To OMX Nordic Exchange Copenhagen Announcement no. 26–08 / Copenhagen August 19, 2008

# Interim report – six months ended 30 June 2008

Highlights and key ratios from the first half of 2008

- Solid sales increase for Savene<sup>®</sup>/Totect<sup>®</sup>, with total sales of 245 kits, including 143 in Q2. Second-quarter sales climbed to DKK 9.6 million from DKK 4.6 million in Q2 2007, representing an increase of 108% on Q2 2007. Total sales in the first six months of 2008 were DKK 16.6 million, compared with DKK 8.3 million in H1 2007. This is an improvement of 99% on 2007. TopoTarget expects to be able to double its sales of Savene<sup>®</sup>/Totect<sup>®</sup> in 2008. In 2007, sales were DKK 21.6 million for 305 kits sold
- Additional positive clinical results in belinostat monotherapy and in combination with chemotherapy in ovarian cancer, leukaemia and malignant lymphoma
- As earlier announced TopoTarget has commenced a process in order to form a partnership with a global pharmaceutical company with sufficient development and commercialisation resources to fully capitalise on belinostat's blockbuster potential. Such a deal is expected to be concluded in 2008
- Loss before tax of DKK 113.7 million for six months ended 30 June 2008, as compared to a loss of DKK 82.7 million in the same period 2007
- Following the acquisition of the global rights to belinostat, TopoTarget has been able to revise its strategy. Increased focus on belinostat and reduced costs for other projects etc. lead to a cost reduction of DKK 35-40 million in the previously expected pre-tax loss for 2008 with the forecast loss now being in the range of DKK 195-220 million. These numbers do not include future licensing revenues.

#### Conference call

TopoTarget will host a conference call this afternoon, 19 August at 14.00 (CET), at which management will present and discuss the results for the first six months of 2008. The conference call will be held in English.

A presentation will be available on TopoTarget's website, <u>www.topotarget.com</u>, before the start of the conference call.

To participate in the conference call please dial:

From Denmark: 70 26 50 40

Outside Denmark: +45 70 26 50 40 or +44 208 817 9301

A replay of the conference call will be available approximately two hours after the conference call and until August 26, 2008 at 5.00 pm (CET) at the following number: +353 1 436 4267 pin code 1307444#.



#### TopoTarget A/S

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# Interim report for the six months ended 30 June 2008

# Copenhagen, Denmark – August 19, 2008 - The Board of Directors of TopoTarget A/S (OMX: TOPO) today adopted the company's interim report for the six months ended 30 June 2008.

Solid sales increase for Savene<sup>®</sup>/Totect<sup>®</sup>, with total sales of 245 kits, including 143 in Q2. Second-quarter sales climbed to DKK 9.6 million from DKK 4.6 million in Q2 2007, representing an increase of 108% on Q2 2007. Total sales in the first six months of 2008 were DKK 16.6 million, compared with DKK 8.3 million in H1 2007. This is an improvement of 99% on 2007.

Operating expenses for the period 1 January – 30 June 2008 were DKK 127.2 million, compared with DKK 110.9 million in the same period of last year. The difference being primarily due to the acquisition of TopoTarget Switzerland S.A. in June 2007. The operating loss for the period was DKK 107.3 million, compared with DKK 85.1 million in the same period of last year. The company posted a loss before tax for the first six months of 2008 of DKK 113.7 million against a pre-tax loss of DKK 82.7 million in the same period of 2007.

Cash, cash equivalents and marketable securities amounted to DKK 173.6 million at 30 June 2008.

# Selected milestones met during H1 2008

<u>Q2:</u>

- Global rights acquired for belinostat TopoTarget's lead anti-cancer project
- Fast Track designation granted by FDA for belinostat in PTCL (peripheral T-cell lymphoma)
- Positive clinical data from a Phase II study of belinostat monotherapy in patients with recurrent or refractory peripheral or cutaneous T-cell lymphoma (PTCL and CTCL) presented at the "10<sup>th</sup> International Conference on Malignant Lymphoma" in Lugano in June 2008
- Positive clinical data presented at ASCO (American Society of Clinical Oncology) 2008, demonstrating substantial anti-tumour activity from a Phase II trial using belinostat, carboplatin and paclitaxel (BelCaP) to treat ovarian cancer
- New positive clinical data presented by the NCI (National Cancer Institute, USA) at the ASCO 2008 Annual Meeting from two belinostat studies, partly for the treatment of advanced myeloid neoplasms in combination with azacitidine (AZC), partly for the treatment of ovarian tumours
- Sales improvement for  $\mathsf{Savene}^{\texttt{®}}$  and  $\mathsf{Totect}^{\texttt{®}}$  with a doubling of sales for H1 2008 vs H1 2007
- The United Kingdom Oncology Nursing Society, UKONS, adopted the EONS (European Oncology Nurses Society) guidelines for using Savene<sup>®</sup> in the treatment of anthracycline extravasation
- Allowance of Valproic Acid patent in Europe covering Avugane<sup>™</sup> for acne
- Allowance of Valproic Acid patent in Europe covering Savicol<sup>™</sup> for colon polyps



