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Ad hoc announcement pursuant to Art. 53 LR

A conference call will be held on November 7, 2022, at 14:30 CET, 13:30 GMT, 08:30 EST. Details are at the end of this news release.

Santhera Announces Half-Year 2022 Financial Results and Provides Corporate Update

- **Revenue from contracts with customers of CHF 6.3 million (H1-2021: CHF 4.5 million)**
- **Operating result of CHF -25.5 million (H1-2021: CHF -19.5 million) and net result of CHF -29.7 million (H1-2021: CHF -20.5 million)**
- **Cash and cash equivalents of CHF 12.7 million (June 30, 2022), together with existing facilities enabling cash reach into Q1-2023**
- **Key milestones reached with U.S. and EU regulatory submissions (NDA, MAA) for vamorolone in Duchenne muscular dystrophy (DMD)**
- **Financing initiatives ongoing to support vamorolone launch and other ongoing activities**

Pratteln, Switzerland, October 31, 2022 – Santhera Pharmaceuticals (SIX: SANN) announces the Company's financial results for the six months ended June 30, 2022, reports on the regulatory and clinical progress with its lead drug candidate vamorolone for the treatment of DMD in the U.S. and Europe, and provides updates on its financing initiatives.

"The year 2022 to date was fully geared towards registration and approval of vamorolone in Duchenne muscular dystrophy (DMD) and I am delighted that, over the last month, we submitted and received validation for a marketing authorization application (MAA) in the EU followed by completion of the rolling submission of a new drug application (NDA) in the U.S. This represents a tremendous achievement for Santhera and a major step towards our goal of bringing this investigational therapy to patients living with DMD," said **Dario Eklund, CEO of Santhera**. "With equally high priority, we are pursuing additional near-term financing, primarily to allow us to fund market entry preparations for vamorolone. We are evaluating various non-dilutive options including but not limited to licensing agreements and monetization of assets in addition to debt and royalty financing and, depending on market conditions, may also consider equity-based funding options."

PIPELINE MILESTONES AND PROGRESS REVIEW

Half-year key events and post-period updates

- New drug application (NDA) submitted to the U.S. Food and Drug Administration (FDA) for vamorolone in DMD
- Marketing authorization application (MAA) submitted to and validated by the European Medicines Agency (EMA) for vamorolone in DMD
- Efficacy, safety and bone health data with vamorolone published in JAMA Neurology and presented at scientific conferences
- Activities advanced to establish launch readiness for vamorolone in the U.S.

- Exclusive license agreement concluded with Sperogenix for vamorolone in rare diseases in the Greater China Region
- Phase 2 trial started with vamorolone in boys aged 2 to <4 years and 7 to <18 years with DMD to assess drug effects in wider age range
- First participant dosed in FDA-funded study with vamorolone in Becker muscular dystrophy
- Lonodelestat development program deprioritized owing to limited resources

The primary operational focus of Santhera in 2022 continues to be the advancement of the regulatory submissions for vamorolone in the U.S. and the EU towards approval. In parallel, the Company plans to advance operational preparations for launches anticipated for 2023 in both regions.

NDA submission to the U.S. FDA for vamorolone in DMD completed

In October, Santhera completed the rolling submission of an NDA to the U.S. FDA, seeking priority review for vamorolone for the treatment of DMD. Typically, within 60 days of the receipt of the dossier, the FDA will inform if a priority review will be granted. A priority review designation indicates FDA's goal to take action on an application within six months (compared to ten months under standard review) which would set an anticipated approval date for as early as mid-2023. Subject to approval, vamorolone is set to become available to patients in the U.S. in H2-2023.

European MAA for vamorolone in DMD submitted – review by the EMA has started

In September, Santhera submitted an MAA for vamorolone for the treatment of DMD to the EMA. Validation, received in October, confirms that the submission is complete and that the review by the EMA's Committee for Medicinal Products for Human Use (CHMP) has begun. Santhera expects the CHMP to complete the review and issue an opinion regarding approval to EMA's European Commission (EC) in late Q3-2023. Subject to EC approval later in 2023, vamorolone will receive marketing authorization in all member states of the European Union, as well as in Norway, Liechtenstein and Iceland.

