

2016

Interim Condensed Report January to June 2016

1

Report on the Six Months Ending June 30, 2016, and Interim Condensed Consolidated Financial Statements

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Santhera Announces Financial Results for the First Half-Year 2016 and Reports Solid Sales Growth

Santhera Pharmaceuticals reports solid sales growth for the first half-year 2016. By end of the reporting period sales of Raxone® for Leber's hereditary optic neuropathy (LHON) had reached CHF 7.2 million, recorded primarily in Germany and France with an increasing sales contribution from additional mid-sized markets. Santhera has filed a Marketing Authorization Application (MAA) in Europe for Raxone for the treatment of Duchenne muscular dystrophy (DMD) in patients not taking glucocorticoids. The MAA was submitted as Type II variation of the existing marketing authorization for LHON and is currently under review by the Committee for Medicinal Products for Human Use (CHMP). Santhera will start a randomized, double-blind, placebo-controlled phase III (SIDEROS) trial shortly to assess the efficacy of Raxone in DMD patients receiving concomitant glucocorticoids. If successful, data from this trial will be used to support a label extension to include all DMD patients irrespective of their glucocorticoid use status. Santhera will also approach the US Food and Drug Administration (FDA) with the intent to re-engage in further discussions on the accelerated approval pathway for the glucocorticoid non-using patients, in whom clinically relevant benefit with Raxone has already been demonstrated.

Key Financials in the First Half-Year 2016

- Increasing sales for Raxone drove topline growth
 - In the first six months of 2016, Raxone generated net sales of CHF 7.2 million (1H 2015: CHF 1.5 million; 2H 2015: CHF 2.8 million), mainly driven by increased Raxone sales to LHON patients in Germany and France.
- Intensified commercial and clinical activities increased operating expenses
 - Operating expenses in the first half-year were CHF 22.6 million (1H 2015: CHF 7.5 million). Preparation of regulatory filings for DMD in Europe and the US and the implementation of late stage clinical trials led to higher development expenses of CHF 8.1 million (1H 2015: CHF 2.9 million). Marketing and sales expenses rose to CHF 8.9 million (1H 2015: CHF 1.5 million) and general and administrative expenses (G&A) to CHF 5.5 million (1H 2015: CHF 3.1 million). These increases reflect the expansion of Santhera's operations, especially the commercial activities, the ongoing roll-out of Raxone for LHON across Europe and market entry preparations for Raxone for DMD. In summary, the operating loss amounted to CHF 17.2 million (1H 2015: CHF -6.2 million) leading to a net result of CHF -18.0 million (1H 2015: CHF -6.4 million).
- Sound financial basis to advance commercial and development strategies as planned

 As of June 30, 2016, Santhera had cash and cash equivalents of CHF 63.6 million (December 31, 2015: CHF 76.9 million). Net change in cash and cash equivalents in the first half-year of 2016 was CHF -13.3 million.

Company Highlights

Solid uptake of Raxone for LHON in Europe

By end of the reporting period Raxone sales were recorded primarily in Germany and France with an increasing sales contribution from additional mid-sized markets. Santhera expects reimbursement decisions by a number of European Authorities in the second half of 2016 and early 2017.

Relevance of pulmonary benefits for patients with DMD reconfirmed at first "Duchenne Pulmonary Outcomes Workshop"

In April 2016, Santhera participated in the "Duchenne Pulmonary Outcomes Workshop", organized by Parent Project Muscular Dystrophy (PPMD), the leading US advocacy organization working to end Duchenne. The workshop convened experts in the research and clinical care of DMD patients who examined current and future assessments of pulmonary function. Santhera presented data from its phase III DELOS trial, which demonstrated clinically relevant efficacy of Raxone (idebenone) in preserving respiratory function, a key objective for DMD therapy. Previously, a patient and caregiver survey conducted by PPMD clearly demonstrated that the DMD community highly values treatment options for pulmonary complications.