<u>Q1:</u>

- In March, TopoTarget announced that a new international ICD-9-CM diagnosis code had been established. The diagnosis code will facilitate coding of the disease and, by extension, the process of obtaining reimbursement for Savene<sup>®</sup>/Totect<sup>®</sup> therapy
- European Oncology Nursing Society (EONS) recommended Savene<sup>®</sup>/Totect<sup>®</sup> for the treatment of anthracycline extravasation in their guidelines
- APO010 patent allowed in the US

# Highlights for the period after 30 June 2008

- FDA acceptance of results for phase IV post marketing study for Totect<sup>®</sup>
- Assignment of Clinical Trials Agreement (CTA) from CuraGen to TopoTarget for belinostat approved by the NCI

# Expected key milestones for the remainder of 2008

### Belinostat milestones:

- Belinostat partnership agreement to be concluded in 2008
- Completion of SPA (Special Clinical Protocol Assessment) filing process with the FDA and initiation of Phase III registration trial for belinostat in PTCL
- Results presented at EORTC (European Organisation for Research and Treatment of Cancer) 21-24 October in Geneva, Switzerland
  - Phase II data from BelCaP i.v. (intra veneous) in bladder cancer
  - Phase Ib data from BelDox (belinostat + doxorubicin) i.v. in solid tumours
  - Phase I data from oral belinostat in solid tumours
  - Phase I data from trial with belinostat as 3 and 6-hour continuous infusion for the treatment of solid tumours
- Results presented at ASH (American Society of Hematology) 6-9 December in San Francisco, USA
  - Phase Ib data from BelIda (belinostat + idarubicin) i.v. in AML (Acute Myeloid Leukaemia)
- Results presented at ESMO (European Society for Medical Oncology) 12-16 September in Stockholm, Sweden
  - Final data from Phase I BelCaP i.v. study in solid tumours and final results with the combination in ovarian cancer.

TopoTarget expects to initiate a randomised Phase II study of BelCaP in Cancer of Unknown Primary, CUP, around the turn of the year.

In addition, the NCI is expected to initiate the following studies:

- Phase II in incremental dose belinostat for the treatment of patients with inoperable hepatocellular carcinoma (liver cancer)
- Randomised Phase II part with belinostat + 5-AZC in patients suffering from AML and MDS (Myeloid Dysplastic Syndrome).



#### Additional milestones:

- Final data for APO866 for the treatment of melanoma, chronic lymphocytic leukaemia and update on the study in cutaneous T-cell lymphoma (CTCL)
- APO010 update and approval of study extension for additional dose escalation
- Siramesine preclinical data to decide whether we can proceed with our investigation of the agent as an anti-cancer therapeutic for human use
- Potential partnership agreement for Avugane<sup>M</sup> and Baceca<sup>®</sup>.

Furthermore, TopoTarget expects to double its Savene $^{(R)}$ /Totect $^{(R)}$  sales for the full year 2008 vs. full year 2007.

# Strategy revised and organisation adjusted

In the first half of 2008, TopoTarget revised its strategy and adjusted its organisation to a more dedicated focus on belinostat. The adjustments were made on the back of very promising data from a broad range of studies with belinostat and a unique opportunity to buy the global rights to the compound.

TopoTarget now pursues two primary goals with belinostat;

- Bringing belinostat to market as quickly as possible
- Forming a partnership with a global pharmaceutical company with sufficient development and commercialisation resources to fully capitalise on belinostat's blockbuster potential

In terms of organisation, TopoTarget has strengthened its medical department, and restructured and consolidated its business development.

Selecting from a number of good opportunities to bring belinostat quickly to market, TopoTarget has given top priority to the haematological malignancy peripheral T-cell lymphoma (PTCL). PTCL is an attractive target in terms of strategy and business potential as it, among other things, is a cancer for which no standard therapy has yet been approved due to weak treatment results. TopoTarget has been granted a Fast Track designation for belinostat in this indication and is working closely with the authorities and investigators. The registration study in PTCL is expected to be initiated during H2 2008 for a potential market approval by 2010.

We believe that belinostat is a best-in-class product. Discussions with several prospective partners have confirmed that belinostat is considered a highly promising pharmaceutical candidate in tomorrow's cancer therapy.

After TopoTarget's acquisition of the global rights to belinostat, the company has streamlined its business procedures and projects, reducing the number of employees outside the medical department and capitalised on the synergies by centralising the organisation at the Copenhagen headquarters. Reductions in technical and administrative personnel has also been carried out after the end of the reporting period at headquarters while still ensuring that key functions remain intact.

