



2017

**Interim Condensed Report
January to June 2017**

Report on the Six Months Ended June 30, 2017, and Interim Condensed Consolidated Financial Statements

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Santhera Announces Financial Results for the First Half-Year 2017 and Reports Commercial and Development Progress

Santhera Pharmaceuticals (SIX: SANN) reports first half-year results as of June 30, 2017:

- 1H 2017 sales of CHF 10.9 million, increase of 51% compared to 1H 2016
- Successful placement of CHF 60 million in convertible bonds
- Cash and short-term financial assets of CHF 78.0 million
- Continued roll-out of commercial launch of Raxone[®] for Leber's hereditary optic neuropathy (LHON)
- Positive Early Access to Medicines Scheme (EAMS) scientific opinion from the UK's Medicines and Healthcare products Regulatory Agency (MHRA) received for Raxone in Duchenne muscular dystrophy (DMD)
- European marketing authorization application (MAA) decision for Raxone in DMD from Committee for Medicinal Products for Human Use (CHMP) anticipated shortly

Company Highlights

- **Roll-out of Raxone for LHON well underway**

Santhera's intention to make Raxone available for LHON patients across Europe are progressing well with new launches in several countries either through own subsidiaries or partnerships. Reimbursement was achieved under different models in several European markets. In May, the Scottish Medicines Consortium approved Raxone for restricted use in patients with LHON. By the end of the first half-year, Santhera sold Raxone in 17 European countries.
- **First positive EAMS Scientific Opinion from UK's MHRA in DMD**

In June, the UK's MHRA granted Raxone a positive scientific opinion through the EAMS for patients with respiratory function decline not taking glucocorticoids in DMD. The MHRA decision allows patients with DMD, who meet criteria defined under this scheme, and who otherwise would not have access to such treatment options, to gain access to Raxone.
- **Review of marketing authorization application for DMD in Europe**

The CHMP is currently assessing Santhera's extension application for Raxone in patients with DMD. An opinion from the CHMP is expected shortly.
- **Commercial operations strengthened to support LHON and prepare for launch in DMD**

Commercial operations in the regional country clusters in Europe were increased to support marketing of Raxone for LHON and to prepare for a timely market entry of Raxone for DMD. In February, US operations were established in the Boston metropolitan area. The US team is currently focused on expanding relationships with patient advocacy groups, market preparation activities, and providing regulatory and medical affairs expertise. This expansion of geographic reach underscores Santhera's commitment to make Raxone available to patients worldwide.

- **SIDEROS trial with Raxone in DMD patients using glucocorticoids on track**

Santhera's randomized, double-blind, placebo-controlled phase III SIDEROS study investigates the efficacy and safety of Raxone in DMD patients with declining respiratory function on any stable glucocorticoid treatment scheme. Currently, the last remaining of the targeted 62 study centers are being initiated. The study is expected to run until 2019 to support the use of Raxone in all patients with DMD experiencing respiratory decline irrespective of their glucocorticoid use status.

- **Israel approves Raxone for LHON**

Post the period end, the Ministry of Health Israel approved Raxone for the treatment of visual impairment in adolescents and adult patients with LHON. This is the first approval for Raxone in LHON outside Europe.

Key Financials in the First Half-Year 2017

- **Strong uptake of Raxone sales**

Net sales of Raxone amounted to CHF 10.9 million (1H 2016: CHF 7.2 million) which corresponds to a 51% increase compared to the same period of the year prior. Turnover was mainly driven by sales to LHON patients in Germany and France with additional markets contributing increasingly to growth. To date, Raxone is sold in 17 European countries.

- **Commercial and development activities reflected in increased expenses**

Operating expenses in the first half-year were CHF 30.5 million (1H 2016: CHF 22.6 million). Advancing late stage clinical trials, as well as the follow-up and preparation of regulatory filings for DMD, led to higher development expenses of CHF 11.7 million (1H 2016: CHF 8.1 million). Marketing and sales expenses reached CHF 12.6 million (1H 2016: CHF 8.9 million) and general and administrative expenses (G&A) were CHF 6.1 million (1H 2016: CHF 5.5 million). This investment increase reflects the expansion of Santhera's operations, including set-up of the US subsidiary, the ongoing roll-out of Raxone for LHON across Europe and market entry preparations for Raxone in DMD. In summary, the operating loss in the first half of this year amounted to CHF 21.4 million (1H 2016: CHF -17.2 million) leading to a net result of CHF -22.7 million (1H 2016: CHF -18.0 million).

