

2014

Interim Report
January to June 2014

Report on the Six Months Ending June 30, 2014, and Interim Consolidated Financial Statements

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Santhera Reports First Half 2014 Financial Results and Provides Corporate Update

Santhera Pharmaceuticals reports significant progress for all programs in the first half year 2014. The Company already generates revenues with Raxone® for the treatment of Leber's Hereditary Optic Neuropathy (LHON) under the French temporary authorization for use (cATU) and named patient programs in certain additional countries. The net cash burn was markedly reduced due to the lean organization, increasing income from product sales and income from share placements.

Santhera made excellent progress on all key programs for Raxone and reached a number of important milestones. In particular, the Company re-filed the Marketing Authorization Application (MAA) for Raxone to treat LHON and achieved positive results from the phase III study in Duchenne Muscular Dystrophy (DMD).

From a financial standpoint, the recent sale of treasury shares in August, which raised an additional CHF 13.4 million, in conjunction with the increased income from product sales, has substantially improved the cash position and ensures that adequate funds are available to support ongoing development and regulatory projects and to commence marketing preparations for a potential launch of Raxone in Europe.

Product and Pipeline Highlights

- **Received temporary approval in France for Raxone as first treatment for LHON**
In January 2014, the French National Agency for Medicines and Health Products Safety (ANSM) granted a temporary approval (cATU) for Raxone to treat LHON. Santhera is providing Raxone, which is fully reimbursed by a special government program, to an increasing number of LHON patients in France.
- **Collected additional clinical data for Raxone in LHON that substantiates clinical efficacy**
Visual acuity data collected throughout the first half of 2014 from LHON patients enrolled in an ongoing worldwide Expanded Access Program (EAP) indicate that about 50% of Raxone-treated patients experience a clinically meaningful recovery of vision. Santhera also completed the collaboration with the European Vision Institute Clinical Research Network (EVICR.net) and collected the largest natural history database for this disease. The additional efficacy data from the EAP and the natural history data set were included in the regulatory filing dossier.
- **European Medicines Agency (EMA) validated and started review of MAA for Raxone in LHON**
Following discussions with several EU member states on the additional clinical efficacy data (from the EAP and natural history data) and the overall content of the revised MAA dossier for LHON, Santhera resubmitted an MAA in May. The filing was validated in early June and the decision by the EMA is expected in 1H 2015. An approval decision would lead to Raxone becoming the first product authorized by the EMA for the treatment of LHON.

- **Reported a successful outcome of the DELOS phase III study in DMD**
In May the first ever positive outcome of a double-blind, placebo-controlled phase III trial in DMD was announced. The study met its primary objective and demonstrated that Raxone/Catena can delay the loss of respiratory function in patients not taking concomitant glucocorticoid steroids. The preservation of respiratory function is considered of major clinical importance for patients with DMD. The Company plans to present results of the trial at the International Congress of the World Muscle Society in Berlin (DE) in October this year and at the Action Duchenne Conference in London (UK) in November.
- **Initiated a clinical development program with omigapil in Congenital Muscular Dystrophies (CMD) with support from private-public partnership**
In July the initiation of a phase I program, called CALLISTO, was announced with omigapil in pediatric CMD patients to be conducted by the U.S. National Institutes of Health (NIH). The program received financial support from an EU grant and several patient organizations. Patient enrolment is planned for late this year.
- **Ongoing collaboration with NIH in phase II trial with Catena in Primary Progressive Multiple Sclerosis (PPMS)**
The company continues to collaborate with the Neuroimmunology Branch of the National Institute of Neurological Disorders and Stroke (NINDS) in a double-blind, placebo-controlled phase II clinical trial (IPPoMS trial) investigating the efficacy of Catena in patients with PPMS.