TopoTarget is in the process of identifying partners to develop and finance trials with other drug candidates in its clinical and preclinical pipeline.

## Belinostat status

Belinostat is an intravenous and oral class I and II HDAC inhibitor for the treatment of solid tumours and haematological malignancies. Belinostat is



TopoTarget's lead clinical drug candidate, for which it has the global rights, and the company focuses its resources on developing it to exploit the product's potential. Intravenous and orally administered belinostat is currently evaluated in 18 clinical studies run by TopoTarget and the NCI.

More than 500 patients have been treated with belinostat which has showed effect in several cancer indications as well as a positive toxicity profile.

#### NCI agrees to CTA assignment

The Clinical Trials Agreement (CTA) for belinostat with the NCI (National Cancer Institute) has been assigned from CuraGen to TopoTarget. Since 2004 nine clinical trials in different indications and drug combinations have been carried out under the CTA. Under the agreement the Division of Cancer Treatment and Diagnosis at the NCI will continue to sponsor and run clinical trials to evaluate the activity of belinostat alone or in combination with other cancer therapies for the treatment of solid and haematological cancers. TopoTarget also has a CRADA (Cooperative Research and Development Agreement) for belinostat with the NCI.

#### **T-cell lymphoma: PTCL and CTCL**

The FDA has granted Fast Track designation for the development programme for belinostat for i.v. treatment of recurrent or refractory PTCL. TopoTarget expects to receive a positive response in connection with the SPA (Special Protocol Assessment) process, allowing for initiation of a final registration trial (Phase III study designed with a view to obtaining regulatory approval) in about 100 patients in 2008.

At the "10<sup>th</sup> International Conference on Malignant Lymphoma" in Lugano, Switzerland, in June 2008, TopoTarget presented positive belinostat data from a Phase II study in patients with recurrent or refractory peripheral or cutaneous T-cell lymphoma (PTCL and CTCL). Two durable and still ongoing complete responses (CR) after belinostat monotherapy were demonstrated in 11 evaluable patients with PTCL. Furthermore, 4 objective responses, 1 CR and 3 PR (Partial Response) in 20 heavily pre-treated evaluable CTCL patients were evident. The time to response in CTCL was quick, a median of 15.5 days, which is a promising finding. In addition, a substantial number of patients with stable disease were observed in both diseases. Intravenous belinostat was shown to be safe and well tolerated. The objective response rate in both arms has met the pre-defined criteria for advancement to the second stage of the Simon twostage design. Enrolment is ongoing in the CTCL and PTCL arms of the study to a total of 34 patients per arm.

#### **Ovarian cancer**

At ASCO 2008, TopoTarget announced positive data from the company's BelCaP programme (full-dose belinostat in combination with full-dose carboplatin and paclitaxel) in patients with relapsed epithelial ovarian cancer. Substantial antitumour activity with BelCaP was evident, with efficacy in 15 out of 16 patients and an overall response rate of 43%. Responses were evident in patients with platinum-sensitive and platinum-resistant tumours, including patients with a platinum-free interval of less than 3 months. BelCaP is well-tolerated presenting a safety profile consistent with that observed with chemotherapy alone.



#### **NCI studies**

NCI presented positive data at the 2008 ASCO conference on belinostat from two clinical trials:

# Belinostat and azacitidine (AZC) in patients with advanced myeloid neoplasms

The combination of belinostat (escalating doses) and azacitidine (a well known compound for the treatment of myeloid dysplastic syndrome) was investigated in 21 patients with AML or myeloid dysplastic syndrome. The combination was well tolerated in full doses of both drugs. The results were positive with 2 complete responses (CR), 1 partial response (PR) and haematological improvement (including improved platelet counts) in 4 patients. The intention is now to continue the study as a randomised study to further assess the effect of the combination.

# Belinostat in patients with platinum-resistant epithelial ovarian tumours and micropapillary/borderline (LMP) ovarian tumours

18 patients with epithelial ovarian cancer (EOC) and 12 patients with borderline ovarian tumours (LMP) were treated with belinostat monotherapy. Efficacy in the form of stable disease (SD) was evident in 9 EOC patients and 9 LMP patients, and 1 LMP patient had a partial response (PR) and further patient had a CA125 response (disease marker in the blood). Patient recruitment is ongoing.

# Savene<sup>®</sup>/Totect<sup>®</sup>

TopoTarget's first marketed product Savene<sup>®</sup>/Totect<sup>®</sup> is used for the prevention of serious tissue damage caused by anthracycline extravasation. Savene<sup>®</sup> was launched in October 2006 in selected European countries and Totect<sup>®</sup> was launched on the US market in October 2007.

