Santhera Pharmaceuticals Holding AG
Hohenrainstrasse 24, 4133 Pratteln, Switzerland

Phone: +41 61 906 89 50 | Fax: +41 61 906 89 51
www.santhera.com

Ad hoc announcement pursuant to Art. 53 LR

Full Year Trading Update

Pratteln, Switzerland, March 4, 2025 – Santhera Pharmaceuticals (SIX: SANN) today provides a trading update for the fiscal year 2024 and an outlook for 2025 and beyond.

Dario Eklund, CEO of Santhera said: "The year 2024 has been a transformational year for Santhera as we strengthened our financial position and advanced the commercial roll out of AGAMREE® (vamorolone) for the treatment of Duchenne muscular dystrophy (DMD) in key European markets. We remain committed to executing our strategy, with a strong focus on maximizing value by expanding access to AGAMREE and ensuring more patients benefit from this important treatment. Looking ahead, we will continue to explore opportunities to expand our pipeline through strategic partnerships and business development initiatives."

Key unaudited financials for 2024

- **Total revenue from contracts with customers:** CHF 39.1 million (2023 CHF103.4 million), driven by strong underlying revenue growth offset by significant licensing milestones recognised in 2023 from out-licensing activities in major territories.
- **Product sales:** CHF 14.8 million (2023 CHF 0.8 million) driven by the successful launch of AGAMREE in Germany and Austria.
- **Royalties & milestones:** CHF 19.3 million (2023 CHF 99.9 million), 2023 revenues were bolstered by out-licensing milestones received from Catalyst Pharmaceuticals in the U.S. and Sperogenix in China.
- **Revenue from supply of product and services to partners:** CHF 5.0 million (2023 CHF 2.7 million)
- **Cash and cash equivalents:** CHF 41.0 million (2023 CHF 30.3 million).
- **Cash runway:** Extended to mid 2026 at which point the Company expects to be cash breakeven.

Operational Highlights

- **Launch progress in own markets:** AGAMREE has been successfully launched in Germany and Austria achieving strong early adoption, with launches expected to follow in Italy, Spain, Nordics, Benelux, Portugal, Ireland, France and Switzerland through 2025 and the first half 2026. UK reimbursement has been secured, with initial sales already achieved in Scotland and the rest of the UK expected to follow by early Q2 2025. Annual revenue was CHF 14.8 million post clawback related to finalisation of pricing in Germany. Gross product revenue excluding the clawback for pricing was CHF 18.2 million for the year with CHF 11.8 million in the second half compared to CHF 6.5 million in the first half. As at the end of the year, less than a year since launch, over 300 patients were on continuing treatment with AGAMREE, representing almost 30% of those currently on steroid treatment. This strong uptake is a reflection of AGAMREE's impact on the DMD community.

- **Catalyst & Sperogenix partnerships:** The Company continues to benefit from collaborations in North America and China, with milestone and royalty flows contributing to Santhera's financial stability. Based on the 2024 royalty monetisation agreement, 75% of the net royalties are paid to our royalty partners until a cap is reached, at which point all royalties return to the company. Catalyst launched AGAMREE in the U.S in March 2024 and reported USD 46 million revenue for the calendar year, surpassing its upgraded guidance figures for the year. They additionally provided guidance for in excess of USD 100 million in sales for 2025, which would trigger a further milestone to Santhera in addition to the royalties received throughout the year on sales.

In China, Sperogenix has commenced an early access program and now, following the regulatory approval in December 2024, is preparing for commercial rollout mid 2025 on a non-reimbursed basis, with full pricing reimbursement expected in early 2026.

- **Other territories:** Agreements were entered into covering European non-direct markets, Israel and Qatar as well as a named patient supply agreement with Clinigen to cover territories where AGAMREE is not yet commercially available. Santhera remains active in expanding territories through additional partnerships.
- **Manufacturing expansion:** To increase manufacturing capacity, streamline supply chain efficiencies, and reduce manufacturing cost, the Company as well as Catalyst are validating second manufacturers. While this could lead to lower product sales to Catalyst, these combined changes would have minimal impact on profit margins.
- **R&D strategy:** The Company continues to generate additional evidence of long-term safety on the use of AGAMREE in DMD and looks forward to long-term data readout from the GUARDIAN study, expected in Q4-25.
- **Pipeline development:** Santhera remains actively engaged in expanding its late-stage pipeline through licensing, distribution agreements, and potential M&A transactions, with updates expected in 2026. The Company will not be investing further in additional indication expansion for AGAMREE in the near term. However, the company has an option to leverage indication expansion studies undertaken by its partners at a future date. Instead, the company will use funds to focus on maximizing the opportunity with AGAMREE in DMD and expanding its product pipeline.