Findings on bone health published for vamorolone alongside efficacy and safety data

Vamorolone is under joint development by ReveraGen and Santhera for DMD patients with the objective 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. In addition to long-term efficacy and safety data with vamorolone, recent publications and presentations further characterized vamorolone's differentiated profile especially with regard to bone health [1-5].

In July 2022, data assessing the impact of long-term treatment with vamorolone on bone health were presented at the *10th International Conference on Children's Bone Health* [1]. After 2.5 years of treatment with vamorolone, bone turnover markers were not suppressed, bone age delay was minimal, and the vertebral fracture burden was lower compared with published data on daily prednisolone. Efficacy data showed that vamorolone can maintain muscle function in boys with DMD, similar to standard of care glucocorticoid treatment.

In August 2022, *JAMA Neurology* published the positive 24-week results from the pivotal VISION-DMD study evaluating vamorolone in patients with DMD compared to placebo and prednisone [2]. Vamorolone met its primary endpoint by demonstrating statistically significant and clinically relevant improvement in time to stand from floor compared to placebo and showed consistent results across multiple secondary endpoints. The relative efficacy of vamorolone 6 mg/kg/day was comparable to that seen with prednisone 0.75 mg/kg/day across primary and secondary efficacy endpoints. Importantly, no

negative impact on biomarkers of bone health and no loss of linear growth were observed with vamorolone. Patients treated with prednisone experienced reductions in serum biomarkers of bone formation, which promptly recovered to baseline values when subjects were switched from prednisone to vamorolone.

In October 2022, key opinion leaders further highlighted the bone-related profile of vamorolone in different presentations at the *World Muscular Society Congress 2022* which can be viewed on Santhera's website here.

Vamorolone, an investigational drug, was generally safe and well tolerated. The most commonly reported adverse events versus placebo were cushingoid features, vomiting and vitamin D deficiency. Adverse events were generally of mild to moderate severity.

U.S. pre-commercialization measures advanced

The U.S. subsidiary made further progress in establishing launch readiness with the hiring into critical roles and a focus on long lead-time priority projects. These include medical and market access activities, working closely with key clinical opinion leaders to facilitate presentations and papers as well as engaging with patient advocacy groups.

Started Phase 2 study evaluating vamorolone in a wider age range of patients with DMD

Health care professionals routinely prescribe glucocorticoid steroids in DMD to preserve muscle strength and function in ambulant boys, starting at an early stage. In most cases treatment is continued until deleterious side effects prevent further therapy and lead to early discontinuation. The clinical development program for vamorolone included patients 4-7 years old and this new study aims at collecting information on vamorolone outside the original age range. The ongoing Phase 2 VBP-006 study (ClinicalTrials.gov ID: NCT05185622) is an open-label, multiple dose study to evaluate the clinical efficacy, safety and tolerability of vamorolone 2 or 6 mg/kg/day over a treatment period of 12 weeks in 44 steroid-naïve boys ages 2 to <4 years, and glucocorticoid-treated and currently untreated boys ages 7 to <18 years with DMD. The estimated study completion date is end of 2023.

First patient dosed in FDA-funded study with vamorolone in Becker muscular dystrophy (BMD)

This Phase 2 pilot study is a randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability and exploratory clinical efficacy on motor function outcomes of vamorolone compared to placebo over a treatment period of 24 weeks in 39 males (aged ≥18 and <65 years) with BMD (ClinicalTrials.gov ID: NCT05166109). The study is funded by a USD 1.2 million grant from the FDA under their "Clinical Studies of Orphan Products Addressing Unmet Needs of Rare Diseases (R01)" grants program. Vamorolone has shown efficacy in the pivotal VISION-DMD study in DMD, a more severe but related disease, and, based on these findings and its mechanisms of action, this developmental compound may show a benefit in BMD.