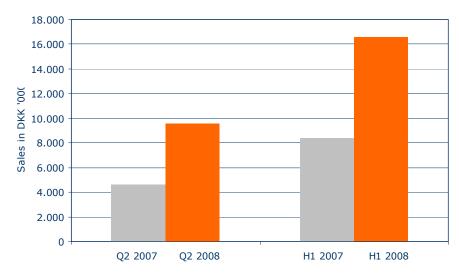
There has been a solid sales increase for Savene<sup>®</sup>/Totect<sup>®</sup>, with total sales of 245 kits, including 143 in Q2. Second-quarter sales climbed to DKK 9.6 million from DKK 4.6 million in Q2 2007, representing an increase and in line with earlier communicated expectations of 108% on Q2 2007. Total sales in the first six months of 2008 were DKK 16.6 million, compared with DKK 8.3 million in H1 2007. This is an improvement of 99% on 2007.

TopoTarget expects to be able to double its sales of Savene<sup>®</sup>/Totect<sup>®</sup> in 2008. 2007 sales amounted to DKK 21.6 million.

The figure below illustrates sales in Q2 and H1 2007 and Q2 and H1 2008 for Savene^{ $\!^{(\!R)}}$  and Totect  $^{(\!R)}$  , measured in TDKK.



Savene® & Totect® sales 2007 vs 2008



Savene<sup>®</sup> has been recommended as the standard treatment of anthracycline extravasation in the new guidelines from the European Oncology Nursing Society (EONS) and later by the United Kingdom Oncology Nursing Society, UKONS.

In March, TopoTarget announced that a new international ICD-9-CM diagnosis code had been established. The diagnosis code will facilitate coding of the disease and, by extension, the process of obtaining reimbursement for Savene<sup>®</sup>/Totect<sup>®</sup> therapy.

## **TopoTarget has besides belinostat four very promising drug candidates with Novel Targets**

A partnership agreement for belinostat in 2008 would allow us to dedicate our efforts to developing the promising anti-cancer drug candidates in our pipeline. The completion of the new and improved production of Zemab will allow us to initiate studies to follow up on the data in the pilot study. Zemab demonstrated an effect, when injected directly into the tumour, in 6 out of 10 cancer patients. 4 out of these 6 tumours totally disappeared.

Zemab is a protein product targeting ErB2/HER2, an antigen on the surface of the cancer cell. This antigen is the target of the drug Herceptin<sup>®</sup> (trastuzumab), which is very successful in the treatment of breast cancer. Herceptin<sup>®</sup> is developed by the American biotech company Genentech and sold for 4.6 billions USD in 2007. Unlike Herceptin<sup>®</sup>, Zemab has a toxin that binds to the protein. When Zemab binds to this antigen, the toxin bound to the protein is allowed to enter the cancer cell where it causes the death of that cell. In its pipeline, Genentech has a similar compound named Trastuzumab-DM1 in Phase II for the treatment of HER2-positive breast cancer patients with metastases. TopoTarget intends to develop Zemab for the treatment of breast cancer and head-and-neck cancer patients. New production of Zemab is ongoing and expected to be finalised in the second half of 2008.

As it is the case with Zemab, Genentech also has a programme similar to TopoTarget's <u>APO010</u>, referred to as Apo2L/TRAIL, which is in Phase II in Non-Hodgkin's Lymphoma and in non-small cell lung cancer (NSCLC) and in Phase I for the treatment of colon cancer. TopoTarget is conducting a Phase I dose-escalating study, in which we have reached the level of treatment where we



expect to see anti-tumour activity. Final results are expected to be available around the turn of the year. It is likely that we can reach even higher doses, and we are currently awaiting approval from the Swiss health authorities for further dose escalation. TopoTarget intends to develop APO010 for the treatment of multiple myeloma and ovarian cancer.

<u>APO866</u> is a specific inhibitor of a key enzyme involved in the synthesis of NAD+ and is being developed in three Phase II clinical trials: advanced melanoma, cutaneous T-cell lymphoma (CTCL), and in a phase I/II clinical trial in B-cell chronic lymphocytic leukaemia (B-CLL).

In October 2007, APO866 was selected as was belinostat by Windhover Information as one of the 10 most interesting oncology products globally that is available for partnering.

Patient recruitment is completed for the CLL and melanoma studies, while recruitment is ongoing in the CTCL study. Analysis of the two first-mentioned studies is expected to be finalised in 2008.

<u>TOP216</u>, which we acquired from BioImage in December 2005, has demonstrated highly promising preclinical effect in the treatment of cancer in our predictive cancer model technology. TopoTarget intends to develop a TOP216 analogue to move into the clinic.

# **Other clinical activities**

In addition to belinostat and Savene<sup>®</sup>/Totect<sup>®</sup> described above, TopoTarget's clinical pipeline consists of seven product candidates, covering a broad range of cancer and other indications. Having consolidated the belinostat rights, TopoTarget is now seeking partnerships for several of the following development programmes.