Guidance & Financial Outlook

- **2025 revenue guidance:** CHF 65-70 million
- **2028 revenue outlook:** EUR 150 million – this covers direct and partnered markets, as well as royalty income from North America and China but not milestones payments received from partners
- **Operating expenses (2025 and going forward on constant portfolio basis):** CHF 50-55 million – this excludes non-cash share compensation

Upcoming Events

- **Capital Markets Day – March 24, 2025**
- **Full-Year 2024 Financial Results – April 29, 2025**
- **Annual General Assembly – May 20, 2025**

Santhera remains committed to delivering long-term value through disciplined financial management, strategic commercial execution, and continued focus on pipeline expansion. The company will provide further insights into its growth strategy during its Capital Markets Day on March 24, 2025.

About AGAMREE® (vamorolone)

AGAMREE is a novel drug with a mode of action based on binding to the same receptor as glucocorticoids but modifying its downstream activity. Moreover, it is not a substrate for the 11-β-hydroxysteroid dehydrogenase (11β-HSD) enzymes that may be responsible for local drug amplification and corticosteroid-associated toxicity in local tissues [1-4]. This mechanism has shown the potential to 'dissociate' efficacy from steroid safety concerns and therefore AGAMREE is positioned as a dissociative

anti-inflammatory drug and an alternative to existing corticosteroids, the current standard of care in children and adolescent patients with DMD [1-4].

In the pivotal VISION-DMD study, AGAMREE met the primary endpoint Time to Stand (TTSTAND) velocity versus placebo (p=0.002) at 24 weeks of treatment and showed a good safety and tolerability profile [1, 4]. The most commonly reported side effects were cushingoid features, vomiting, weight increase and irritability. Side effects were generally of mild to moderate severity.

Currently available data show that AGAMREE, unlike corticosteroids, has no restriction of growth [5] and no negative effects on bone metabolism as demonstrated by normal bone formation and bone resorption serum markers [6].

▼ *This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.*

References:

[1] Dang UJ et al. (2024) Neurology 2024;102:e208112. doi.org/10.1212/WNL.0000000000208112. Link.

[2] Guglieri M et al (2022). JAMA Neurol. 2022;79(10):1005-1014. doi:10.1001/jamaneurol.2022.2480. Link.

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

[4] Heier CR et al (2019). Life Science Alliance DOI: 10.26508

[5] Ward et al., WMS 2022, FP.27 - Poster 71. Link.

[6] Hasham et al., MDA 2022 Poster presentation. Link.

About Duchenne Muscular Dystrophy

Duchenne muscular dystrophy (DMD) is a rare inherited X-chromosome-linked disease, which almost exclusively affects males. DMD is characterized by inflammation which is present at birth or shortly thereafter. Inflammation leads to fibrosis of muscle and is clinically manifested by progressive muscle degeneration and weakness. Major milestones in the disease are the loss of ambulation, the loss of self-feeding, the start of assisted ventilation, and the development of cardiomyopathy. DMD reduces life expectancy to before the fourth decade due to respiratory and/or cardiac failure. Corticosteroids are the current standard of care for the treatment of DMD.

About Santhera

Santhera Pharmaceuticals (SIX: SANN) is a Swiss specialty pharmaceutical company focused on the development and commercialization of innovative medicines for rare neuromuscular 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), in the UK by the Medicines and Healthcare products Regulatory Agency (MHRA), in China by the National Medical Products Administration (NMPA) and Hong Kong by the Department of Health (DoH). Santhera has out-licensed rights to AGAMREE for North America to Catalyst Pharmaceuticals and for China and certain countries in Southeast Asia to Sperogenix Therapeutics. For further information, please visit www.santhera.com.

AGAMREE® is a trademark of Santhera Pharmaceuticals.

For further information please contact:
public-relations@santhera.com or
Catherine Isted, Chief Financial Officer
Catherine.Isted@Sanathera.com

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