

Ad hoc announcement pursuant to Art. 53 LR

*A conference call will be held on April 27, 2023, at 14:30 CEST / 13:30 BST / 08:30 EDT. Details are at the end of this news release.*

## **Santhera Announces Preliminary Unaudited 2022 Annual Results Ahead of Full Report Publication by End of May and Provides Corporate Update**

- Revenue from contracts with customers of CHF 7.5 million (2021: CHF -1.6 million)
- Operating result of CHF -52.0 million (2021: CHF -56.9 million) and net result of CHF -70.1 million (2021: CHF -55.5 million)
- Cash and cash equivalents of CHF 1.4 million (December 31, 2022), together with existing financing facilities, enable cash reach into Q4-2023
- Key milestones reached with U.S., EU and UK regulatory submissions (NDA, MAA) for vamorolone in Duchenne muscular dystrophy (DMD)
- Financing initiatives ongoing to support vamorolone launch and other activities

**Pratteln, Switzerland, April 27, 2023 – Santhera Pharmaceuticals (SIX: SANN) announces the Company’s preliminary unaudited financial results for the year ended December 31, 2022, reports on progress with its lead drug candidate vamorolone for the treatment of DMD in the U.S. and Europe, and provides updates on its strategic and financing initiatives. As permitted by SIX Exchange Regulation, the Company will publish the full 2022 Annual Report by the end of May.**

2022 was a key year, culminating in two important regulatory filings, in the U.S. and the EU, for vamorolone in Duchenne muscular dystrophy (DMD), followed by a third in the UK in early 2023. In parallel, Santhera started expanding its U.S. operations and market entry preparations, concluded first outlicensing agreements which can give rise to non-dilutive cash inflows, and implemented various measures to secure funding and strengthen its capital structure.

“In 2022, and into 2023, we have been fully engaged with advancing vamorolone in DMD and I am delighted that we currently have three parallel applications for marketing authorization under review, in the U.S., EU and UK. This represents a tremendous achievement for Santhera and a major step towards our goal of bringing this innovative treatment option to patients living with DMD,” said **Dario Eklund, CEO of Santhera**. “With equal vigor, we are pursuing additional near-term financing and partnering opportunities, primarily to allow us to fund market entry preparations for vamorolone. We continue to evaluate various non-dilutive options including licensing agreements and monetization of assets in addition to debt and royalty financing and, depending on market conditions, we may also consider equity-based funding options.”

## **REVIEW OF PIPELINE AND BUSINESS PROGRESS**

### **2022 key events and post-period updates**

- Marketing authorization applications submitted and under review in the U.S., EU and UK with decision on approvals expected in late 2023
- Efficacy, safety and bone health data with vamorolone in patients with DMD published in JAMA Neurology and presented at scientific conferences
- Launch readiness activities for vamorolone advanced in the U.S. and started in EU
- Exclusive license agreement concluded with Sperogenix for vamorolone in rare diseases in the Greater China Region
- Phase 2 trials started with vamorolone in boys aged 2 to <4 years and 7 to <18 years with DMD and in males aged  $\geq 18$  and <65 years with Becker muscular dystrophy (BMD)
- Lonodelestat developed to Phase 2 readiness in two indications

### **Vamorolone on track for U.S. and European approvals and launches in late 2023**

*USA.* Santhera completed the NDA for vamorolone in DMD in October 2022. In January 2023, the FDA accepted the NDA for standard review and set the target date for its decision on approval to October 26, 2023, the date of the Prescription Drug User Fee Act (PDUFA). At the recent mid-cycle review meeting, 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 not to request an Advisory Committee Meeting. As part of the ongoing NDA review, the FDA completed several inspections at various sites, including those of the contract manufacturer, the sponsor and certain clinical trial sites, all with satisfactory outcomes. Subject to approval, vamorolone could become available to patients in the U.S. in the final quarter of 2023.

*European Union.* In October 2022, the European Medicines Agency (EMA) validated the marketing authorization application (MAA) for vamorolone for the treatment of DMD submitted in the prior month. The review is on track and Santhera expects the Committee for Medicinal Products for Human Use (CHMP) to issue an opinion in the third quarter 2023. Subject to a positive CHMP opinion, the European Commission (EC) is expected to decide on a marketing authorization for the EU late in 2023, with a potential launch of vamorolone in first EU countries starting immediately after approval.

*United Kingdom.* In March 2023, Santhera announced that it had submitted a 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.