- **Successful placement of CHF 60 million convertible bonds**

In February, Santhera successfully placed CHF 60 million senior unsecured convertible bonds with a 5-year maturity and a coupon of 5.00% per annum. Net proceeds from this placement will primarily be used to fund the commercialization of Raxone in the currently approved indication LHON, to prepare the market entry and commercial launch in the subsequent indications, and to further advance clinical development programs and for other corporate purposes. The additional funds significantly enhanced the Company's financial flexibility in executing its intended development and commercial plans.

- **Solid liquidity base allows for strategy implementation as planned**

As of June 30, 2017, freely available liquid funds (cash and cash equivalents including short-term financial assets) amounted to CHF 78.0 million (December 31, 2016: CHF 49.8 million).

Revenue Guidance

Santhera reiterates its revenue outlook and currently expects net sales of Raxone for full year 2017 to reach CHF 21 to 23 million.

Interim Condensed Consolidated Financial Statements

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Interim Consolidated Balance Sheet

	in CHF thousands	Notes	June 30, 2017 (reviewed)	Dec. 31, 2016 (audited)
Assets				
Tangible assets		9	588	517
Intangible assets		9	25,038	26,549
Financial assets long-term			411	270
Restricted cash long-term		6	6,000	0
Deferred tax asset			1,202	1,106
Noncurrent assets			33,239	28,442
Prepaid expenses and accrued income			1,245	583
Inventories		5	9,522	7,676
Trade and other receivables			5,178	4,276
Financial assets short-term		8	5,984	0
Restricted cash short-term		6	3,000	0
Cash and cash equivalents		6	71,986	49,815
Current assets			96,915	62,350
Total assets			130,154	90,792
Equity and liabilities				
Share capital		7	6,280	6,280
Capital reserves and share premium			386,042	382,322
Retained earnings			-331,261	-308,549
Employee benefit reserve			-4,601	-4,734
Treasury shares			-468	-172
Other components of equity			-793	-796
Total equity			55,199	74,351
Convertible bonds		8	52,425	0
Derivative financial instruments		8	4,783	0
Pension liabilities			6,439	6,183
Total noncurrent liabilities			63,647	6,183
Trade and other payables			3,256	4,458
Accrued expenses			8,052	5,800
Total current liabilities			11,308	10,258
Total liabilities			74,955	16,441
Total equity and liabilities			130,154	90,792

Interim Consolidated Income Statement (Reviewed)

	for the half-year ended June 30, in CHF thousands	Notes	2017	2016
Net sales		9	10,859	7,210
Cost of goods sold			-1,954	-1,911
<i>Of which amortization intangible asset</i>			-1,519	-1,519
Other operating income			242	61
Development		10	-11,703	-8,101
Marketing and sales		10	-12,622	-8,949
General and administrative		10	-6,113	-5,479
Other operating expenses		10	-75	-38
Operating expenses		10	-30,513	-22,567
Operating result			-21,366	-17,207
Financial income			846	509
Financial expenses			-2,135	-424
Result before taxes			-22,655	-17,122
Income taxes		11	-57	-849
Net result			-22,712	-17,971
Basic and diluted loss per share (in CHF)			-3.62	-2.87

Interim Consolidated Statement of Comprehensive Income (Reviewed)

for the half-year ended June 30, in CHF thousands	2017	2016
Net result	-22,712	-17,971
<i>Items never to be reclassified subsequently to net income in subsequent periods:</i>		
Actuarial gains/(losses) on defined benefit plans	133	-1,397
<i>Items to be reclassified subsequently to net income in subsequent periods:</i>		
Currency translation differences	3	-9
Other comprehensive result	136	-1,406
Total comprehensive result	-22,576	-19,377

