

# Interim report for Q4 2012



# Highlights

## Highlights from Q4 2012

- On October 3, 2012, Topotarget announced favorable results of belinostat in combination with doxorubicin in soft tissue sarcoma
- On October 15, 2012, it was announced that belinostat was granted an EU Orphan Drug Designation for the treatment of PTCL
- On November 26, 2012, Topotarget held an Extraordinary General Meeting regarding an amendment to the company's Articles of Association and a revision in the company's remuneration guidelines
- Topotarget's strategic review process is on-going

## Highlights after Q4 2012

- On January 24-26, 2013, an abstract was presented at the T-Cell Lymphoma Forum in San Francisco. The abstract concluded that belinostat is well-tolerated with a favorable safety profile in patients with PTCL and that belinostat is a candidate for being an effective and well-tolerated alternative for the treatment of PTCL

“We are very pleased with belinostat meeting the primary endpoint as well as the favorable safety profile in the PTCL BELIEF study. We are now working diligently towards an NDA filing in the US”.

CEO, Anders Vadsholt

## Highlights from the financial results for the period January 1 to December 31, 2012

- Topotarget recognized revenues of DKK 2.4 million during the period (DKK 65.6 million in the same period in 2011)
- The research and development costs were DKK 46.5 million during the period (DKK 54.3 million in the same period in 2011)
- The administration expenses were DKK 34.7 million during the period (DKK 40.8 million in the same period in 2011)
- The net financial loss amounted to DKK 1.2 million during the period (net income

of DKK 1.1 million in the same period in 2011)

- The net loss from continued operations before tax for the period was DKK 81.4 million (net loss of DKK 30.3 million for the same period in 2011)
- The Group's net cash and cash equivalents as of December 31, 2012 totaled DKK 41.5 million (DKK 114.3 million at year-end 2011)

# Financial highlights

<b>Financial highlights and ratios</b>	<b>12 months 2012</b>	<b>12 months 2011</b>
DKK '000		
Revenue	2,395	65,598
Research and development costs	(46,522)	(54,345)
Administrative expenses	(34,706)	(40,765)
Operating (loss)	(80,210)	(31,352)
Net financials	(1,156)	1,087
Net loss from continued operations before tax	(81,366)	(30,265)
Net loss from discontinued operations	99	(3,999)
Total comprehensive income for the period	(81,267)	(33,011)
Basic and diluted EPS continued operations	(0.61)	(0.22)
Basic and diluted EPS discontinued operations	-	(0.25)
<b>Consolidated balance sheet</b>		
Cash and cash equivalents	41,460	114,302
Equity	249,997	330,729
Total assets	277,686	370,476
<b>Consolidated cash flow statement</b>		
Cash flow from operating activities	(72,616)	(88,847)
Cash flow from investing activities	(226)	(1,919)
Cash flow from financing activities	-	-
<b>Consolidated ratios</b>		
Number of fully paid shares at end of period	132,652,050	132,652,050
Average number of shares for the period	132,652,050	132,652,050
Assets/equity	1.1	1.1
Market price at end of period	2.15	2.51
Net asset value per share	1.88	2.79
<b>Average number of full-time employees</b>	<b>23</b>	<b>42</b>

# Management report

The fourth quarter of 2012 has brought further confirmation that belinostat is an oncology drug with great potential to fulfill important medical needs for cancer patients. We received favorable results in our CLN-14 study with soft tissue sarcoma and we were granted an EU Orphan Drug Designation for belinostat in PTCL (peripheral T-cell lymphoma). Prior to October 2012, we announced that the CLN-19 BELIEF study in PTCL, using belinostat as a single drug, had reached its primary endpoint – and the positive news has continued into 2013 as it has again been established that our compound has a favorable safety profile.