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

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 with regard to bone health [1-5].

The publications highlighted clinical observations from treatment with vamorolone indicating an absence of deleterious effects on bone metabolism with the potential to reduce vertebral fractures. Vamorolone has shown that it does not depress bone biomarkers, allows for bone biomarkers that were depressed because of prednisone treatment to recover after switching to vamorolone, and results also indicate fewer and less severe spinal fractures after long-term treatment with vamorolone compared to an

external control study. Furthermore, no growth stunting has been observed in the pivotal VISION-DMD study and over the 30 months duration of extension treatment with vamorolone. The most commonly reported adverse events versus placebo from the VISION-DMD study were cushingoid features, vomiting and vitamin D deficiency. Adverse events were generally of mild to moderate severity. Vamorolone is an investigational medicine and is currently not approved for use by any health authority.

Expanding on areas of unmet needs such as bone health, Santhera has launched the educational website [www.DoMoreForDMD.com](http://www.DoMoreForDMD.com). This website is intended to raise awareness about the effects that DMD and the treatment with corticosteroids may have, and highlights the current care considerations from experts in different areas.

#### **Pre-commercialization measures advancing**

Santhera's U.S. subsidiary made further progress in establishing launch readiness through hiring into critical roles and focusing on priority projects. These include medical and market access activities, working closely with key clinical opinion leaders to advance education through presentations and scientific publications as well as engaging with patient advocacy groups. A similar program of activities has begun in Europe.

Upon approval, Santhera envisages launching vamorolone in the U.S. and selected European countries with our own organization. Ensuring prompt availability of vamorolone to patients and a successful implementation of the commercialization plans across regions, the Company will need to raise additional financial funds.

#### **Raxone sales in France resumed**

In 2019, Santhera out-licensed rights for Raxone (idebenone) outside North America and France to Chiesi Group. Since August 2021 and until the recent settlement of reimbursement matters, Santhera has provided Raxone to patients with Leber hereditary optic neuropathy (LHON) in France for free. Following an agreement reached in February 2023 and the inclusion of Raxone on the list of reimbursed products in France, sales of Raxone have resumed in April 2023.

This now enables Santhera to progress negotiations on completing outlicensing of Raxone and to initiate discussions with the FDA on submitting Raxone for approval for LHON in the U.S., which are further supported by encouraging clinical data from two recent studies with positive results as part of the now completed post-authorization measures (PAMS).

#### **Clinical and early access programs with vamorolone**

Clinical studies with vamorolone were initiated to investigate its effects in a broader patient age group in DMD and in patients with 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. A second Phase 2 pilot study is evaluating the safety, tolerability and exploratory clinical efficacy on motor function outcomes of vamorolone compared to placebo in males aged  $\geq 18$  and <65 years with BMD.

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 plans to submit a similar request in the UK, namely an EAMS (early access to medicines scheme), before summer 2023. 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.

**Lonodelestat development paused to focus on vamorolone advancement**

Santhera's focus in the near-term is on advancing vamorolone through the regulatory process towards approval and on preparations for market entry. Consequently, and as previously communicated, Santhera has paused the development program for lonodelestat, its second clinical development candidate targeting pulmonary indications. Preparations for Phase 2 studies in acute respiratory distress syndrome (ARDS) and in cystic fibrosis (CF) 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.

**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. The Company aims to develop vamorolone for additional indications with partners to ensure the full potential of this product is made available to the patients. Having already out licensed the product in the Greater China region to Sperogenix, Santhera is seeking collaborations with a view of granting sublicensing rights to vamorolone in DMD and potentially in other indications in other jurisdictions. Likewise, the Company is looking to partner lonodelestat whose development is currently paused as it prioritizes its vamorolone strategy.

**Strategy Committee evaluating all strategic options for Santhera**

Santhera recently formed a dedicated Strategy Committee to evaluate all strategic options for the Company, and its primary focus is clear: bringing vamorolone to patients as quickly and effectively as possible and assessing the product's potential in additional indications. Beyond this, it will focus on the advancement of potential outlicensing agreements with respect to vamorolone, lonodelestat and Raxone in certain geographies. Additionally, the Strategy Committee supports the evaluation of other options such as the monetization of assets, royalty financing, standby equity distribution agreements and, depending on market conditions, equity-based funding.

In connection with the recent financing, Bradley Meyer, Senior Advisor at Ducera Partners, has been appointed as Board observer. Santhera will propose him to its shareholders for election as a new Board member at the forthcoming Annual General Meeting of June 27, 2023.