Interim Consolidated Statement of Cash Flows (Reviewed)

for the half-year ended June 30, in CHF thousands	Notes	2017	2016
Result before taxes		-22,655	-17,122
Depreciation of tangible assets		110	73
Amortization of intangible assets		1,557	1,546
Expenses for equity rights plans		3,692	1,984
Change in fair value of derivatives	8	-549	0
Change in pension liabilities		389	247
Taxes paid		-152	-19
Change in net working capital		-3,087	48
Total financial result		1,289	-85
Interest paid		-25	-10
Cash flow from operating activities		-19,431	-13,338
Investments in tangible assets		-180	-176
Disposal of intangible assets		0	6
Investments in intangible assets		-45	-11
Investments in other financial assets short-term		-5,984	0
Investments in other financial assets long-term		-143	-78
Change in restricted cash		-9,000	0
Cash flow from investing activities		-15,352	-259
Proceeds from option exercise		0	336
Net purchase of treasury shares		-268	0
Proceeds from convertible bonds		57,269	0
Cash flow from financing activities		57,001	336
Effects of exchange rate changes on cash and cash equivalents		-47	-34
Net increase/(decrease) in cash and cash equivalents		22,171	-13,295
Cash and cash equivalents at January 1		49,815	76,859
Cash and cash equivalents at June 30		71,986	63,564

Interim Consolidated Statement of Changes in Equity (Reviewed)

	in CHF thousands	Notes	Share capital	Capital reserves and share premium	Retained earnings	Employee benefit reserve	Treasury shares	Translation differences	Total
Balance at January 1, 2016			6,263	377,031	-273,134	-2,958	-177	-778	106,247
Net result			0	0	-17,971	0	0	0	-17,971
Other comprehensive income			0	0	0	-1,397	0	-9	-1,406
Total comprehensive result for the period			0	0	-17,971	-1,397	0	-9	-19,377
Share-based payment transactions		10	0	1,984	0	0	0	0	1,984
Capital increase option exercise			12	324	0	0	0	0	336
Balance at June 30, 2016			6,275	379,339	-291,105	-4,355	-177	-787	89,190
Balance at January 1, 2017			6,280	382,322	-308,549	-4,734	-172	-796	74,351
Net result			0	0	-22,712	0	0	0	-22,712
Other comprehensive income			0	0	0	133	0	3	136
Total comprehensive result for the period			0	0	-22,712	133	0	3	-22,576
Share-based payment transactions		10	0	3,692	0	0	0	0	3,692
Change in treasury shares			0	28	0	0	-296	0	-268
Balance at June 30, 2017			6,280	386,042	-331,261	-4,601	-468	-793	55,199

Notes to the Interim Condensed Consolidated Financial Statements (Reviewed)

1 General Information

Santhera Pharmaceuticals Holding AG (the **Company**, together with its subsidiaries **Santhera** or **Group**) is a specialty pharmaceutical company focused on the development and commercialization of products for the treatment of neuromuscular and mitochondrial diseases, an area which includes many orphan and niche indications with high unmet medical need.

The Company, having the listing of its registered shares (**Shares**) on the SIX Swiss Exchange (**SIX**), is a Swiss stock corporation and the parent company of the Group. Its purpose is to acquire, dispose and manage investments. The Company has its registered offices at Hammerstrasse 49 in 4410 Liestal, Switzerland.

The consolidated interim financial statements were approved for publication by the Board of Directors (**Board**) on September 5, 2017.

2 Summary of Significant Accounting Policies

The accounting policies used in the preparation of the interim financial statements are consistent with those used in the preparation of the Group's annual financial statements for the year ended December 31, 2016, except for the adoption of new standards and interpretations as of January 1, 2017, as noted below.

Basis of preparation

These unaudited consolidated interim financial statements were prepared in accordance with IAS 34, Interim Financial Reporting, of the International Financial Reporting Standards (**IFRS**) and should be read in conjunction with the annual financial statements for the year ended December 31, 2016.

The presentation currency is Swiss francs (**CHF**). All figures included are rounded to the nearest CHF 1,000 except where otherwise indicated.

Changes in accounting policies

Except for minor amendments to IFRS as detailed in the year-end report 2016, the consolidated interim financial statements have been prepared using the same accounting principles as the annual financial statements for the year ending December 31, 2016. While the Company has not completed the analysis of the impact of adoption, the adoption of IFRS 15 is not expected to have material effects on the consolidated financial statements. As part of the Company's analysis, the Company is evaluating and implementing changes to its policies, procedures and controls.

3 Seasonality

The operating result is not subject to significant seasonal variations during the financial year.

4 Exchange Rates of Principal Currencies

	Income statement in CHF		Balance sheet in CHF	
	Half year ended June 30, 2017	average rates	June 30, 2017	as of period end
		Half-year ended June 30, 2016		Dec. 31, 2016
1 Euro (EUR)	1.0762	1.0960	1.0930	1.0737
1 US dollar (USD)	0.9947	0.9822	0.9586	1.0160
1 British pound (GBP)	1.2516	1.4080	1.2453	1.2498
1 Canadian dollar (CAD)	0.7459	0.7380	0.7380	0.7532

5 Inventories

This position consists mainly of active pharmaceutical ingredient and semi-finished products which are kept by Santhera as stock for market supply, development and inventory risk management purposes (security stock) for Raxone. This stock was further increased.