# $\mbox{Baceca}^{\mbox{$^{\otimes}$}}$ - an HDAC inhibitor for the treatment of basal cell carcinoma (BCC)

TopoTarget has completed two randomised and blinded Phase II proof-ofconcept trials to investigate Baceca<sup>®</sup> monotherapy and in combination with two different vitamin A like compounds for the treatment of basal cell carcinoma (BCC). The results of a Danish, double-blind, randomised and placebo-controlled study to evaluate the efficacy and tolerability of Baceca<sup>®</sup> in combination with the retinoid tazarotene showed a 69% clinical and pathological complete remission obtained at three months after the end of the 16 weeks treatment period with the combination treatment. This response rate confirmed the positive results of an earlier Italian pilot study. In a second Phase II trial performed in Russia using an eight week treatment course with Baceca<sup>®</sup> in combination with another retinoid (Isotrex<sup>®</sup>), Baceca<sup>®</sup> showed clear anti-cancer efficacy.

# Savicol<sup>™</sup> – an HDAC inhibitor for the treatment of familial adenomatous polyposis (FAP)

TopoTarget is continuing its Phase II trial, evaluating the effect of Savicol<sup>™</sup> in the treatment of FAP. The development process has been delayed due to slower-than-expected patient recruitment. This randomised, placebo-controlled Phase II study takes place in a number of countries across Europe. An evaluation of the final treatment results is expected in the first half of 2009.



# Topotect – a Topoisomerase II inhibitor – a protectant to enable chemotherapy treatment of brain metastasis

An ongoing Phase I-II trial is seeking to identify the potential of combining Topotect and etoposide. Recruitment of patients has been slow in this rare subset of metastasis patients. Final results are expected in 2009.

#### Avugane<sup>™</sup> – an HDAC inhibitor for the treatment of acne vulgaris

Based on Phase II proof-of-concept results showing comparable efficacy and advantageous tolerability compared with a standard, marketed retinoid therapy, TopoTarget is now running a double-blind, randomised, placebo-controlled Phase II clinical trial in mild to moderate acne vulgaris. Data is expected from this trial in 2008.

**TopoTarget A/S** 



# Highlights and key figures

Consolidated income statements	H1, 2008	H1, 2007	2007
	DKK ' 000	DKK ' 000	DKK ' 000
Revenues	19,914	25,796	44,890
Production costs	(6,267)	(13,711)	(25,838)
Research and development costs	(70,381)	(46,086)	(129,111)
Sales and distribution costs	(25,370)	(26,270)	(57,722)
Administrative expenses	(25,180)	(24,875)	(52,020)
Financial income and expenses	(6,396)	2,493	5,754
Loss before tax	(113,680)	(82,653)	(214,047)
Basic and diluted EPS (DKK)	(1.79)	(1.78)	(3.92)
Consolidated balance sheets	30 June	30 June	31 December
	2008	2007	2007
	DKK ' 000	DKK ' 000	DKK ' 000
Cash and cash equivalents and marketable securities	173,611	519,884	403,617
Assets	797,987	949,619	834,175
Equity	613,934	791,340	665,068
Consolidated cash flow statements	H1, 2008	H1, 2007	2007
	DKK ' 000	DKK ' 000	DKK ' 000
Cash flows from operating activities	(104,816)	(97,294)	(208,933)
Cash flows from investing activities	(43,734)	30,699	25,666
Cash flows from financing activities	(246)	332,266	332,026
Consolidated key figures	30 June	30 June	31 December
	2008	2007	2007
	DKK ' 000	DKK ' 000	DKK ' 000
Number of fully paid shares in issue as at period end	66,304,510	61,304,510	61,304,510
Weighted average number of shares in issue for the period	62,320,994	46,442,543	53,955,186
Assets/equity	1.30	1.20	1.25
Share price, closing (DKK)	11.20	30.00	16.76
Share price, book value (DKK)	9.26	12.91	10.85
Average number of employees	124	112	141



# Comments on the interim financial statements for the six months ended 30 June 2008

Sales of Savene<sup>®</sup> in Europe and Totect<sup>®</sup> in the US were higher in Q1 and Q2 2008 compared to Q1 and Q2 2007, rising to DKK 16.6 million in H1 2008 from DKK 8.3 million in H1 2007.

The company generated total revenue of DKK 19.9 million during the period 1 January to 30 June 2008 compared with DKK 25.8 million in the same period of last year. Included in revenues are invoicing to CuraGen and the Savene<sup>®</sup> sales in Europe and Totect<sup>®</sup> sales in the US referred to above. The lower total revenue in H1 2008 is primarily due to lower re-invoicing of research and development costs to CuraGen, which amounted to DKK 2.6 million in H1 2008 against DKK 13.2 million in H1 2007.