## **PTCL BELIEF study**

Topotarget and North American partner Spectrum Pharmaceuticals have announced that the primary endpoint has been met for the belinostat pivotal BELIEF study, evaluating the efficacy and safety of belinostat for the treatment of patients with relapsed/refractory PTCL. This is an important milestone for Topotarget and for belinostat as it is a prerequisite for the Special Protocol Assessment (SPA) agree-

ment that the U.S. Food and Drug Administration (FDA) has provided for belinostat for the treatment of PTCL. Spectrum Pharmaceuticals has the responsibility to file the New Drug Application (NDA) for belinostat in PTCL in the US.

Belinostat's safety profile was shown at the T-Cell Lymphoma Forum in San Francisco, USA, on January 24-26, 2013. The presentation concluded that belinostat is well-tolerated and that the drug's favorable safety profile in patients with PTCL makes belinostat a candidate for a well-tolerated alternative for the treatment of PTCL. The positive safety outcome from this trial, as well as experience from earlier belinostat trials, shows that full doses of belinostat can be combined with other cytotoxic regimens making combination therapy for cancer patients feasible.

Topotarget is entitled to receive one million shares of common stock in Spectrum Pharmaceuticals and a double-digit million USD cash payment if Spectrum Pharmaceuticals receives an acceptance to file from the FDA. If belinostat is approved

by the FDA, Topotarget will further receive a double-digit million USD cash payment as well as royalty from upcoming sales in Spectrum Pharmaceuticals' territory. Spectrum Pharmaceuticals expects to file an NDA with the FDA in mid-2013, with a potential acceptance to file within 75 days from filing and a potential approval from the FDA in 2014.

## **Strategic review**

In August 2012, Topotarget initiated a strategic review process in order to be able to evaluate and execute on different strategic options. These options include partnering of belinostat outside the territory of Spectrum Pharmaceuticals, a merger with an industrial partner, or a sale of the company. The review is on-going.

## **Looking forward**

For the year 2013, Topotarget will continue to focus on, initially in the US, bringing belinostat to the market. We continue to strive towards helping and prolonging the lives of cancer patients and look forward to taking steps that will help us get closer to reaching this goal.

## Events in Q4 2012

### **Favorable results of belinostat in combination with doxorubicin in STS**

On October 3, 2012, Topotarget announced favorable results of belinostat in combination with doxorubicin in soft tissue sarcoma; the study (CLN-14) had met the predefined protocol criteria.

### **Belinostat receives EU ODD for the treatment of PTCL**

On October 15, 2012, the European Commission granted Topotarget an Orphan

Drug Designation for belinostat for the treatment of PTCL.

### **Extraordinary General Meeting**

On November 2, 2012, Topotarget announced that an Extraordinary General Meeting (EGM) would be held on November 26, 2012. The agenda was 1) to get approval to authorize the company's Board of Directors to take up a loan against issuance of convertible bonds, and 2) to get approval of a revised set of general

guidelines for incentive remuneration of Topotarget's Board of Directors and management. Both proposals were adopted as proposed. An agreement, made with a company related to Topotarget's Chairman of the Board (Orfacare Consulting), is described in Note 1 of this interim financial statement.

## Events after Q4 2012

### **Favorable belinostat safety profile**

At the T-Cell Lymphoma Forum in San Francisco, USA, on January 24-26, 2013, an abstract was presented with preliminary safety data from the pivotal phase II BELIEF study (CLN-19) of belinostat as a single agent in patients with relapsed and/or refractory peripheral T-cell lymphoma (PTCL). The abstract concluded that belinostat is well-tolerated with a favorable safety profile in patients with PTCL and that belinostat is a candidate for being an effective and well-tolerated alternative

for the treatment of PTCL. A total of 129 patients, 53% men, median age 63 years (range 29–81 years), were treated with belinostat in the trial. Severe non-hematological adverse events (grade 3/4 in more than 5% of the patients) were asthenia/fatigue (9%), pneumonia (7%), and dyspnea (6%). Hematological toxicities classified as severe (grade 3/4) were thrombocytopenia (6%) in patients with platelet counts of 100,000 or more, anemia, leukopenia, and neutropenia were each 13%. Cytostatic agents and combinations of anticancer

agents like CHOP (cyclophosphamide, doxorubicin, vincristine, and prednisolone) used for the treatment of patients with PTCL are known to decrease marrow activity resulting in fewer red blood cells (anemia), white blood cells (leukopenia and neutropenia), and platelets (thrombocytopenia) – a condition also known as myelosuppression. The low incidence of myelosuppression makes it feasible to combine belinostat with other cytotoxic regimens for treatment of PTCL.