Financial Highlights

- **Financing and initial Raxone sales eliminated cash burn during six month period**
As of June 30, 2014, Santhera had cash and cash equivalents of CHF 5.0 million. Net change in cash and cash equivalents in the first half year of 2014 was reduced to almost zero (TCHF 4; 1H 2013: CHF -4.7 million) as a result of the private share placement with new investor IGLU Group, the sale of shares under the SEDA and increasing income from product sales. By mid-year 2014, the Company's equity amounted to CHF 6.7 million (end of 2013: CHF 7.1 million). Together with the funds received from the recent sale of treasury shares as well as stock option exercises the Company's cash position at the end of August 2014 amounts to CHF 18.9 million.
- **Increasing sales of Raxone**
In the first six months of 2014, net sales were CHF 0.8 million, mainly driven by the first sales of Raxone for LHON under the cATU in France as well as sales for DMD and LHON patients under Named Patient and Special Access Programs.
- **Reduced operating expenses**
Operating expenses of CHF 3.9 million (1H 2013: CHF 6.0 million) were comprised of CHF 1.9 million in development, CHF 0.2 million in marketing and sales expense, and CHF 1.8 million in general and administrative expenses. The lower expenses were the result of a continued focus on core program operations. As a result, Santhera narrowed its operating loss to CHF -3.1 million (1H 2013: CHF -4.8 million).

- **Markedly improved net result**

On a comparable basis, Santhera reported an improved net result of CHF –3.1 million (1H 2013: CHF –3.2 million, which included extraordinary financial income of CHF 1.5 million from the settlement of finance lease liabilities).

Outlook

Santhera's main priorities in the near term are the successful regulatory filings of Raxone/Catena for LHON and DMD in Europe and the US. In Europe, the regulatory review for Raxone for LHON is underway and a decision is expected in the first half of 2015. Subject to a positive decision from the EMA, Raxone has the potential to become the first product authorized for the treatment of LHON. Based on the data package filed in the European MAA, Santhera will now approach the U.S. Food and Drug Administration (FDA) to discuss a regulatory path to potential U.S. approval in this indication.

Following the successful outcome of the phase III trial with Raxone/Catena in DMD, Santhera also plans to seek regulatory approval for the treatment of DMD in Europe and the U.S. Discussions with European and U.S. regulators have been initiated to identify the most expeditious regulatory approval pathway for this indication.

The company believes that, with the additional CHF 13.4 million, it has sufficient cash to support its currently planned development and regulatory programs and to make necessary preparations, as appropriate, for the commercial introduction of Raxone in Europe.

Interim Consolidated Balance Sheet

	in CHF thousands	Notes	June 30, 2014 (unaudited)	Dec. 31, 2013 (audited)
Assets				
Tangible assets			152	39
Intangible assets		5	4,210	4,225
Financial assets long-term			85	85
Noncurrent assets		8	4,447	4,349
Prepaid expenses and accrued income			74	301
Inventories			0	0
Trade and other receivables			312	42
Cash and cash equivalents		6	5,040	5,044
Current assets			5,426	5,387
Total assets			9,873	9,736
Equity and liabilities				
Share capital		7	4,669	3,934
Capital reserves and share premium			277,193	274,896
Retained earnings			-268,398	-265,304
Employee benefit reserve			83	405
Treasury shares			-177	-221
Other components of equity			-6,633	-6,604
Total equity			6,737	7,106
Pension liabilities			1,365	997
Total noncurrent liabilities			1,365	997
Trade and other payables			807	597
Accrued expenses			964	1,036
Total current liabilities			1,771	1,633
Total liabilities			3,136	2,630
Total equity and liabilities			9,873	9,736

Interim Consolidated Income Statement (Unaudited)

for the half year ended June 30, in CHF thousands	Notes	2014	2013
Net sales	8	829	1,127
Cost of goods sold		-75	-127
Gross profit		754	1,000
Other operating income		23	155
Development	9	-1,913	-3,155
Marketing and sales	9	-157	-754
General and administrative	9	-1,790	-2,048
Operating expenses	9	-3,860	-5,957
Operating result		-3,083	-4,802
Financial income		10	1,680
Financial expenses		-20	-111
Result before taxes		-3,093	-3,233
Income taxes		-1	7
Net result		-3,094	-3,226
Basic and diluted loss per share (in CHF)		-0.70	-0.88

Interim Consolidated Statement of Comprehensive Income (Unaudited)

for the half year ended June 30, in CHF thousands	2014	2013
Net result	-3,094	-3,226
<i>Items never to be reclassified subsequently to net income in subsequent periods:</i>		
Actuarial gains/(losses) on defined benefit plans	-322	555
<i>Items to be reclassified subsequently to net income in subsequent periods:</i>		
Currency translation differences	-29	71
Other comprehensive result	-351	626
Total comprehensive result	-3,445	-2,600