In the first six months of 2008, production costs amounted to DKK 6.3 million as compared with DKK 13.7 million in the same period of 2007. The lower costs relative to revenue were mainly due to the fact that research and development costs are no longer re-invoiced to CuraGen after TopoTarget bought back the rights to belinostat on 21 April 2008.

In the period 1 January to 30 June 2008, research and development costs amounted to DKK 70.4 million as compared with DKK 46.1 million in the yearearlier period. The company recorded higher research and development costs primarily because TopoTarget is conducting clinical studies of belinostat and because TopoTarget Switzerland S.A., which was acquired in June 2007, is included in full in H1 2008.

Sales and distribution costs amounted to DKK 25.4 million in the first half-year 2008, down from DKK 26.3 million in the same period of 2007. TopoTarget has retained its focus on allocating sales and distribution costs to the most profitable markets and has made cost adjustments, which started to materialise in Q2 2008.

In the period 1 January to 30 June 2008, administrative expenses amounted to DKK 25.2 million as compared with DKK 24.9 million in the year-earlier period. TopoTarget Switzerland S.A., which was acquired in June 2007, is included in full in H1 2008.

Net financial expenses amounted to DKK 6.4 million in the first six months, as compared with net financial income of DKK 2.5 million in the year-earlier period. The difference was primarily due to interest expenses on the loan provision for payment of the expected milestone to the former owners of TopoTarget Switzerland S.A. concerning APO866 and large currency translation differences on consolidation of group enterprises.

In the first six months of 2008, tax amounted to an income of DKK 2.3 million as compared with DKK 0.0 million in the same period of 2007. The tax income was due to a reduction in the deferred tax liability concerning TopoTarget Switzerland S.A.

In the period 1 January to 30 June 2008, the company recorded a loss after tax of DKK 111.4 million as compared with a loss after tax of DKK 82.7 million in the same period of 2007.

On 21 April 2008, TopoTarget bought back all rights to belinostat from CuraGen, our former business partner. The consideration was agreed to comprise a cash payment of USD 26 million (approximately DKK 122.8 million), 5 million new TopoTarget shares issued in a private placement and a commercial milestone payment totalling USD 6 million (approximately DKK 28.3 million), which is defined as 10% of the first USD 60 million of belinostat sales or partnership



revenues. The milestone payment is recognised as current liability in the balance sheet at the fair value at the contract date.

At 30 June 2008, total assets amounted to DKK 798.0 million. Of this amount, cash bank deposits and short-term securities amounted to DKK 173.6 million.

At 30 June 2008, equity amounted to DKK 613.9 million compared with DKK 791.3 million at the same time in 2007. The change consists of a loss of DKK 240.4 million during the period from 1 July 2007 to 30 June 2008, the capital increase in May 2008 totalling DKK 55.5 million, additions during the period of share-based payment totalling DKK 8.8 million and fair value adjustment of the bond portfolio totalling minus DKK 1.3 million.

#### **Outlook and other forward-looking statements**

Following the acquisition of the global rights to belinostat, TopoTarget has been able to revise its strategy. Increased focus on belinostat and reduced costs for other projects etc. lead to a cost reduction of DKK 35-40 million in the previously expected pre-tax loss for 2008 with the forecast loss now being in the range of DKK 195-220 million. These numbers do not include future licensing revenues.



#### Statement by the Board of Directors and Senior Management

The Board of Directors and the Senior Management today discussed and adopted the interim report for the six months ended 30 June 2008.

The interim report is presented in accordance with IAS 34 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 30 June 2008 and of the results of the Group's operations and cash flows for the six months ended 30 June 2008.

In our opinion, the management's report gives a true and fair view of developments in the activities and financial position of the Group, the results for the period and of the Group's financial position in general and gives a fair description of significant risk and uncertainty factors that may affect the Group.

#### Copenhagen, 19 August 2008

#### Senior Management

Peter Buhl Jensen CEO

#### **Board of Directors**

Håkan Åström Chairman	Jesper Zeuthen	Jeffrey Buchalter
Anders Gersel Pedersen	Ingelise Saunders	Torbjørn Bjerke
Potor Ruhl Joncon		

Peter Buhl Jensen



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#### **Background information**

#### About TopoTarget

TopoTarget (OMX: TOPO) is an international biotech company headquartered in Denmark, dedicated to finding "Answers for Cancer" and developing improved cancer therapies. The company is founded and run by clinical cancer specialists and combines years of hands-on clinical experience with in-depth understanding of the molecular mechanisms of cancer. Focus lies on highly predictive cancer models and key cancer targets (including HDACi, NAD+, mTOR, FasLigand and topoisomerase II inhibitors). TopoTarget has a broad cllinical pipeline with 9 products in development, including belinostat which has shown proof of concept as monotherapy in treating haematological malignancies and positive results in solid tumours where it can be used in combination with full doses of chemotherapy. The company's first marketed product Savene®/Totect® was approved by EMEA in 2006 and the FDA in 2007 and is marketed by TopoTarget's own sales force in Europe and the US. For more information, please refer to www.topotarget.com.