# Belinostat active clinical trials

## (TOPOTARGET OR SPECTRUM PHARMACEUTICALS)

Indication	Study	Sponsor	Phase I	Phase II	Pivotal	Target #	Enrollment status	Milestone	Time frame
PTCL	BELIEF (CLN-19)	SPPI	→			100	Completed	Top-line results NDA filing	H1 2013 Mid-2013
Solid + STS	CLN-14	TT	→	→		55	Phase II, stage I completed	Results phase II, stage I	Q3 2013
Drug-drug interaction	CLN-20	SPPI/TT	→			39	Recruiting	Top-line results	H1 2013
NSCLC	SPI-1014-Bel	SPPI/TT	→			35	Recruiting	Recruitment completed	n/a

Note: TT = Topotarget / SPPI = Spectrum Pharmaceuticals

### Peripheral T-cell lymphoma (PTCL) – BELIEF (CLN-19)

The pivotal study of belinostat for the treatment of relapsed or refractory PTCL is about to finalize. In September 2011, the study was closed for recruitment after the inclusion of 129 patients. There is a Special Protocol Assessment in place with the FDA and under these terms the study has to reach a response rate of at least 20% as the primary endpoint – the primary endpoint was met in September 2012.

The safety data presented at the T-Cell Lymphoma Forum on January 24-26, 2013 showed a favorable safety profile of belinostat when compared to the approved treatments for patients with PTCL and it was emphasized that combining belinostat with cytotoxic regimens is feasible. Belinostat appears to have low mye-

losuppression and even patients with a poor bone marrow reserve tolerated belinostat. The number of patients requiring dose reductions is also low. In total, 12% of the 129 patients need dose reduction and 17% of 24 patients in the study had platelet counts below 100,000/ $\mu$ L. Grade 3/4 hematologic toxicities were: Thrombocytopenia 6% in patients with platelet counts of  $\geq$ 100,000 – anemia, leukopenia, and neutropenia were each 13%. No cardiac death is reported and QTC grade 3 was seen in no more than 2% of the patients.

A New Drug Application (NDA) submission to the FDA is expected to be filed by Spectrum Pharmaceuticals in mid-2013. Following FDA's acceptance of the NDA, Topotarget is entitled to receive one million shares of common stock in Spectrum Pharmaceuticals and a double-digit mil-

lion USD cash payment. If belinostat is granted market authorization by the FDA, Topotarget will further receive a double-digit million USD cash payment.

PTCL is a hematological disease including a heterogeneous group of malignancies of T-cell origin that represents about 10-15% of all cases of non-Hodgkin's lymphoma. It is an aggressive, high-grade type of cancer with a poor prognosis of expected survival of approximately two years from diagnosis without treatment. The projections for annual cancer incidences point to 15,500 new cases of PTCL in the US, Japan, and in top-5 EU countries. The study was initiated by Topotarget and is sponsored, conducted, and finalized by our partner Spectrum Pharmaceuticals.

### Solid tumors and soft tissue sarcoma (STS) – CLN-14

After the maximum tolerated dose of belinostat in combination with doxorubicin was established in patients with solid tumors, an expansion cohort was initiated in patients with STS. The expansion cohort is planned in two stages, with 20 patients to be included in the first stage and 20 patients in the second phase. Initial results met the protocol criteria and were presented in a press release in September 2012. The initial results of the study were promising, but the study design does not facilitate a clear evaluation with respect to the effect of belinostat in the combination. Thus, to confirm the preliminary evidence for activity, a randomized trial would have to be conducted. Based on the current data, Topotarget will use the option of stopping the study as allowed by the study design and explore other potential opportunities within the indication as well as considering conducting a randomized trial in STS.