6 Cash and Cash Equivalents and Restricted Cash

6.1 Cash and cash equivalents

	in CHF thousands	June 30, 2017	Dec. 31, 2016
Cash at banks and on hand			
in CHF		61,308	44,358
in EUR		7,700	4,661
in USD		1,794	149
in GBP		1,075	546
in CAD		109	67
other currencies		0	34
Total at period end		71,986	49,815

6.2 Restricted cash

	in CHF thousands	June 30, 2017	Dec. 31, 2016
Long-term		6,000	0
Short-term		3,000	0
Total at period end		9,000	0

Restricted cash is designated for interest payments due related to the convertible bonds during the first 3 years. These funds are kept on an escrow account with the bond agent.

7 Share Capital

7.1 Ordinary share capital

During the reporting period ending June 30, 2017, no Shares were issued out of conditional share capital upon the exercise of stock options. As a result, as of June 30, 2017, the issued nominal share capital amounted to CHF 6,279,857, divided into 6,279,857 Shares at a nominal value of CHF 1 each. In the same period for 2016, 11,800 Shares were issued from conditional capital upon the exercise of stock options.

7.2 Authorized share capital

The Board is authorized to increase the share capital at any time until May 10, 2018 through the issuance of up to 1,500,000 Shares with a nominal value of CHF 1 each.

7.3 Conditional share capital

As of June 30, 2017, the Company had conditional share capital, pursuant to which the share capital may be increased by

- (i) a maximum amount of CHF 700,000 through the issuance of up to 700,000 Shares with the exercise of option rights. This part of the conditional share capital was increased from formerly CHF 532,941, as per December 31, 2016, to CHF 700,000 as approved at the Annual Shareholders' Meeting on April 4, 2017. During the first half of 2017, no equity rights were exercised. In the same period 2016, 11,800 options were exercised, reducing the available conditional capital to CHF 538,200 as per June 30, 2016 (see note 12 "Equity Rights Plans").
- (ii) a maximum amount of CHF 930,000 by issuing up to 930,000 Shares through the exercise of warrants/options and/or notes granted in connection with bonds or similar debt instruments linked with option and/or conversion rights granted by the Company.

8 Financial Assets and Liabilities

Santhera measures certain financial instruments at fair value. Fair values are categorized into the following hierarchy based on the inputs used to measure them:

- Level 1: Quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2: Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly (as prices) or indirectly (derived from prices).
- Level 3: Unobservable inputs for the asset or liability. These inputs reflect the best estimates of Santhera based on criteria that market participants would use to determine prices for assets or liabilities at the reporting date.

8.1 Financial assets short-term

Financial assets (units in a fund) are classified as held for trading. They are measured at fair value through profit or loss and based on quoted prices (level 1). A loss of TCHF 16 (financial expenses) resulted during the reporting period (no such financial assets were held during the same period in 2016).

8.2 Financial liabilities

On February 17, 2017, Santhera issued senior unsecured convertible bonds in the nominal amount of CHF 60 million. Transaction costs of CHF 2.7 million lead to a net amount of CHF 57.3 million (consisting of Senior unsecured convertible bonds (CHF 52.0 million) and embedded derivative financial instruments (CHF 5.3 million). The bonds, listed on the SIX, are interest bearing (5%) with a maximum term of 5 years and are convertible into registered Shares of Santhera with a nominal value of CHF 1 each. The initial conversion price is fixed at CHF 86.4006 and will be reset after the first year if the volume weighted average price (**VWAP**) of the Shares during a specified period of time will be below the reference share price (CHF 71.9969). The new conversion price must not be lower than 75% of the conversion price at issuance. In addition, Santhera may call the convertible bonds at any time on or after the second anniversary of the issue date at par, plus accrued interest, if any, if the VWAP of the Shares is at least 160% of the conversion price. The convertible bonds are measured at amortized costs applying the effective interest method.