#### TopoTarget Safe Harbour Statement

This announcement may contain forward-looking statements, including statements about our expectations of the progression of our preclinical and clinical pipeline including the timing for commencement and completion of clinical trials and with respect to cash burn guidance. Such statements are based on management's current expectations and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. TopoTarget cautions investors that there can be no assurance that actual results or business conditions will not differ materially from those projected or suggested in such forward-looking statements as a result of various factors, including, but not limited to, the following: The risk that any one or more of the drug development programs of TopoTarget will not proceed as planned for technical, scientific or commercial reasons or due to patient enrolment issues or based on new information from non-clinical or clinical studies or from other sources; the success of competing products and technologies; technological uncertainty and product development risks; uncertainty of additional funding; TopoTarget's history of incurring losses and the uncertainty of achieving profitability; TopoTarget's stage of development as a biopharmaceutical company; government regulation; patent infringement claims against TopoTarget's products, processes and technologies; the ability to protect TopoTarget's patents and proprietary rights; uncertainties relating to commercialization rights; and product liability expo-sure; We disclaim any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, unless required by law.



#### **Condensed income statements**

	Note	Q2, 2008 DKK ' 000	Q2, 2007 DKK ' 000	H1, 2008 DKK ' 000	H1, 2007 DKK ' 000	2007 DKK ' 000
Revenue	2,3	9,997	15,378	19,914	25,796	44,890
Production costs	4	(1,935)	(9,297)	(6,267)	(13,711)	(25,838)
Research and development costs	4,5	(40,835)	(22,571)	(70,381)	(46,086)	(129,111)
Sales and distribution costs	4	(12,285)	(14,868)	(25,370)	(26,270)	(57,722)
Administrative expenses	4	(11,847)	(13,233)	(25,180)	(24,875)	(52,020)
Operating loss		(56,905)	(44,591)	(107,284)	(85,146)	(219,801)
Financial income and expenses	-	(99)	553	(6,396)	2,493	5,754
Loss before taxes		(57,004)	(44,038)	(113,680)	(82,653)	(214,047)
Tax on profit/(loss) for the period	_	426	0	2,275	0	2,447
Net loss for the period	=	(56,578)	(44,038)	(111,405)	(82,653)	(211,600)
Basic and diluted EPS (DKK)		(0.89)	(0.93)	(1.79)	(1.78)	(3.92)



#### **Condensed balance sheets - assets**

	Note			
		30 June 2008 DKK ' 000	30 June 2007 DKK ' 000	2007 DKK ' 000
Intangible assets	5	568,202	371,389	370,639
Property, plant and equipment		16,153	19,726	18,415
Non-current investments	-	1,938	1,527	1,657
Non-current assets	-	586,294	392,642	390,711
Inventories		6,467	2,032	3,310
Receivables		31,615	35,061	36,537
Securities	6	35,295	115,860	116,505
Cash and cash equivalents	-	138,316	404,024	287,112
Current assets	-	211,693	556,977	443,464
Assets	=	797,987	949,619	834,175



### Condensed balance sheets - equity and liabilities

Note

		30 June 2008 DKK ' 000	30 June 2007 DKK ' 000	2007 DKK ' 000
Equity		613,934	791,340	665,068
Non-current liabilities	7	110,630	110,609	48,655
Current liabilities		73,423	47,670	120,452
Liabilities		184,053	158,279	169,107
Equity and liabilities		797,987	949,619	834,175
Accounting policies	1			



#### **Condensed cash flow statements**

	H1, 2008 DKK ' 000	H1, 2007 DKK ' 000	H1, 2007 DKK ' 000
Operating loss	(107,284)	(85,146)	(219,801)
Reversal of share-based payments	4,771	2,891	6,862
Depreciation, amortisation and impairment losses	3,305	2,307	7,331
Working capital changes	(6,211)	(19,839)	(12,799)
Cash flows from operating activities before interest	(105,419)	(99,787)	(218,407)
Received and paid interest etc.	603	2,493	9,474
Cash flows from operating activities	(104,816)	(97,294)	(208,933)
Purchase of intangible assets	(123,624)	(4,469)	(4,451)
Purchase of property, plant and equipment	(1,045)	(5,060)	(8,577)
Sale of property, plant and equipment	2	76	612
Acquisition of subsidiary net of cash	0	23,127	23,127
Purchase of investments	(281)	(381)	(510)
Purchase of securities	(84,419)	(21,177)	(44,051)
Sale of securities	165,634	38,583	59,516
Cash flows from investing activities	(43,734)	30,699	25,666
Instalment on loans	(246)	(236)	(476)
Proceeds from the issuance of shares	0	332,502	332,502
Cash flows from financing activities	(246)	332,266	332,026
Increase/decrease in cash and cash equivalents	(148,796)	265,671	148,759
Cash and cash equivalents at 1 January	287,112	138,353	138,353
Cash and cash equivalents at 30 June	138,316	404,024	287,112
Cash and cash equivalents comprise:			
Deposit on demand and cash	38,271	63,979	287,067
Special-term deposits	100,045	340,045	45
Total	138,316	404,024	287,112