Marketing Authorization Application (MAA) filed in Europe for Raxone for DMD

In May 2016, Santhera submitted a MAA to the European Medicines Agency (EMA) for Raxone for the treatment of DMD in patients with respiratory function decline and not taking concomitant glucocorticoids. The new indication was submitted as Type II variation of the Company's existing marketing authorization for Raxone which was granted last year. Shortly thereafter, on June 21, the EMA validated Santhera's application thereby confirming that the submission is complete and the review process by the Committee for Medicinal Products for Human Use (CHMP) has begun.

Update on US filing strategy for DMD

In July 2016, Santhera reported that the FDA commented on the proposed subpart H approval pathway and requested that a second phase III trial be completed providing additional data to support NDA filing for Raxone in all DMD patients, irrespective of their glucocorticoid use status. The FDA confirmed that a positive outcome of the planned SIDEROS trial has the potential to provide the supplementary efficacy data to support NDA filing in all DMD patients whether they use glucocorticoid or not. Santhera will work closely with the DMD patient community and clinical experts with the intent to engage the FDA in further discussions on an accelerated pathway to approval in the glucocorticoid non-using patients, in whom clinically relevant benefit has already been demonstrated.

Publication on bronchopulmonary benefits of Raxone in DMD in Neuromuscular Disorders

In June, additional data from the pivotal phase III trial (DELOS) were published in *Neuromuscular Disorders*, the official journal of the World Muscle Society (McDonald et al., Neuromuscular Disorders 2016, 26: 473–480). These data show that DMD patients treated with Raxone have a reduced risk of bronchopulmonary complications including fewer hospitalizations caused by such complications and a reduced need for systemic antibiotic treatment compared to patients receiving placebo.

Received US fast-track designation for omigapil – CALLISTO study on track

In May, Santhera received Fast Track Designation from the FDA for omigapil for the treatment of congenital muscular dystrophy (CMD). Previously, omigapil was granted Orphan Drug Designation for CMD in both the EU and the US. Santhera, in collaboration with the US National Institutes of Health (NIH), is currently conducting a clinical phase I study (CALLISTO) with omigapil in CMD patients. CALLISTO assesses the pharmacokinetics, safety, and tolerability of omigapil in ambulatory and non-ambulatory children affected by CMD. On August 30, Santhera announced that the Office of Orphan Products Development (00PD) at the FDA has granted Santhera an award of USD 246'000 in support of its ongoing CALLISTO trial.

SIDEROS trial with Raxone in DMD-patients using glucocorticoids to start imminently

The first patient is expected to be enrolled shortly in Santhera's randomized, double-blind, placebo-controlled phase III SIDEROS study. The trial is designed to confirm the efficacy of Raxone in patients currently taking glucocorticoids who are experiencing respiratory function decline, a patient population previously not enrolled in the positive phase III DELOS trial. If successful, this study will provide data to support the use of Raxone in all DMD patients experiencing respiratory decline irrespective of their glucocorticoid use status. Raxone for DMD was granted Orphan Drug Designation in the EU and the US and Fast Track Designation in the US.

Outlook and Guidance

The Marketing Authorization Application for Raxone in DMD is currently under review by the CHMP and Santhera expects a response from the regulatory authority in the first quarter 2017.

In July 2016, Santhera was advised by the FDA that the successful completion of the SIDEROS trial together with data from the previously successful phase III DELOS trial will provide the necessary data to support NDA filing for Raxone in all DMD patients irrespective of the glucocorticoid use status. In the interest of patients and due to the fact that the benefit of Raxone has already been demonstrated in the glucocorticoid non-using patients, Santhera will approach the FDA with the intent to re-engage in further discussions on an accelerated pathway to approval specifically for this patient population.

Santhera currently expects net sales of Raxone in 2016 to reach CHF 16 to 18 million.