Interim Consolidated Statement of Cash Flows (Unaudited)

for the half year ended June 30, in CHF thousands	Notes	2014	2013
Result before taxes		-3,093	-3,233
Depreciation of tangible assets		35	23
Amortization and impairment of intangible assets		4	548
Expenses for share options		338	218
Change in pension liabilities		46	72
Settlement of finance lease liabilities		0	-1,262
Change in deferred tax assets		-2	0
Taxes paid		-1	-4
Change in net working capital		93	1,099
Total financial result		10	-1,569
Interest received		0	2
Interest paid		-4	-13
Cash flow from operating activities		-2,574	-4,119
Investments in tangible assets		-147	0
Investments in intangible assets		-17	0
Proceeds from / investment in other financial assets		0	276
Cash flow from investing activities		-164	276
Capital increase from private placement	7	1,000	0
Proceeds from option exercise	7	316	0
Proceeds from sale of treasury shares SEDA ¹	7	1,444	0
Cost of issuance share capital		-22	0
Amortization of finance lease		0	-9
Settlement of finance lease liabilities		0	-900
Cash flow from financing activities		2,738	-909
Effects of exchange rate changes on cash and cash equivalents		-4	41
Net increase/(decrease) in cash and cash equivalents		-4	-4,711
Cash and cash equivalents at January 1		5,044	12,283
Cash and cash equivalents at June 30		5,040	7,572

¹ Standby Equity Distribution Agreement (see note 7 "Share Capital")

Interim Consolidated Statement of Changes in Equity (Unaudited)

	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, 2013			3,677	274,441	-259,549	-368	-177	-6,659	11,365
Net result			0	0	-3,226	0	0	0	-3,226
Other comprehensive income			0	0	0	555	0	71	626
Total comprehensive result for the period			0	0	-3,226	555	0	71	-2,600
Share-based payment transactions		9	0	218	0	0	0	0	218
Balance at June 30, 2013			3,677	274,659	-262,775	-187	-177	-6,588	8,983
Balance at January 1, 2014			3,934	274,896	-265,304	405	-221	-6,604	7,106
Net result			0	0	-3,094	0	0	0	-3,094
Other comprehensive income			0	0	0	-322	0	-29	-351
Total comprehensive result for the period			0	0	-3,094	-322	0	-29	-3,445
Share-based payment transactions		9	0	338	0	0	0	0	338
Capital increase option exercise			92	224	0	0	0	0	316
Capital increase SEDA			355	1,045	0	0	44	0	1,444
Capital increase private placement			288	712	0	0	0	0	1,000
Cost of issuance share capital			0	-22	0	0	0	0	-22
Balance at June 30, 2014			4,669	277,193	-268,398	83	-177	-6,633	6,737

Notes to the Unaudited Consolidated Financial Statements

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. 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 8, 2014.

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, 2013, except for the adoption of new standards and interpretations as of January 1, 2014, 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, 2013.

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

Going concern

Due to the additional cash-in of CHF 13.4 million in gross, received in August 2014 (*see note 13 "Subsequent Events"*), and the product sales under Named Patient Programs (**NPP**), particularly under the temporary approval *Autorisation temporaire d'utilisation dite de cohorte (cATU)*, for Raxone[®] in the treatment of Leber's Hereditary Optic Neuropathy (**LHON**), the Company has sufficient cash to support its currently planned development and regulatory programs and to make necessary preparations, as appropriate, for the commercial introduction of Raxone[®] in Europe.

Having filed a Marketing Authorization Application (**MAA**) with the European Medicines Agency (**EMA**) in LHON in 2014, Santhera is awaiting a regulatory decision, expected in 2015. A positive outcome of the MAA in LHON is expected to be followed by a launch of Raxone[®]/Catena[®] and may help Santhera to

reach profitability, while a negative opinion of the EMA could have a major impact on the plans of the Company (including but not limited to the time of achieving profitability, questions regarding the regulatory pathway in other indications, necessity of additional clinical trials).

The positive outcome of a phase III trial in Duchenne Muscular Dystrophy (**DMD**) in May 2014 forms the basis for regulatory filings in the EU and the US. Depending on the outcome of the MAA in LHON, the potential regulatory filing in DMD and the related commercialization strategy of Raxone®/Catena® in these indications Santhera may require additional funds in order to finance its activities until revenues reach a level to sustain positive cash flows.