The embedded financial derivatives (conversion right, reset mechanism and early redemption option) are valued by an independent consultant initially and at period end at fair value, applying a simulation based valuation approach. The valuation of the embedded derivatives is on level 3. The simulation is mainly based on the historical volatility of Santhera shares. The period of volatility data used is measured according to the remaining life of the convertible bonds. The volatility used as per June 30, 2017, was 88%.

The value of the derivatives on February 17, 2017, amounted to CHF 5.3 million and at period end to CHF 4.8 million; the change in the fair value was recognized in financial income (TCHF 549).

Sensitivity analysis:

	Increase/decrease in volatility assumption	Effect on result before taxes in CHF thousands
Change in volatility	+5%	343
	-5%	-273

9 Segment and Geographic Information

9.1 Segment information

Santhera operates in one business segment, namely development and commercialization of products for the treatment of neuromuscular and mitochondrial diseases. The Board, the Executive Management and senior managers, being the chief operating decision makers, assess the reporting data and allocate resources as one segment on an aggregated consolidated level according to operating expenses by function. Santhera generates revenue from sales of Raxone for the treatment of LHON. Geographic revenue information is based on location of the customer.

9.2 Geographic information

Net sales

	half-year ended June 30, in CHF thousands	2017	2016
Europe		10,802	7,179
Rest of the world		57	31
Total		10,859	7,210

In the reporting period 2017, net sales amounted to CHF 10.9 million. Raxone was sold into 17 European countries, with the majority of sales reached in France and Germany (in the reporting period 2016, sales went into 11 European countries, with a majority of sales reached in France and Germany).

Noncurrent assets (excluding financial instruments and deferred tax assets)

	in CHF thousands	June 30, 2017	Dec. 31, 2016
Switzerland		25,447	26,966
Rest of Europe		129	100
North America		50	0
Total		25,626	27,066

10 Operating Expenses by Nature

	half-year ended June 30, in CHF thousands	2017	2016
External development expenses		-6,812	-5,993
Patent and license expenses		-147	-122
Marketing expenses		-5,547	-3,925
Employee expenses		-15,609	-9,904
<i>Of which non-cash-relevant expenses for share-based payments</i>		-3,692	-1,984
General and administrative expenses		-1,833	-2,188
Depreciation, amortization and impairment		-147	-101
Lease expenses		-343	-296
Other operating expenses		-75	-38
Total operating expenses		-30,513	-22,567

Increased expenses for the reporting period in 2017 mainly result from additional staff hired for marketing activities.

11 Income Taxes

	half-year ended June 30, in CHF thousands	2017	2016
Current income taxes		-152	-19
Deferred taxes		95	-830
Total		-57	-849

Movements on deferred taxes relate to temporary differences on inventory.

12 Equity Rights Plans

Santhera has established equity rights plans to align the long-term interests of the members of the Board, the Executive Management and employees. Rights granted under these plans are equity-settled. New grants are only possible under Share Appreciation Rights Plans (**SARP**).

The fair value of equity rights (share appreciation rights (**SAR**) or stock options) is determined at each grant date by using the Hull-White pricing model. For the calculation of the fair value of SAR granted during the reporting period in 2017, the same range of valuation parameters, as disclosed in the financial statements as of December 31, 2016, was applied. The non-cash-relevant expenses for all unvested SAR and stock options in the reporting period 2017 amounts to CHF 3.7 million compared to CHF 2.0 million in the same period in 2016.

12.1 Share Appreciation Rights Plans

Santhera has established a Board Share Appreciation Plan 2016 (**BSARP 2016**) and an Employee Share Appreciation Rights Plan 2016 (**ESARP 2016**). In 2017 Santhera has introduced a Board Share Appreciation Rights Plan (**BSARP 2017**) for the members of its Board and an Employee Share Appreciation Rights Plan (**ESARP 2017**) for the Executive Management, employees and consultants. SAR grants are made mainly periodically at the full discretion of the Board or as contractually agreed with employees. SARP introduced in 2017 foresee vesting of 1/3 of the SAR on the first anniversary; the remaining 2/3 vest each following quarter end through the second and third year after the grant date (8 times 1/12 of the SAR granted). New grants are possible under BSARP 2016 and 2017 as well as ESARP 2016 and 2017.

In the reporting period ended June 30, 2017, a total of 316,986 SARs with exercise prices between CHF 54.85 and CHF 77.80 were granted. In the half-year period ending June 30, 2016, no SAR were granted.