**Santhera's next steps**

Santhera's key objectives for the remainder of the year and into 2024 are approvals and launches of vamorolone in DMD in the U.S. and Europe along with raising additional financing to fund the Company's operations and ambitious commercialization plans.

## **PRELIMINARY UNAUDITED 2022 FINANCIAL RESULTS & FINANCING**

- Revenue from contracts with customers of CHF 7.5 million (2021: CHF -1.6 million)
- Operating result of CHF -52.0 million (2021: CHF -56.9 million)
- Net result of CHF -70.1 million (2021: CHF -55.5 million)
- Cash flow from operating activities of CHF -29.7 million (2021: CHF -37.4 million)
- Cash and cash equivalents of CHF 1.4 million (Dec 31, 2022)
- Top- and bottom-line results impacted by French pricing/reimbursement agreement for Raxone
- Financing initiatives to secure operations and advance launch preparations for vamorolone

### **Settlement reached on pricing and reimbursement for Raxone in France**

Since its launch in 2015, 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 *Direction de la Sécurité sociale* (DSS) in France after the temporary pricing was challenged and Raxone was removed from the list of reimbursed drugs. Pricing and reimbursement discussions with the *Comité économique des produits de santé* (CEPS) started in 2021 and were still ongoing by the end of 2022. Due to uncertainties around the outcome of these negotiations, the Company accrued an additional CHF 8.1 million in 2022 towards a settlement, of which CHF 6.0 million was recognized against net sales and CHF 2.1 million as marketing and sales expenses. As of December 31, 2022, Santhera had recognized a total accrual amount of CHF 24.9 million in noncurrent provisions.

In February 2023, Santhera concluded the negotiations with the CEPS securing a final pricing reimbursement. The newly agreed price for Raxone in France is lower than the price applied under the temporary pricing scheme, leading to a settlement payment of approximately EUR 25 million (CHF 24.9 million), with 30% due in mid-2024 and the remainder one year later. The first payment is currently expected to be covered by the direct sales generated in France until mid-2024, while the second payment will be covered by direct sales thereafter. Outside of France and North America, Santhera has out-licensed Raxone to Chiesi Group.

### **2022 full-year revenue**

In 2022, Santhera reported revenue from contracts with customers of CHF 7.5 million (2021: CHF -1.6 million). Net sales amounted to CHF -5.6 million (2021: CHF -5.0 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 reimbursement negotiations in France, as described above. In 2022, Santhera recognized revenue from out-licensing transactions in the amount of CHF 11.2 million (2021: CHF 1.1 million). This largely reflects an upfront milestone payment from the out-licensing of vamorolone for the Greater China Region with Sperogenix.

### **Operating expenses and result**

Cost of goods sold amounted to CHF 3.6 million (2021: CHF 3.8 million) and represents continuing supply of Raxone and amortization of intangibles. Operating expenses of CHF 56.1 million (2021: CHF 51.9 million) were higher, primarily due to additional intangible impairment and increased expenses related to vamorolone.

Development expenses amounted to CHF 30.5 million (2021: CHF 29.7 million). The increase was primarily due to the additional intangible impairment expense of CHF 6.2 million related to Ionodelestat.

The remaining amount includes 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 10.9 million (2021: CHF 9.3 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, which was partially offset by lower pre-commercialization activities for vamorolone. The remaining amount includes market readiness preparations for vamorolone in the U.S.

General and administrative expenses amounted to CHF 14.6 million (2021: CHF 12.7 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 52.0 million which is in a similar range year-on-year (2021: CHF -56.9 million).

#### **Financial income and expenses**

Financial income of CHF 5.6 million (2021: CHF 22.9 million) was lower than in the previous year due to a non-recurring recognized gain on exchange of 2017/22 Bonds in 2021. Financial expenses of CHF 23.3 million (2021: CHF 20.7 million) increased year-on-year due to the recognition of a higher change in fair value of financial instruments (net) which was only partially compensated by lower financing transaction costs, together with an increase in interest expense. The net financial expense amounted to CHF 17.7 million (2021: financial income of CHF 2.2 million).

#### **Net result**

The net result 2022 was a loss of CHF 70.1 million, compared to a net loss of CHF 55.5 million for the year 2021.

#### **Cash balance and cash flows**

As of December 31, 2022, the Company had cash and cash equivalents of CHF 1.4 million compared to CHF 21.2 million as of December 31, 2021.

