ongoing corporate developments. Participants are invited to call one of the following numbers (no dial-in code is required):

Switzerland/Europe: +41 58 310 50 00

United Kingdom: +44 207 107 06 13

USA: +1 631 570 56 13

A replay will be accessible at <https://www.santhera.com/ad-hoc-news> from about two hours after the call has ended.

Upcoming conference participations

Sep 11-13, 2023 H.C. Wainwright Global Investment Conference, New York, USA

Oct 3-7, 2023 Annual Congress of the World Muscle Society (WMS), Charleston, USA

References

- [1] Guglieri M et al (2022). JAMA Neurol. 2022;79(10):1005-1014. doi:10.1001/jamaneurol.2022.2480. [Link](#).
- [2] Mah JK et al (2022). JAMA Netw Open. 2022;5(1):e2144178. doi:10.1001/jamanetworkopen.2021.44178. [Link](#).
- [3] Guglieri, et al (2022) JAMA. doi:10.1001/jama.2022.4315
- [4] Heier CR et al (2019). Life Science Alliance DOI: 10.26508
- [5] Liu X, et al (2020). Proc Natl Acad Sci USA 117:24285-24293

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.

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