### Drug-drug interaction – CLN-20

The aim of the CLN-20 study is to support the NDA filing with safety data on potential drug-drug interactions. The study is conducted in the Topotarget/Spectrum Pharmaceuticals collaboration and is overlooked by Spectrum Pharmaceuticals. Approximately 39 patients are expected to be included in the study. The study is recruiting according to plan and top-line results are anticipated in H1 2013.

### Non-small cell lung cancer (NSCLC) – SPI-1014

This is a phase I/II maximum tolerated dose study of belinostat in combination with carboplatin plus paclitaxel (BelCaP) in chemotherapy-naïve patients with stage IV NSCLC. The study was initiated in March 2011 and up to 35 patients are expected to be enrolled. Several dose levels have been investigated so far. Topotarget/Spectrum Pharmaceuticals are co-sponsors and

Spectrum Pharmaceuticals is overlooking the US-based study.

### NCI-sponsored studies

The National Cancer Institute (NCI) is a prestigious and world-leading oncology research association and is sponsoring a vast number of studies in oncology and malignant hematological diseases. Topotarget and Spectrum Pharmaceuticals are in collaboration with the NCI studying belinostat and investigating treatment options in several indications with a high unmet medical need. These studies are conducted in support of the development program sponsored by Topotarget and Spectrum Pharmaceuticals. The NCI sponsors and conducts the studies under their auspices and therefore the timelines and communication/publication given are under the control of the NCI.

## NCI-SPONSORED STUDIES IN COLLABORATION WITH TOPOTARGET AND SPECTRUM PHARMACEUTICALS

Trial	Initiated
NCI7251: A Phase I Trial of PXD101 (Belinostat) in Combination with 13-cis-Retinoic Acid in Advanced Solid Tumor Malignancies.	Q4 2006
NCI8238: A Phase I Study of Belinostat in Combination with Cisplatin and Etoposide in Adults with Advanced Cancers.	Q3 2009
NCI8602: A Phase 1/2 Study of PXD101 (Belinostat) in Combination with Cisplatin, Doxorubicin and Cyclophosphamide in the First Line Treatment of Advanced or Recurrent Thymic Malignancies.	Q2 2010
NCI8846: A Phase I Pharmacokinetic Study of Belinostat for Solid Tumors and Lymphomas in Patients with Varying Degrees of Hepatic Dysfunction.	Q1 2011

Please note that the NCI is responsible for any communication relating to the above studies



# Financial review of Q4 2012

The financial report for Q4 2012 comprises the parent company Topotarget A/S and the four wholly-owned subsidiaries Topotarget UK Ltd, Topotarget Germany AG, Topotarget Switzerland S.A., and Topotarget Netherlands B.V. (the Group).

Unless otherwise stated, the financial review is based on the Group's consolidated financial information for the period October 1 to December 31, 2012 with comparative figures for the Group for the same period in 2011.

## Income statement

The total comprehensive income for the period was DKK -18.0 million (DKK -18.0 million for the same period in 2011).

## Revenues

Topotarget recognized revenues of DKK 1.2 million during the period (DKK 0.2 million in the same period in 2011). Revenues are primarily composed of income as per our collaboration agreement with Spectrum Pharmaceuticals.

## Costs

Production costs, which amounted to DKK 0.3 million (DKK 0.4 million in the

same period in 2011), include Topotarget personnel costs related to the Spectrum Pharmaceuticals collaboration agreement.

Research and development costs were DKK 8.5 million (DKK 9.8 million in the same period in 2011). The reduction in costs by 13% is primarily due to the finalization of clinical projects.

Administrative expenses were DKK 7.0 million (DKK 10.9 million in the same period in 2011). The decrease in costs is mainly due to reductions in the number of employees and the hereto related costs.

Discontinued operations comprise the divestment of activities from the Group's US subsidiary, including Totect<sup>®</sup>, which was sold in December 2011. In the beginning of 2013, Totect<sup>®</sup> was put up for divestment by the buyer and in this relation, Topotarget's management has made a reassessment of the company's receivables. The discontinued operations showed a net expense of DKK 1.8 million (DKK 1.3 million net expense in the same period in 2011).