Changes in accounting policies

Santhera has adopted smaller amendments to various standards including IAS 32, IAS 39 and IFRS 10 and the interpretation IFRIC 21 Levies of the International Financial Reporting Standards that have become effective on January 1, 2014. None of these changes have had an impact on 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 statement in CHF (average)		Balance sheet in CHF (as of period end)	
	Six months ended June 30, 2014	Six months ended June 30, 2013	June 30, 2014	Dec. 31, 2013
1 euro (EUR)	1.2213	1.2295	1.2159	1.2257
1 US dollar (USD)	0.8909	0.9365	0.8911	0.8904
1 Canadian dollar (CAD)	0.8126	0.9221	0.8354	0.8325

5 Intangible Assets and Impairment Testing

IAS 36 requires assets not available for use to be tested for impairment on an annual basis and additionally when noting triggering events by comparing the carrying value to its recoverable amount. The recoverable amount is the higher of fair value less costs of disposal and value in use.

Based on the current situation, the Company has not identified triggers for impairment. Uncertainties remain as to whether a successful market registration can be achieved for LHON. A risk of future adjustments to the carrying amount of the Raxone®/Catena® projects remains should the Company fail to obtain such registrations (*see note 2 "Going concern"*).

6 Cash and Cash Equivalents

	in CHF thousands	June 30, 2014	Dec. 31, 2013
Cash at banks and on hand			
in CHF		4,342	4,347
in EUR		379	331
in USD		265	279
in CAD		54	87
Total at period end		5,040	5,044

In accordance with Santhera's treasury management policies, cash and cash equivalents in foreign currencies are to a large extent kept in line with planned expenses over the relevant planning horizon.

7 Share Capital

Ordinary share capital

During the reporting period ending June 30, 2014, 91,634 Shares were issued out of conditional share capital upon the exercise of stock options. In the same period for 2013, no Shares were issued. Santhera issued 355,000 additional Shares from conditional capital for the SEDA. In February 2014, additional 288,317 Shares were issued from authorized capital for a private placement. As a result, the issued nominal share capital amounted to CHF 4,669,000, divided into 4,669,000 Shares as of June 30, 2014.

Authorized share capital

On the occasion of the Annual Shareholders' Meeting (**ASM**) on May 20, 2014, Santhera's shareholders approved an extension of the authorized share capital of the Company. The Board is authorized to increase the share capital at any time until May 21, 2016 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, 2014, the Company had conditional share capital, pursuant to which the share capital may be increased by

- (i) a maximum amount of CHF 800,000 through the issuance of up to 800,000 Shares with the exercise of option rights. This part of the conditional share capital was increased from formerly CHF 684,414, as per December 31, 2013, to CHF 800,000 as approved at the ASM on May 20, 2014.
- (ii) a maximum amount of CHF 800,000 by issuing up to 800,000 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. This part of the conditional share capital had been completely consummated before, at the ASM on May 20, 2014, shareholders approved an increase to CHF 800,000.

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, the Executive Management and the Management Team, being the chief operating decision makers, assess the reporting data and allocate resources as one segment on an aggregated consolidated level according operating expenses by function. Santhera generates revenue from sales under NPP of Raxone® for LHON under the cATU in France and of Catena® under NPP. Geographic revenue information is based on location of the customer. In April 2013, Santhera voluntarily withdrew Catena® from the Canadian market in consultation with Health Canada, the national health authority, and as a result, did not achieve any further revenues in North America after the market withdrawal.

Geographic information

Net sales	six months ended June 30, in CHF thousands	2014	2013
Europe		829	254
North America		0	873
Total		829	1,127

Noncurrent assets (excluding financial instruments and deferred tax assets)

	in CHF thousands	June 30, 2014	Dec. 31, 2013
EU		3,561	3,590
Switzerland		799	674
North America		2	0
Total		4,362	4,264

9 Operating Expenses by Nature

	six months ended June 30, in CHF thousands	2014	2013
External development expenses		-777	-1,218
Patent and license expenses		-103	-255
Marketing expenses		-83	-323
Employee expenses		-1,964	-2,487
<i>of which non-cash-relevant expenses for share-based payments</i>		-338	-218
General and administrative expenses		-761	-929
Depreciation, amortization and impairment		-39	-571
Lease expenses		-133	-174
Total operating expenses		-3,860	-5,957

10 Stock Option Plans

Santhera has established employee stock option plans (**ESOP**), the ESOP 2004, the ESOP 2008, the ESOP 2010, the 2006 Executive Incentive Plan (**EIP**) and the 2011 Board Stock Option Plan (**BSOP**) to align the long-term interests of the Board, the Executive Management, employees and consultants. Options granted under these stock option plans are equity settled. New grants are only possible currently under the ESOP 2010 and BSOP.