Interim Condensed Consolidated Financial Statements

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Interim Consolidated Balance Sheet

ir	CHF thousands	Notes	June 30, 2016 (reviewed)	Dec. 31, 2015 (audited)
Assets				
Tangible assets		9	493	398
Intangible assets		9	28,025	29,559
Financial assets long-term			266	190
Deferred tax asset			2,231	3,061
Noncurrent assets			31,015	33,208
Prepaid expenses and accrued income			899	1,513
Inventories		6	5,798	3,441
Trade and other receivables			3,604	2,131
Cash and cash equivalents		7	63,564	76,859
Current assets			73,865	83,944
Total assets			104,880	117,152
Equity and liabilities Share capital		8	6,275	6,263
		8	6.275	6.263
Capital reserves and share premium			379,339	377,031
Retained earnings			-291,105	-273,133
Employee benefit reserve			-4,355	-2,958
Treasury shares			–177	-177
Other components of equity			-787	-779
Total equity			89,190	106,247
Pension liabilities			5,601	3,957
Total noncurrent liabilities			5,601	3,957
Trade and other payables			3,833	3,666
Accrued expenses			6,256	3,282
Total current liabilities			10,089	6,948
Total liabilities			15,690	10,905
Total equity and liabilities		_	104,880	117,152

Interim Consolidated Income Statement (Reviewed)

for the half-year ended June 30, in CHF thousands	Notes	2016	2015 1
Net sales	9	7,210	1,455
Cost of goods sold		-1,911	- 159
Of which amortization intangible asset		-1,519	0
Other operating income		61	23
Development	10	-8,101	-2,863
Marketing and sales	10	-8,949	-1,535
General and administrative	10	-5,479	-3,133
Other operating expenses	10	-38	-4
Operating expenses	10	-22,567	-7,535
Operating result		−17,207	-6,216
Financial income		509	104
Financial expenses		-424	-266
Tillalicial expelises		-424	-200
Result before taxes		-17,122	-6,378
Income taxes	11	-849	-2
Net result		-17,971	-6,380
Basic and diluted loss per share (in CHF)		-2.87	-1.28

Some amounts have been restated in comparison with the interim report 2015. For further details related to the nature of the corrections please refer to the annual report 2015 (refer there to note 2 "Correction of errors"). As a result of the restatement, net result for the half-year ended June 30, 2015, decreased by TCHF 169 and basic and diluted loss per share increased by CHF 0.04 compared to the amounts disclosed in the interim report 2015.

Interim Consolidated Statement of Comprehensive Income (Reviewed)

for the half-year ended June 30, in CHF thousands	2016	2015 1
Net result	-17,971	-6,380
Items never to be reclassified subsequently to net		
income in subsequent periods:		
Actuarial gains/(losses) on defined benefit plans	-1, 397	94
Items to be reclassified subsequently to net income		
in subsequent periods:		
Currency translation differences	-9	-18
Other comprehensive result	-1,406	76
Total comprehensive result	-19,377	-6,304

Some amounts have been restated in comparison with the interim report 2015. For further details related to the nature of the corrections please refer to the annual report 2015 (refer there to note 2 "Correction of errors"). As a result of the restatement, other comprehensive result for the half-year ended June 30, 2015, increased by TCHF 487 compared to the amounts disclosed in the interim report 2015.

Interim Consolidated Statement of Cash Flows (Reviewed)

for the half-year ended June 30, in CHF thousands Notes	2016	2015 ¹
Result before taxes	-17,122	-6,378
Depreciation of tangible assets	73	33
Amortization of intangible assets	1,546	7
Expenses for share options	1,984	773
Change in pension liabilities	247	110
Taxes paid	- 19	-2
Change in net working capital	48	-1,873
Total financial result	-85	162
Interest received	0	1
Interest paid	- 10	0
Cash flow from operating activities	-13,338	-7,167
		_
Investments in tangible assets	-176	-73
Disposal of intangible assets	6	0
Investments in intangible assets	-11	-59
Investments in other financial assets	-78	0
Cash flow from investing activities	-259	-132
Proceeds from option exercise	336	519
Cash flow from financing activities	336	519
Effects of exchange rate changes on cash and cash equivalents	-34	− 179
Net increase/(decrease) in cash and cash equivalents	-13,295	-6,959
Cash and cash equivalents at January 1	76,859	17,435
Cash and cash equivalents at June 30	63,564	10,476

Some amounts have been restated in comparison with the interim report 2015. For further details related to the nature of the corrections please refer to the annual report 2015 (refer there to note 2 "Correction of errors").