## Net financials

The net financials showed a net expense of DKK 1.5 million (DKK 2.7 million net income in the same period in 2011). The financial expense is mainly due to exchange rate fluctuations.

## Balance sheet

The balance sheet amounted to DKK 277.7 million in total assets as of December 31, 2012 (DKK 370.5 million in the same period in 2011).

The Group's net cash and cash equivalents as of December 31, 2012 totaled DKK 41.5 million (DKK 114.3 million at year-end 2011) and the equity amounted to DKK 250.0 million (DKK 330.7 million at year-end 2011).

Non-current liabilities as of December 2012 were DKK 3.2 million (DKK 13.6 million in the same period in 2011). The reason for the large reduction is the reclassification of the CuraGen loan from non-current liabilities to current liabilities in the amount of DKK 11.4 million (see Note 1).

# Statement by the Board of Directors and executive management

The Board of Directors and executive management today discussed and adopted the interim report for Topotarget for the period January 1 to December 31, 2012.

The interim report is presented in accordance with IAS 34 as adopted by the EU and additional Danish disclosure requirements on the presentation of interim reports by listed companies.

The interim report is not audited or reviewed.

We consider the accounting policies to be appropriate. Accordingly, the interim report gives a true and fair view of the Group's assets, liabilities, and financial position at December 31, 2012 and of the Group's operations and cash flows for the period January 1 to December 31, 2012.

Within the next twelve months, management expects to receive significant milestone payments from Spectrum Pharmaceuticals that will enable the continued development of belinostat after mid-2013. Consequently, Topotarget has prepared its financial statement on a go-

ing concern basis. Management acknowledges that there are some risks associated with this strategy which is set out under "Accounting policies" in Note 1 of this interim financial statement.

In our opinion, the interim report gives a true and fair view of the development in the activities and the financial position of the Group, the results for the period, and of the Group's financial position in general and further gives a fair description of significant risks and uncertain factors that may affect the Group.

Copenhagen, January 31, 2013

## Executive management

Anders Vadsholt  
Chief Executive Officer

## Board of Directors

Bo Jesper Hansen  
Chairman

Anker Lundemose

Gisela Schwab

Ingelise Saunders

Jeffrey H. Buchalter

Karsten Witt

Per Samuelsson

## Consolidated statement of comprehensive income for the period

	Q4 2012	Q4 2011	12 months 2012	12 months 2011
DKK '000				
Revenue	1,157	207	2,395	65,598
Production costs	(315)	(412)	(1,377)	(1,840)
Research and development costs	(8,485)	(9,848)	(46,522)	(54,345)
Administrative expenses	(7,017)	(10,913)	(34,706)	(40,765)
<b>Operating loss</b>	<b>(14,659)</b>	<b>(20,966)</b>	<b>(80,210)</b>	<b>(31,352)</b>
Financial income and expenses	(1,488)	2,716	(1,156)	1,087
<b>Net loss from continued operations before tax</b>	<b>(16,148)</b>	<b>(18,250)</b>	<b>(81,366)</b>	<b>(30,265)</b>
Tax on profit/(loss) for the period	-	1,586	-	1,253
<b>Net loss from continued operations</b>	<b>(16,148)</b>	<b>(16,664)</b>	<b>(81,366)</b>	<b>(29,012)</b>
Net profit/(loss) from discontinued operations	(1,845)	(1,340)	99	(3,999)
<b>Total comprehensive income for the period</b>	<b>(17,993)</b>	<b>(18,004)</b>	<b>(81,267)</b>	<b>(33,011)</b>
Total comprehensive income attributable to:				
Owners of the company	(17,993)	(18,004)	(81,267)	(33,011)
Non-controlling interests	-	-	-	-
<b>Total comprehensive income for the period</b>	<b>(17,993)</b>	<b>(18,004)</b>	<b>(81,267)</b>	<b>(33,011)</b>
Basic and diluted EPS continued operations	(0.14)	(0.13)	(0.61)	(0.22)
Basic and diluted EPS continued and discontinued operations	(0.14)	(0.14)	(0.61)	(0.25)
<b>Average number of employees</b>	<b>18</b>	<b>43</b>	<b>23</b>	<b>42</b>