Net cash outflow for operating activities was slightly lower year-on-year and amounted to CHF 29.7 million (2021: CHF 37.4 million). Net cash inflow from financing activities was lower year-on-year and amounted to CHF 13.9 million (2021: CHF 46.0 million). The increase in net additional proceeds from exchangeable notes were largely offset by the repurchase of convertible bonds. In comparison, 2021 saw a one-time income from a capital increase (2022: nil).

#### **Shareholders' equity**

Total consolidated net equity deficit as of December 31, 2022, amounted to CHF -48.5 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.

#### **Equity-linked financings and share capital**

In a difficult market environment throughout 2022 and to date, 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 February 2022, the senior unsecured convertible bonds (2017/22 Bonds) with a remaining amount of CHF 13.9 million were fully repaid and delisted from the SIX Swiss Exchange. Of the senior unsecured convertible bonds (2021/24 Bonds) maturing in August 2024, an aggregate amount of CHF 13.6 million was still outstanding at December 31, 2022, with CHF 6.0 million being repurchased during the year. Of the private convertible bonds (2021/24 Private Bonds) in the amount of CHF 15.0 million issued to Highbridge, CHF 3.0 million were converted into shares during the period, leaving a remainder of CHF 12.0 million at December 31, 2022. In summary, this significantly reduced total of convertible bonds during 2022 from CHF 48.5 million to approximately CHF 25.5 million, now maturing in August 2024.

*Share capital and treasury stock.* The Annual General Meeting (AGM) of June 30, 2022, approved a reduction of the nominal value of the shares from CHF 1.00 to CHF 0.01 per share. During 2022, a total of 20,712,700 new shares were issued for financing transactions and share-based compensation, with the unused portion held as treasury shares. In order to provide additional fundraising flexibility, the Extraordinary General Meeting (EGM) of November 29, 2022, approved an ordinary share capital increase by up to 40,000,000 registered shares by February 28, 2023, none of which were placed during the period under review. In summary and as of December 31, 2022, Santhera's issued shares amounted to CHF 753,205.10 and the Company held 9,438,017 treasury shares.

Post balance sheet date, in February 2023, Santhera completed the ordinary capital increase resolved by its shareholders on November 29, 2022, by issuing 40,000,000 shares. Santhera delivered 3,000,000 of these shares at CHF 0.75 per share. The remaining 37,000,000 shares were kept as treasury stock. As at April 26, 2023, the Company holds 38,514,652 treasury shares to facilitate the ongoing facilities provided by Highbridge and for future equity-based financings.

*Authorized and conditional share capitals.* During the year ended December 31, 2022, the Company's shareholders approved the increase of authorized and conditional capitals at the AGM and EGM, held in June and November, respectively. Shares were issued out of both capitals for financing transactions and to treasury shares. On the balance sheet date (December 31, 2022), Santhera's authorized capital amounted to 36,860,687 shares and its conditional capital amounted to 35,191,205 shares, each with a nominal value of CHF 0.01 per share. Santhera plans to use these shares for financing activities, if required.

#### **Amendments of Highbridge facility to satisfy near-term cash requirements**

In June 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, allowing for periodic drawdowns (subject to certain conditions) and exchangeable by Highbridge for shares at a discount to the volume-weighted average price (VWAP). An initial drawdown tranche of CHF 20 million was received on June 3, 2022.

In September 2022, Santhera and Highbridge amended the existing financing arrangement to provide for the immediate drawdown of a CHF 10 million tranche. As part of this new money financing and further commitments, Santhera agreed on a new conversion price of CHF 1.20 for the remaining outstanding private convertible bond issued to Highbridge in 2021 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.

Post balance sheet date, in February 2023, Santhera and Highbridge further amended the existing financing arrangement. Under the amended agreement, Highbridge will 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. This is intended to fund Santhera up to the PDUFA date in October 2023 when an FDA decision on vamorolone in the U.S. is expected.

The Company had outstanding exchangeable instruments as of December 31, 2022, in the aggregate amount of CHF 28 million (December 31, 2021: CHF 2 million) reflecting an issue during the year 2022 of CHF 40 million offset by repayments through exchange for shares.

### **Funding outlook**

Santhera has treasury shares, conditional and authorized capitals which are available for future placement or issue, subject to market conditions. This, in combination with the recent drawdown from the amended Highbridge facility, is expected to provide a liquidity runway for operations into Q4-2023, or up to the PDUFA-date (October 26, 2023), when approval of vamorolone in the U.S. is expected.