Lonodelestat development paused owing to resource constraints

Vamorolone is the main strategic focus and in the near-term will consume all financial and human resources. Santhera's focus for months to come will be on advancing vamorolone through the regulatory process towards approval and on preparations for market entry. As a consequence, Santhera has put the development program for lonodelestat, its second clinical development candidate targeting pulmonary indications, on hold. Preparations for a Phase 2 study in an acute pulmonary indication are far advanced, however, continuation of the program will be subject to funding. Santhera explores various opportunities via collaboration and/or partnerships to resume the project as quickly as possible.

Post-authorization measures (PAMs) with Raxone in LHON completed

In July 2022, the last part of the PAMs for Raxone (idebenone) was completed. Cornerstone of the PAMs were the long-term Phase 4 studies LEROS and PAROS with Raxone for the treatment of Leber's hereditary optic neuropathy (LHON). As previously reported, LEROS met the primary endpoint, the proportion of eyes with clinically relevant benefit after 12 months treatment with Raxone, with high statistical significance (p=0.002). PAROS, a prospective non-interventional study in routine clinical settings in LHON patients treated with Raxone®, suggested a maintenance of treatment effect and showed a similar safety profile observed to that from the LEROS study. This clinically robust evidence of long-term effectiveness and safety confirms and extends previous findings and is expected to facilitate market access, allowing patients to benefit where currently no effective treatments alternatives are available. Santhera intends to discuss a path forward towards U.S. approvability with drug regulators.

In 2019, Santhera out-licensed rights for Raxone (idebenone) for the treatment of LHON outside North America and France to Chiesi Group while remaining the EU marketing authorization holder for the product.

Strategic licensing agreements to exploit pipeline potential and tap non-dilutive funding

Santhera continues to pursue out-licensing agreements in the rare disease space to further exploit the potential of its pipeline products, and for securing additional funding. As previously announced, two agreements were closed in H1-2022:

In January 2022, the Company entered into an exclusive license agreement for the Greater China area with Sperogenix Therapeutics, a China-based company specializing in orphan diseases. Under this agreement, Sperogenix has in-licensed vamorolone for rare disease indications for a total consideration of up to USD 124 million and plans to initiate a regulatory filing for vamorolone for DMD in China upon U.S. FDA approval, which could lead approval in China as early as 2024.

In February 2022, Santhera signed an agreement with SEAL Therapeutics to further develop a gene therapy approach intended for the treatment of congenital muscular dystrophy in exchange for payments based on future proceeds of SEAL Therapeutics.

FINANCIAL HALF-YEAR PERFORMANCE & FINANCING OUTLOOK

- Net revenue from contracts with customers of CHF 6.3 million (H1-2021: CHF 4.5 million)
- Operating result of CHF -25.5 million (H1-2021: CHF -19.5 million)
- Net result of CHF -29.7 million (H1-2021: CHF -20.5 million)
- Cash flow from operating activities CHF -12.0 million (H1-2021: CHF -18.6 million)
- Cash and cash equivalents of CHF 12.7 million (June 30, 2022)
- Additional accrual due to uncertainties over Raxone reimbursement in France impacted H1-2022 results
- Full repayment of 2017/22 Bonds and further reduction of outstanding convertible bonds to CHF 31.5 million
- Financing agreement with Highbridge amended to meet immediate liquidity requirements
- Renegotiated the timing of vamorolone approval milestone payment reducing near-term financial obligations of the Company by CHF 20 million

Update on reimbursement negotiations for Raxone in France

Since its launch in 2018, Raxone was reimbursed in France for the treatment of patients with LHON under a temporary financing scheme. From August 2021, Santhera has supplied Raxone free of charge based on an agreement reached with the authorities in France after the temporary pricing was challenged and Raxone removed from the list of reimbursed drugs. Reimbursement discussions are still ongoing. Due to ongoing uncertainties with the status of pricing reimbursement negotiations, the Company has accrued an additional CHF 8.1 million towards a settlement, of which CHF 6.0 million was recognized against sales, and CHF 2.1 million recognized as marketing and sales expenses. As of June 30, 2022, Santhera has recognized a total accrual amount of CHF 25.0 million included within noncurrent liabilities. Once an agreement is reached, including for the final pricing for Raxone, Santhera expects to be able to settle the liability from future sales of Raxone in France.