## Condensed balance sheet

	<b>Total 2012</b>	<b>Total 2011</b>
DKK '000		
<b>Assets</b>		
Intangible assets	228,902	229,626
Tangible assets	2,655	4,963
Non-current investments	501	608
<b>Non-current assets</b>	<b>232,058</b>	<b>235,197</b>
Inventories	-	-
Receivables	4,169	11,210
Short-term securities	-	9,768
Cash and cash equivalents	41,460	114,302
<b>Current assets</b>	<b>45,629</b>	<b>135,279</b>
<b>Assets</b>	<b>277,686</b>	<b>370,476</b>
<b>Equity and liabilities</b>		
<b>Equity</b>	<b>249,997</b>	<b>330,729</b>
Non-current liabilities	3,212	13,585
Current liabilities	24,478	26,163
<b>Liabilities</b>	<b>27,690</b>	<b>39,748</b>
<b>Equity and liabilities</b>	<b>277,686</b>	<b>370,476</b>

## Condensed cash flow statement

	<b>Total 2012</b>	<b>Total 2011</b>
DKK '000		
Operating loss	(80,210)	(31,352)
Operating loss from discontinued operations	-	(6,560)
Reversal of share-based payments	535	3,521
Depreciation, amortization, and impairment losses	2,647	414
Working capital changes	3,800	(58,458)
<b>Cash flow from operating activities before interest</b>	<b>(73,228)</b>	<b>(92,435)</b>
Received and paid interests etc.	612	2,335
Refunded income taxes	-	1,253
<b>Cash flow from operating activities</b>	<b>(72,616)</b>	<b>(88,847)</b>
Purchase of intangible assets	-	-
Purchase of tangible assets	(344)	(2,283)
Sale of tangible assets	118	-
Purchase of investments	-	364
<b>Cash flow from investing activities</b>	<b>(226)</b>	<b>(1,919)</b>
<b>Cash flow from financing activities</b>	<b>-</b>	<b>-</b>
Increase/decrease in cash and cash equivalents	(72,842)	(90,766)
Cash and cash equivalents at January 1	114,302	205,068
<b>Cash and cash equivalents at December 31</b>	<b>41,460</b>	<b>114,302</b>
<b>Total cash and cash equivalents at December 31</b>	<b>41,460</b>	<b>114,302</b>

## Consolidated statement of changes in equity for the period January 1 to December 31, 2012

Group	Number of shares	Share capital	Share premium account	Retained earnings	Total
		DKK '000	DKK '000	DKK '000	DKK '000
Equity at January 1, 2012	132,652,050	132,652	34,743	163,334	330,729
Net loss for the period	-	-	-	(81,267)	(81,267)
Other comprehensive income for the period	-	-	-	-	-
<b>Total comprehensive income for the period</b>	-	-	-	<b>(81,267)</b>	<b>(81,267)</b>
Recognition of share-based payment	-	-	535	-	535
Reversal of expired warrants	-	-	(1,429)	1,429	-
Share capital increase through warrant exercise	-	-	-	-	-
<b>Equity at December 31, 2012</b>	<b>132,652,050</b>	<b>132,652</b>	<b>33,849</b>	<b>83,496</b>	<b>249,997</b>

The share capital is an undistributable reserve, while the other reserves are distributable for dividend purposes subject to the provisions of the Danish Public Companies Act.