In order to support the preparation and execution of the launch plans for vamorolone in the U.S. and Europe, 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.

### **DECISION OF SIX EXCHANGE REGULATION**

SIX Exchange Regulation has permitted Santhera to publish its 2022 Annual Report by May 31, 2023, at the latest. Santhera is in the process of completing the 2022 Annual Report and the postponement enables Santhera and its auditors to complete the preparation and audit of the financial statements, also taking into account material events after the balance sheet date. As required by SIX Exchange Regulation, Santhera hereby reprints the following extract of the decision of SIX Exchange Regulation (translation from the German original):

*The exemption from the obligations for maintaining listing and thus the deferral of the publication of the annual report for the year 2022 as well as the filing of this report with SIX Exchange Regulation Ltd by Wednesday, May 31, 2023 at the latest is hereby approved subject to the following provision (lit. a) and conditions (lit. b):*

- a. SIX Exchange Regulation Ltd reserves the right to potentially suspend trading in the securities of Santhera Pharmaceuticals Holding Ltd for a certain period of time if it does not publish its annual report for the year 2022 in accordance with the provisions on ad hoc publicity (art. 53 Listing Rules in conjunction with the Directive on Ad hoc Publicity) and submit it to SIX Exchange Regulation Ltd by 11:59 p.m. on Wednesday, May 31, 2023, at the latest.*
- b. Santhera has to publish a media release regarding the present decision in accordance with the provisions on ad hoc publicity (art. 53 Listing Rules in conjunction with the Directive on Ad hoc Publicity) by 7:30 a.m. on Thursday, April 27, 2023 at the latest. Such media release*
  - has to include the full text of clause I of the present decision in a prominent place;*
  - must mention the reasons for postponing the publication and filing of the annual report for the year 2022;*
  - must mention the unaudited key figures such as net sales, EBITDA, EBIT, net profit/loss, total assets, equity etc. with regard to the business results 2022.*



<b>Full-year Financial Information</b>
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The preliminary unaudited figures presented in this press release are subject to change. The Company plans to publish its audited 2022 Annual Report during May 2023.

### Consolidated Income Statement

IFRS, in CHF thousands	<b>2022</b> (preliminary unaudited)	2021 (audited)
Net sales	<b>(5,578)</b>	(4,963)
Revenue from out-licensing transactions	<b>11,190</b>	1,126
Net sales to licensing partner	<b>1,861</b>	2,242
<b>Revenue from contracts with customers</b>	<b>7,473</b>	(1,595)
Cost of goods sold	<b>(3,592)</b>	(3,767)
<i>Of which amortization intangible assets</i>	<b>(3,040)</b>	(3,040)
Other operating income	<b>259</b>	346
Development	<b>(30,536)</b>	(29,715)
Marketing and sales	<b>(10,857)</b>	(9,332)
General and administrative	<b>(14,565)</b>	(12,725)
Other operating expenses	<b>(158)</b>	(100)
<b>Operating expenses</b>	<b>(56,116)</b>	(51,872)
<b>Operating result</b>	<b>(51,976)</b>	(56,888)
Financial income	<b>5,593</b>	22,901
Financial expenses	<b>(23,303)</b>	(20,730)
<b>Result before taxes</b>	<b>(69,686)</b>	(54,717)
Income taxes	<b>(460)</b>	(809)
<b>Net result</b>	<b>(70,146)</b>	(55,526)