Santhera continues to supply the product in the French market following the out-licensing and transfer of Raxone outside North America and France to Chiesi Group in 2019.

Net revenue

In the first half-year 2022, Santhera reported net revenue from contracts with customers of CHF 6.3 million (H1-2021: CHF 4.5 million).

Net sales amounted to CHF -5.9 million (H1-2021: CHF 2.9 million). The negative sales are attributable to an additional CHF 6.0 million that has been accrued and offset against sales in the context of ongoing reimbursement negotiations in France, as described above. Until an agreement is reached with the Comité économique des produits de santé (CEPS) on the future pricing of Raxone for LHON, the Company continues to provide Raxone to patients in France free of charge. Outside of France and North America, Santhera has out-licensed Raxone to Chiesi Group.

During the six months ended June 30, 2022, Santhera recognized revenue from out-licensing transactions in the amount of CHF 11.2 million (H1-2021: CHF 0 million). This largely reflects an initial income from the out-licensing transaction of vamorolone for the Greater China Region with Sperogenix.

Cost of goods

Cost of goods sold amounted to CHF 1.9 million (H1-2021: CHF 2.0 million) and represents continuing supply of Raxone and amortization of intangibles.

Operating expenses and result

Operating expenses of CHF 30.0 million (H1-2021: CHF 21.9 million) were higher, primarily due to higher external development expenses related to vamorolone.

Development expenses amounted to CHF 16.9 million (H1-2021: CHF 13.6 million). The increase was primarily due to higher expenses for third-party clinical and regulatory service providers for finalizing data analysis and the assembly of the regulatory dossiers for vamorolone in DMD to U.S. and European authorities.

Marketing and sales expenses were CHF 5.9 million (H1-2021: CHF 2.0 million). The increase was a result of the additional accrual of CHF 2.1 million in relation to ongoing reimbursement negotiations in France, as described above, as well as ongoing pre-commercialization activities for vamorolone.

General and administrative expenses of CHF 7.1 million (H1-2021: CHF 6.3 million), for which the increase year-on-year reflects the addition of personnel in key functions in view of market readiness preparations for vamorolone in the U.S.

The operating result amounted to CHF -25.5 million (H1-2021: CHF -19.5 million).

Financial income and expenses
The net financial expense amounted to CHF 3.6 million (H1-2021: CHF 0.4 million). The change from prior year same period is largely a reflection of a recognized gain on exchange of the 2017/22 Bonds in H1-2021, which had been partially offset by the costs associated with financing transactions.

Net result
The net result for the half-year ended June 30, 2022, was a loss of CHF 29.7 million or CHF -0.52 per share, compared to a net loss of CHF 20.5 million or CHF -0.92 per share for the half-year ended June 30, 2021.

Cash flow and cash balance
As of June 30, 2022, the Company had cash and cash equivalents of CHF 12.7 million compared to CHF 21.2 million as of December 31, 2021.

Net cash outflow for operating activities was lower year-on-year and amounted to CHF 12.0 million (H1-2021: CHF 18.6 million).

Net cash inflow from financing activities was lower year-on-year and amounted to CHF 3.5 million (H1-2021: CHF 14.3 million) as the net additional proceeds from exchangeable notes was largely offset by the repayment of convertible bonds.

Shareholders' equity
Total consolidated net equity deficit as of June 30, 2022, amounted to CHF -13.8 million compared to total equity of CHF 1.3 million as of December 31, 2021, as a result of the net loss incurred for the period.