### Consolidated statement of changes in equity for the period January 1 to December 31, 2011:

Equity at January 1, 2011	132,652,050	132,652	31,222	196,345	360,219
Net loss for the period	-	-	-	(33,011)	(33,011)
Other comprehensive income for the period	-	-	-	-	-
<b>Total comprehensive income for the period</b>	-	-	-	<b>(33,011)</b>	<b>(33,011)</b>
Recognition of share-based payment	-	-	3,521	-	3,521
Reversal of expired warrants	-	-	-	-	-
Share capital increase through warrant exercise	-	-	-	-	-
<b>Equity at December 31, 2011</b>	<b>132,652,050</b>	<b>132,652</b>	<b>34,743</b>	<b>163,334</b>	<b>330,729</b>

The share capital is an undistributable reserve, while the other reserves are distributable for dividend purposes subject to the provisions of the Danish Public Companies Act.

# Note 1

## Management's significant accounting assumptions and estimates

### Accounting policies

The interim financial statements have been prepared in accordance with IAS 34, interim financial reporting, and additional requirements for interim financial statements of listed companies. No interim financial statements have been prepared for the parent company.

The accounting policies applied in the interim report are unchanged relative to the accounting policies applied in Topotarget's annual report for 2011, and are in accordance with the International Financial Reporting Standards (IFRS) as adopted by the EU and additional Danish disclosure requirements for annual reports of listed companies. The interim report has been prepared on a going concern basis.

The interim report is presented in Danish kroner (DKK), which is the parent company's functional currency.

### Implementation of new and revised standards and interpretations

The consolidated financial statements are presented in accordance with the new and revised standards (IFRS/IAS) and interpretations (IFRIC) which apply for financial years starting on or after January 1, 2012.

### Standards and interpretations not yet in force

At the date of the interim report for the twelve months of 2012, a number of new or amended standards and interpretations have not yet entered into force and are therefore not included in this report. These new and revised standards and interpretations are not expected to result in any changes to the accounting policies applied.

### Going concern

The going concern statement is based on milestone payments from Spectrum Pharmaceuticals during H2 2013. It is the management's best assessment that a number of risk factors could affect the milestone payments from Spectrum Pharmaceuticals. Topotarget is entitled to receive one million shares of common stock in Spectrum Pharmaceuticals and a double-digit million USD cash payment, if Spectrum Pharmaceuticals receive FDA's acceptance to file the belinostat NDA. The CLN-19 study has met the study's primary endpoint and has shown a strong safety profile. Preparation to file mid-2013 is being pursued according to Spectrum Pharmaceuticals. A delay of the NDA filing might have a negative impact on the projected cash flow. The main risk is of course if FDA does not accept the filing or requires additional data.

Apricus Biosciences, Inc. announced a planned divestiture of its oncology supportive care business including the rights to Totect®. The divestiture will affect the USD 2 million milestone payments relating to a technology transfer of Totect®. We are evaluating the possible consequences for Topotarget.

Management will regularly assess liquidity needs and the ability to raise additional financing, should the expected milestone be delayed, to prolong the runway towards expected milestone payments. Consequently, Topotarget has prepared its financial statement on a going concern basis, even with the obvious risks described above, which are associated with this strategy.

### Revenue recognition

Revenue is recognized when it is probable that future economic benefits will flow to the company and such economic benefits can be measured reliably. In addition, recognition requires that all significant risks and rewards of ownership of the rights or services included in the transaction have been transferred to the buyer. Income from agreements with multiple components and where the individual components cannot be separated is recognized over the period of the agreement. In addition, recognition requires that all significant risks and rewards of ownership of the goods or services included in the transaction have been transferred to the buyer. If all risks and returns have not been transferred, revenue is recognized as deferred income until all components of the transaction have been completed.

## Note 1 – continued

### **Financial liabilities**

Included in the non-current liabilities and the current liabilities is a potential payment of USD 3.0 million to CuraGen in relation to the purchase of the full belinostat rights in April 2008.

The reclassification from non-current liabilities relates to a potential partial payment payable within 12 months.

### **Other**

A company related to the Chairman of the Board (Orfacare Consulting) provides consultation regarding a potential M&A transaction. Orfacare is entitled to receive compensation upon completion of a successful M&A transaction, but does not receive a fixed compensation.