In the reporting period ended June 30, 2014, a total of 352,000 options with exercise prices between CHF 3.78 and CHF 4.27 were granted. The majority of these options were exceptionally granted in January 2014, in order to reduce the risk of losing employees at a time when the company was in a very critical financial situation. In the period ending June 30, 2013, 3,500 options were granted at exercise prices between CHF 3.56 and CHF 4.04.

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 2014, the same range of valuation parameters as disclosed in the financial statements as of December 31, 2013, was applied, except for the CHF risk-free interest rate (between 0.98% and 1.25%). The non-cash-relevant expenses for all unvested stock options in the reporting period 2013 amounts to TCHF 338 compared to TCHF 218 in the same period in 2013.

Options outstanding

	six months ended June 30, number of options	2014	2013
At January 1		323,421	425,348
Granted ¹		352,000	3,500
Forfeited		0	-46,176
Expired		-5,215	-43
Exercised		-91,634	0
At June 30²		578,572	382,629

¹ The weighted average fair value of the stock options granted during the reporting period in 2014 was CHF 1.96 (CHF 2.09 in the comparative reporting period 2013).

² Based on the closing price of CHF 46.95 of the Santhera Shares on June 30, 2014, a total of 197,022 stock options were in the money, whereof 117,207 were vested (on June 30, 2013, the closing Share price was CHF 2.25; a total of 57,945 options were in the money which all were vested).

11 Commitments

As part of its ordinary course of business, Santhera has entered into several contracts for e.g. clinical development services. Commitments are within current market prices and can be terminated at the Company's discretion.

12 Related Party Transactions

During the reporting period 2014, a total of 28,000 options were granted to members of the Board and 52,000 options to the sole member of the Executive Management. In the same period in 2013, a total of 3,500 options were granted to members of the Board and no options to the Executive Management.

13 Subsequent Events

In July 2014, Santhera announced a public-private partnership for the clinical development program with omigapil, a drug candidate in-licensed from Novartis and repositioned for therapeutic use in Congenital Muscular Dystrophy (**CMD**). The clinical development program will be initiated with a phase I study in pediatric CMD patients (the CALLISTO study) to be conducted at the National Institute of Neurological Disorders and Stroke, a component of the US National Institutes of Health. The program is financially supported in the amount of CHF 1.3 million by EndoStem, an EU 7th Framework Programme, and two patient organizations, namely Cure CMD and the Swiss Foundation for Research on Muscle Diseases. Patient enrolment is expected to start in late 2014.

In August 2014, Santhera announced that it completed the sale of 200,000 registered shares of common stock at an average price of CHF 66.85 per Share. The Company received CHF 13.4 million in gross proceeds from the sale. The Shares were sold by an independent broker within a period of one month. The treasury shares with a par value of CHF 1.00 were issued from the Company's conditional capital.

Report on the Review of Interim Condensed Consolidated Financial Statements

Basel, 8 September 2014

Introduction

We have reviewed the interim condensed consolidated financial statements (consolidated balance sheet, consolidated income statement, consolidated statement of comprehensive income, consolidated statement of cash flows, consolidated statement of changes in equity and explanatory notes, pages 6 to 15) of Santhera Pharmaceuticals Holding AG for the period from 1 January 2014 to 30 June 2014. 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

Patrick Fawer
Licensed audit expert
(Auditor in charge)

Jörg Schmidt
Licensed audit expert

Trademarks

Raxone[®] and Catena[®] are trademarks 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.

Santhera Pharmaceuticals Holding AG

Hammerstrasse 49

4410 Liestal

Switzerland

Phone +41 61 906 89 50

Fax +41 61 906 89 51

www.santhera.com

Contact

Thomas Meier

Chief Executive Officer

Phone +41 61 906 89 50

thomas.meier@santhera.com