Interim Consolidated Statement of Changes in Equity (Reviewed)

in CHF thousands Not es	Share capital	Capital reserves and share premium	Retained earnings	Employee benefit reserve	Treasury shares	Transla- tion differ- ences	Total
Balance at January 1, 2015	4,974	293,650	-279,083	-1,287	-177	-762	17,315
Net result	0	0	-6,380	0	0	0	-6,380
Other comprehensive income	0	0	0	94	0	-18	- 76
Total comprehensive result for the period $\ensuremath{^{\mbox{\tiny 1}}}$	0	0	-6,380	94	0	-18	-6,304
Share-based payment transactions 10	0	773	0	0	0	0	773
Capital increase option exercise	75	589	0	0	0	0	664
Balance at June 30, 2015	5,049	295,012	-285,463	-1,193	-177	-780	12,448

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	324
Balance at June 30, 2016	6,275	379,339	-291,105	-4,355	-177	-787	89,190

Some amounts have been restated in comparison with the interim report 2015. For further details related to the nature of the corrections please refer to the annual report 2015 (refer there to note 2 "Correction of errors"). As a result of the restatement share based payment transactions increased by CHF169 in the six month period ended June 30, 2016.

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 no current therapy.

The Company, having the listing of its registered shares (Shares) on the SIX Swiss Exchange, is a Swiss stock corporation and the parent company of the Group. 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, 2016.

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, 2015, except for the adoption of new standards and interpretations as of January 1, 2016, as noted below.

Basis of preparation

These unaudited consolidated interim financial statements were prepared in accordance with IAS 34 Interim Financial Reporting and should be read in conjunction with the annual financial statements for the year ended December 31, 2015.

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

The accounting policies adopted in the preparation of the interim condensed consolidated financial statements are consistent with those followed in the preparation of the Group's annual consolidated financial statements for the year ended December 31, 2015.

In 2016 the Group has implemented various minor amendments to existing standards and interpretations, which have no impact on the Group's overall results and financial position or on disclosures in this interim report.

3 Seasonality

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

4 Exchange Rates of Principal Currencies

	Income sta	tement in CHF average rates		e sheet in CHF s of period end
	Six months ended June 30, 2016	Six months ended June 30, 2015	June 30, 2016	Dec. 31, 2015
1 Euro (EUR)	1.0960	1.0583	1.0884	1.0826
1 US dollar (USD)	0.9822	0.9475	0.9793	0.9927
1 British pound (GBP)	1.4080	n/a	1.3189	1.4694
1 Canadian dollar (CAD)	0.7380	0.7680	0.7558	0.7157

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/Catena.

6 Cash and Cash Equivalents

	in CHF thousands	June 30, 2016	Dec. 31, 2015
Cash at banks and on hand			
in CHF		59,134	69,570
in EUR		2,726	6,270
in GBP		1,526	772
in USD		51	191
in CAD		55	56
other currencies		72	0
Total at period end		63,564	76,859

7 Share Capital

Ordinary share capital

During the reporting period ending June 30, 2016, 11,800 Shares were issued out of conditional share capital upon the exercise of stock options. As a result, as of June 30, 2016, the issued nominal share capital amounted to CHF 6,274,598, divided into 6,274,598 Shares at a nominal value of CHF 1 each.

In the same period for 2015, 74,721 Shares were issued from conditional capital upon the exercise of stock options.

Authorized share capital

On the occasion of the Annual Shareholders' Meeting (ASM) on May 11, 2016, Santhera's shareholders approved the increase and extension of the authorized share capital of the Company. 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.

Conditional share capital

As of June 30, 2016, the Company had conditional share capital, pursuant to which the share capital may be increased by

- (i) a maximum amount of CHF 550,000 through the issuance of up to 550,000 Shares with the exercise of option rights. This part of the conditional share capital was increased from formerly CHF 401,694, as per December 31, 2015, to CHF 550,000 as approved at the ASM on May 11, 2016. During the first half of 2016, 11,800 options were exercised, reducing the available conditional capital to CHF 538,200 as per June 30, 2016. In the same period 2015, 74,721 options were exercised, reducing the available conditional capital to CHF 725,279 as per June 30, 2015 (see note 12 "Stock Option Plans").
- (ii) a maximum amount of CHF 650,000 by issuing up to 650,000 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 Segment and Geographic Information

Segment information

Santhera operates in one business segment, namely development and commercialization of products for the treatment of neuromuscular and mitochondrial diseases. The Board and the Executive Management, 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.