**Consolidated Balance Sheet**

IFRS, in CHF thousands	Dec 31, 2022 (preliminary unaudited)	Dec 31, 2021 (audited)
<b>Assets</b>		
Tangible assets	1,008	1,324
Intangible assets	59,206	64,596
Financial assets long-term	444	468
Deferred tax assets	3	88
<b>Noncurrent assets</b>	<b>60,661</b>	<b>66,476</b>
Prepaid expenses	513	1,069
Inventories	108	428
Trade and other receivables	1,091	1,936
Cash and cash equivalents	1,353	21,208
<b>Current assets</b>	<b>3,065</b>	<b>24,641</b>
<b>Total assets</b>	<b>63,726</b>	<b>91,117</b>
<b>Equity and liabilities</b>		
Share capital	753	54,608
Capital reserves and share premium	581,116	509,513
Retained deficit	(626,571)	(556,425)
Employee benefit reserve	2,722	(437)
Treasury shares	(94)	(5,020)
Translation differences	(682)	(911)
<b>Total equity</b>	<b>(42,756)</b>	<b>1,328</b>
Noncurrent convertible bonds	21,080	25,796
Noncurrent derivative financial instruments	4,335	3,683
Noncurrent warrant financial instruments	5,171	4,723
Noncurrent lease liabilities	607	1,203
Noncurrent provisions	24,961	16,808
Pension liabilities	1,844	4,794
<b>Noncurrent liabilities</b>	<b>57,998</b>	<b>57,007</b>
Trade and other payables	6,964	4,585
Accrued expenses	10,265	9,710
Income tax payable	553	266
Current lease liabilities	623	609
Current Exchangeable Notes	22,403	1,488
Current convertible bonds	0	13,880
Current derivative financial instruments	5,440	402
Current warrant financial instruments	2,225	1,650
Current provisions	11	192
<b>Current liabilities</b>	<b>48,484</b>	<b>32,782</b>
<b>Total liabilities</b>	<b>106,482</b>	<b>89,789</b>
<b>Total equity and liabilities</b>	<b>63,726</b>	<b>91,117</b>

### Consolidated Statement of Cash Flows

IFRS, in CHF thousands	2022 (preliminary unaudited)	2021 (audited)
<b>Result before taxes</b>	<b>(69,686)</b>	<b>(54,717)</b>
Depreciation and impairment of tangible assets	608	634
Amortization and impairment of intangible assets	9,250	3,090
Share-based compensation	5,452	2,761
Change in fair value of financial instruments, net	1,364	(8,656)
Realized gain on exchange of convertible bonds	0	(13,439)
Realized gain on repurchase of convertible bonds	(1,504)	0
Change in pension liabilities	104	507
Reversal of current provisions	(67)	(589)
Change in noncurrent provisions	8,153	16,808
Taxes paid	(78)	(70)
Change in net working capital	1,513	1,767
Total financial result	17,635	16,485
Interest received	0	1
Interest paid	(2,488)	(1,941)
<b>Net cash flow from/(used in) operating activities</b>	<b>(29,744)</b>	<b>(37,359)</b>
Investments in tangible assets	(53)	(2)
Investments in intangible assets	(3,903)	(13)
Change in financial assets long-term	24	84
<b>Net cash flow from/(used in) investing activities</b>	<b>(3,932)</b>	<b>69</b>
Proceeds from capital increase	0	20,272
Proceeds from sale of treasury shares	475	81
Purchase of treasury shares	0	(56)
Proceeds from exercise of equity rights	37	0
Proceeds from Exchangeable Notes	40,000	22,000
Repayment of Exchangeable Notes	(7,000)	(3,500)
Proceeds from convertible bonds	0	13,792
Repayment of convertible bonds	(13,935)	0
Repurchase of convertible bonds	(4,511)	0
Financing transaction costs	(215)	(3,439)
Cost of issuance of capital	(270)	(2,389)
Payment of lease liabilities	(688)	(739)
<b>Net cash flow from/(used in) financing activities</b>	<b>13,893</b>	<b>46,022</b>
Effects of exchange rate changes on cash and cash equivalents	(72)	65
<b>Net increase/(decrease) in cash and cash equivalents</b>	<b>(19,855)</b>	<b>8,797</b>
Cash and cash equivalents at January 1	21,208	12,411
<b>Cash and cash equivalents at December 31</b>	<b>1,353</b>	<b>21,208</b>

## Share Capital

	Dec 31, 2022 (preliminary unaudited)	Dec 31, 2021 (audited)
(number of shares with par value of CHF 0.01)		
Ordinary shares issued	75,320,510	54,607,810
Treasury shares	9,438,017	5,019,879
Conditional capital for equity rights	5,034,583	5,425,677
Conditional capital for convertible rights	30,156,622	21,878,228
Authorized capital	36,860,687	27,303,905

## Conference Call

Santhera will host a conference call on April 27, 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 2022 annual 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.

## Corporate calendar

May 31, 2023 Annual Report 2022 publication (latest date)  
June 27, 2023 Annual General Meeting

## References

- [1] Guglieri M et al (2022). JAMA Neurol. 2022;79(10):1005-1014. doi:10.1001/jamaneurol.2022.2480. [Link](#).
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- [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). 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](http://www.santhera.com).

*Raxone® is a trademark of Santhera Pharmaceuticals.*

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