Year-to-date debt and equity-linked financing
In February 2022, Santhera fully repaid its senior unsecured convertible bonds (2017/22 Bonds) with a remainder amount of CHF 13.9 million. Of the senior unsecured convertible bonds (2021/24 Bonds) maturing in August 2024, an aggregate amount of CHF 19.6 million was still outstanding on June 30, 2022, unchanged from December 31, 2021 as no repayment or conversion into shares took place during the period. Of the private convertible bonds (2021/24 Private Bonds) in the amount of CHF 15 million issued to Highbridge, CHF 3 million were converted into shares during the period, leaving a remainder of CHF 12 million at June 30, 2022. In summary, this significantly reduced total and short-term convertible debt from an original amount of CHF 60 million maturing in February 2022 to approximately CHF 31.5 million maturing in August 2024.

During the six months ending June 30, 2022, in order to provide additional fundraising flexibility, Santhera issued new shares to be held as treasury shares totaling 19,107,892 with a nominal value of CHF 1 each. As a result, Santhera's issued share capital amounts to CHF 73,725,702 as of June 30, 2022. Santhera expects to hold its treasury shares until market conditions allow for a favorable financing transaction.

Concurrently with the ordinary capital increase, and as approved by the Extraordinary General Meeting (EGM) on December 15, 2021 and the Annual General Meeting (AGM) on June 30, 2022, Santhera's authorized capital has increased during the six months ending June 30, 2022, from CHF 27,303,905 to CHF 36,860,687 and its conditional capital for financing has increased from CHF 21,878,228 to

CHF 31,370,336. Together with the 19,485,946 treasury shares held as of June 30, 2022, the Company plans to use these shares for financing activities if required.

With the shareholders' approval at the AGM held on June 30, 2022, Santhera reduced the nominal value of the shares from CHF 1.00 to CHF 0.01 per share with effective date September 6, 2022.

On June 2, 2022, the Company entered into an amendment to the timing of an upcoming milestone payment to partner ReveraGen, resulting in a reduction of the milestone payment (expected in the second half of 2023) due upon FDA approval in exchange for an increase of the sales milestone in the same amount. Thereby near-term financial obligations of the Company were reduced by CHF 20 million.

In addition, on June 2, 2022, the Company upsized its existing financing arrangement with certain funds managed by Highbridge Capital Management, LLC (Highbridge) by up to an additional CHF 40 million. An initial unconditional drawdown of CHF 20 million was received on June 3, 2022. The remaining balance of CHF 20 million is divided into two tranches of CHF 10 million each, available for drawdown subject to Highbridge Capital Management's consent.

Amendment of Highbridge facility to satisfy immediate cash requirements

On September 28, 2022, Santhera and Highbridge agreed to amend the existing financing arrangement that has been announced on June 2, 2022, and again mentioned above, to provide for the immediate drawdown of a CHF 10 million tranche in senior secured Exchangeable Notes and amend certain provisions. Of this amount, approximately CHF 5 million was used to repurchase part of the outstanding convertible bonds issued to Highbridge in 2021 and due in 2024 at a 25 percent discount to its nominal value plus interest. The 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 has agreed on a new conversion price of CHF 1.20 for the remaining outstanding private convertible bond and a new exercise price of CHF 0.80 per share for the existing warrants held by Highbridge. A further tranche of CHF 10 million available for drawdown is conditional on management achieving certain milestones and other conditions.

Funding outlook

Santhera still has treasury shares, conditional and authorized capital from past EGM and AGM authorizations which are available for future placement, subject to market conditions. This, in combination with cash balances of CHF 12.7 million (at June 30, 2022), the recent drawdown from the Highbridge facility and remaining facilities, is expected to provide a liquidity runway into Q1-2023.

In order to ensure the execution of the Company's operating plans to mid-2023, when approval of vamorolone for DMD in the U.S. is expected at the earliest, Santhera will need to secure additional funds. Santhera is pursuing strategic options including but not limited to non-dilutive funding in the form of out-licensing agreements and/or the monetization of assets and, in parallel, is also evaluating debt financing, royalty financing, standby equity distribution agreement or, depending on market conditions, equity-based funding.