Geographic information

Net sales

Net suits	six months ended June 30, in CHF thousands	2016	2015
Europe		7,179	1,455
Rest of the world		31	0
Total		7,210	1,455

Noncurrent assets (excluding financial instruments and deferred tax assets)

	in CHF thousands	June 30, 2016	Dec. 31, 2015
Switzerland		28,429	29,876
European Union		89	80
North America		0	1
Total		28,518	29,957

9 Operating Expenses by Nature

six months ended June 30, in CHF thousands	2016	2015 ¹
External development expenses	-5,993	-2,290
Patent and license expenses	-122	-98
Marketing expenses	-3,925	-320
Employee expenses	-9,904	-4,573
of which non-cash-relevant expenses for share-based payments	-1,984	-773
General and administrative expenses	-2,188	-1,160
Depreciation, amortization and impairment	-101	-40
Reversal of impairment on inventories	0	1,111
Lease expenses	-296	-161
Other operating expenses	-38	-4
Total operating expenses	-22,567	-7,535

Some amounts have been restated in comparison with the interim report 2015. For further details please refer to the annual report 2015 (refer there to note 2 "Correction of errors").

Increased expenses for the reporting period in 2016 result from additional staff hired for marketing activities in LHON as well as development operations for LHON and DMD.

10 Income Taxes

	six months ended June 30, in CHF thousands	2016	2015
Income taxes		-19	-2
Deferred taxes		-830	0
Total		-849	-2

Movements on deferred taxes relate to temporary differences on inventory.

11 Stock Option Plans

Santhera has established Employee Stock Option Plans (ESOP), the ESOP 2004, the ESOP 2008, the ESOP 2010, the ESOP 2015, the 2006 Executive Incentive Plan (EIP) and Board Stock Option Plans (BSOP), the BSOP 2011 and 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. New grants are currently only possible under the ESOP 2015 and BSOP 2015.

In the reporting period ended June 30, 2016, a total of 142,392 options with exercise prices between CHF 69.30 and CHF 89.45 were granted. In the half-year period ending June 30, 2015, a total of 94,260 options with exercise prices between CHF 84.10 and CHF 105.50 were granted.

The fair value of stock options is determined at each grant date by using the Hull-White option pricing model. For the calculation of the fair value of stock options granted during the reporting period in 2016, the same range of valuation parameters as disclosed in the financial statements as of December 31, 2015, was applied, except for the CHF risk-free interest rate (between 0.00% and -0.30%) and the expected volatility (39%). The non-cash-relevant expenses for all unvested stock options in the reporting period 2016 amounts to TCHF 1,984 compared to TCHF 773 in the same period in 2015.

Options outstanding

	six months ended June 30, number of options	2016	2015
At January 1		223,834	477,580
Granted ¹		142,392	94,260
Forfeited		-5,071	-2,700
Expired		-4,963	0
Exercised		-11,800	-74,721
At June 30 ²		344,392	494,419

The weighted average fair value of the stock options granted during the reporting period in 2016 was CHF 24.18 (CHF 43.09 in the comparative reporting period 2015).

12 Related Party Transactions

During the reporting period 2016, a total of 6,562 options were granted to members of the Board and 30,550 options were granted to members of the Executive Management. In the same period in 2015, a total of 7,000 options were granted to members of the Board and 53,500 options to members of the Executive Management.

13 Subsequent Events

None.

Based on the closing price of CHF 76.90 of the Santhera Shares on June 30, 2016, a total of 72,308 stock options were in the money, whereof 50,646 were vested (on June 30, 2015, the closing Share price was CHF 90.00; a total of 440,166 options were in the money, whereof 381,431 were vested).

Report on the Review of Interim Condensed Consolidated Financial Statements

Basel, September 5, 2016

Introduction

We have reviewed the 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 six-month period ended 30 June 2016 (pages 6 to 15). 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 AG

Isl Jolanda Dolente Licensed audit expert (Auditor in charge) Isl Nicole Riggenbach 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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