Number of SAR outstanding

	half-year ended June 30, number of SAR	2017
Outstanding at January 1		56,581
Granted ¹		316,986
Exercised		0
Forfeited		0
Expired		0
Outstanding at June 30²		373,567

¹ The weighted average fair value of the SAR granted during the reporting period in 2017 was CHF 26.75 (no grants in the comparative reporting period 2016).

² Based on the closing price of CHF 66.60 of the Santhera Shares on June 30, 2017, a total of 330,149 SAR were in the money, whereof 0 were vested (on June 30, 2016, no SAR were granted at all).

12.2 Stock Option Plans

Santhera has established Employee Stock Option Plans (**ESOP**), the ESOP 2004, the ESOP 2010, the ESOP 2015, and Board Stock Option Plans (**BSOP**), the BSOP 2015 to align the long-term interests of the Board, the Executive Management and employees. Options granted under the stock option plans are equity-settled. No grants are made under ESOP and BSOP anymore.

In the reporting period ended June 30, 2017, no stock options were granted. In the half-year period ending June 30, 2016, a total of 142,392 options with exercise prices between CHF 69.30 and CHF 89.45 were granted.

Number of stock options outstanding

	six months ended June 30, number of options	2017	2016
Outstanding at January 1		313,365	223,834
Granted ¹		0	142,392
Forfeited		-9,687	-5,071
Expired		-240	-4,963
Exercised		0	-11,800
Outstanding at June 30²		303,438	344,392

¹ There is no weighted average fair value calculated for the reporting period, since no stock options were granted (in the comparative reporting period 2016 the weighted average fair value of stock options granted was CHF 24.18).

² Based on the closing price of CHF 66.60 of the Santhera Shares on June 30, 2017, a total of 38,249 stock options were in the money, whereof 35,574 were vested (on June 30, 2016, the closing Share price was CHF 76.90; a total of 72,308 options were in the money, whereof 50,646 were vested).

13 Related Party Transactions

During the reporting period 2017, a total of 15,120 SAR were granted to members of the Board and 104,033 SAR were granted to members of the Executive Management. In the same period in 2016, a total of 6,562 options were granted to members of the Board and 30,550 options to members of the Executive Management.

14 Subsequent Events

None.

To the Board of Directors of
Santhera Pharmaceuticals Holding AG, Liestal

Basle, 4 September 2017

Report on the review of interim condensed consolidated financial statements



Introduction

We have reviewed interim condensed consolidated financial statements (Interim Consolidated Balance Sheet, Interim Consolidated Income Statement, Interim Consolidated Statement of Comprehensive Income, Interim Consolidated Statement of Cash Flows, Interim Consolidated Statement of Changes in Equity and Notes) of Santhera Pharmaceuticals Holding AG for the period from 01 January 2017 to 30 June 2017. The Board of Directors is responsible for the preparation and presentation of these interim condensed consolidated financial statements in accordance with International Financial Reporting Standard IAS 34 "Interim Financial Reporting". Our responsibility is to express a conclusion on these interim condensed consolidated financial statements based on our review.



Scope of Review

We conducted our review in accordance with International Standard on Review Engagements 2410 "Review of Interim Financial Information Performed by the Independent Auditor of the Entity". A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.



Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim condensed consolidated financial statements are not prepared, in all material respects, in accordance with International Financial Reporting Standard IAS 34 "Interim Financial Reporting".

Ernst & Young Ltd

/s/ Jolanda Dolente
Licensed audit expert
(Auditor in charge)

/s/ Fabian Meier
Licensed audit expert

Trademarks

Raxone® is a trademark of Santhera Pharmaceuticals.

Forward-Looking Statements

This Interim Report expressly or implicitly contains certain forward-looking statements concerning Santhera Pharmaceuticals Holding AG and its business. Such statements involve certain known and unknown risks, uncertainties and other factors, which could cause the actual results, financial condition, performance or achievements of Santhera Pharmaceuticals Holding AG to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. There can be no guarantee that any of the development projects described will succeed or that any new products or indications will be brought to market. Similarly, there can be no guarantee that Santhera Pharmaceuticals Holding AG or any future product or indication will achieve any particular level of revenue. In particular, management's expectations could be affected by, among other things, uncertainties involved in the development of new pharmaceutical products, including unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the Company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing and other political pressures. Santhera Pharmaceuticals Holding AG is providing the information in this Interim Report as of the date of the publication, and does not undertake any obligation to update any forward-looking statements contained herein as a result of new information, future events or otherwise.

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