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 at al (2019). Life Science Alliance DOI: 10.26508
[5] Liu X, et al (2020). Proc Natl Acad Sci USA 117:24285-24293

Half-year Report

The Santhera Half-year Report 2022 is available for download on the Company's website at www.santhera.com/financial-reports.

Conference Call

Santhera will host a conference call on November 7, 2022, at 14:30 CET / 13:30 GMT / 08:30 EST. CEO Dario Eklund, CFO Andrew Smith and CMO Shabir Hasham, MD, will discuss the 2022 half-year financial 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.

2022 Half-year Financial Information

Santhera's 2022 Half-year Report see www.santhera.com/investors-and-media/investor-toolbox/financial-reports.

Interim condensed consolidated income statement (for the six months ended June 30, in CHF thousands, except per share data)	**H1-2022** **(unaudited)**	H1-2021 (unaudited)
Net sales	**(5,873)**	2,853
Revenue from out-licensing transactions	**11,190**	-
Net sales to licensing partner	**933**	1,639
Revenue from contracts with customers	**6,250**	4,492
Cost of goods sold	**(1,875)**	(2,031)
of which amortization intangible assets	***(1,519)***	*(1,519)*
Development	**(16,870)**	(13,592)
Marketing and sales	**(5,917)**	(2,008)
General and administrative, other	**(7,203)**	(6,338)
Operating expenses	**(29,990)**	(21,938)
Operating result	**(25,536)**	(19,477)
Financial result, net	**(3,596)**	(389)
Income taxes	**(592)**	(653)
Net result	**(29,724)**	(20,519)
Basic and diluted loss per share (in CHF)	**(0.52)**	(0.92)

Interim condensed consolidated balance sheet (in CHF thousands)	**Jun 30, 2022** **(unaudited)**	Dec 31, 2021 (audited)
Cash and cash equivalents	**12,697**	21,208
Other current assets	**1,866**	3,433
Noncurrent assets	**65,219**	66,476
Total assets	**79,782**	91,117
Equity	**(13,845)**	1,328
Noncurrent liabilities	**55,051**	57,007
Current liabilities	**38,576**	32,782
Total equity and liabilities	**79,782**	91,117

Interim condensed consolidated cash flow statement (for six months ended June 30, in CHF thousands)	**H1-2022** **(unaudited)**	H1-2021 (unaudited)
Net cash flow from/(used in) operating activities	**(11,957)**	(18,607)
Net cash flow from/(used in) investing activities	**–**	(75)
Net cash flow from/(used in) financing activities	**3,488**	14,276
Cash and cash equivalents at January 1	**21,208**	12,411
Cash and cash equivalents at June 30	**12,697**	7,991
Net increase/(decrease) in cash and cash equivalents	**(8,511)**	(4,420)

Share capital (number of shares with par value of CHF 1)	**Jun 30, 2022** **(unaudited)**	Dec 31, 2021 (audited)
Ordinary shares issued	**73,725,702**	54,607,810
Treasury shares	**19,485,946**	5,019,879
Conditional capital for equity rights	**5,415,677**	5,425,677
Conditional capital for convertible rights	**31,370,336**	21,878,228
Authorized capital	**36,860,687**	27,303,905

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 as an alternative to standard corticosteroids. Santhera has submitted a new drug application (NDA) to the U.S. FDA and a marketing authorization application (MAA) to the European Medicines Agency (EMA) for vamorolone for the treatment of DMD. The clinical stage pipeline also includes lonodelestat to treat cystic fibrosis (CF) and other neutrophilic pulmonary diseases. Santhera out-licensed rights to its first approved product, Raxone® (idebenone), outside North America and France for the treatment of Leber's hereditary optic neuropathy (LHON) to Chiesi Group. For further information, please visit www.santhera.com.

Raxone® is a trademark of Santhera Pharmaceuticals.

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