#### Statement of equity for the period 1 January to 30 June 2008

	Share-						
	Number of shares	Share- capital DKK ' 000	based payments DKK ' 000	Retained earnings DKK ' 000	Total DKK ' 000		
Equity at 1 January 2008	61,304,510	61,304	17,332	586,432	665,068		
Fair value adjustment of available-for-sale financial assets	0	0	0	227	227		
Transferred to the income statement concerning							
value adjustment of available-for-sale financial assets	0	0	0	(227)	(227)		
Recognised directly in equity	0	0	0	<u> </u>	<u> </u>		
Net loss for the period	0	0	0	(111,405)	(111,405)		
Total net income	0	0	0	(111,405)	(111,405)		
Recognition of share-based payment	0	0	4,771	0	4,771		
Share capital increase through non-cash payment	5,000,000	5,000	0	50,500	55,500		
Other transactions total	5,000,000	5,000	4,771	50,500	60,271		
Equity 30 June 2008	66,304,510	66,304	22,103	525,527	613,934		

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.

#### Statement of equity for the period 1 January to 30 June 2007

	Number of shares	Share- capital DKK ' 000	Share- based payments DKK ' 000	Retained earnings DKK ' 000	Total DKK ' 000
Equity 1 January 2007	45,684,880	45,685	10,668	374,297	430,650
Fair value adjustment of available-for-sale financial assets	0	. 0	. 0	. 9	. 9
Recognition of share-based payment	0	0	2,891	0	2,891
Exercise of share-based payment	0	0	(198)	198	0
Recognised directly in equity	0	0	2,693	207	2,900
Net loss for the period	0	0	0	(82,653)	(82,653)
Total net income	0	0	2,693	(82,446)	(79,753)
Share capital increase through exercise of warrants	21,600	21	0	500	521
Share capital increase through cash payment	12,000,000	12,000	0	319,981	331,981
Share capital increase through non-cash payment	3,598,030	3,598	0	104,343	107,941
Other transactions	15,619,630	15,619	0	424,824	440,443
Equity 30 June 2007	61,304,510	61,304	13,361	716,675	791,340

Expenses relating to the cash capital increase have been deducted in "retained earnings" in the amount of TDKK 28,019.

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.

#### NOTER

#### 1. REGNSKABSPRAKSIS



#### Notes to the consolidated interim financial statements

#### **1. 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 the company's annual report for 2007, 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 annual report for 2007 contains a more detailed description of the company's accounting policies, including a definition of the ratios used, which are calculated in accordance with the definitions in "Recommendations & Financial Ratios 2005" issued by the Danish Society of Financial Analysts.

Due to reorganisation in Germany and Switzerland the allocation of costs have been changed. Some of the costs, in previous years classified as administration costs, is from 1 January 2008 recognised as research and development costs.

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

The following new and revised standards and interpretations are effective from the financial year 2008:

- IFRIC 11, IFRS 2 Group and treasury share transactions.
- IFRIC 12, Service concession arrangements
- IFRIC 14, IAS 19 The limit on a defined benefit asset, minimum funding requirements and their interaction.

The application of these new and revised standards and interpretations has not resulted in changes in the accounting policies with respect to recognition and measurement.

### 2. REVENUE

	Q2, 2008 DKK ´000	Q2, 2007 DKK ´000	H1, 2008 DKK ´000	H1, 2007 DKK ´000	2007 DKK ´000
Sales of goods	9,631	4,621	16,637	8,348	21,613
Sales of services Milestone payments	366 0	9,061 1,696	3,277 0	13,207 4,241	18,404 4,873
	<u> </u>				· · · · · ·
Total	9,997	15,378	19,914	25,796	44,890



### **3. SEGMENT INFORMATION**

#### **Primary segments**

The Group's activities are exclusively in the business segment "Pharmaceuticals for treatment within the cancer area"

### Secondary segments

The Group's revenue is divided into the following secondary geographical segments:

	Revenue						
	Q2, 2008 DKK ´000	Q2, 2007 DKK ´000	H1, 2008 DKK ´000	H1, 2007 DKK ´000	2007 DKK ´000		
Denmark	292	145	510	502	966		
Europe USA	6,100 3,749	4,487 10,746	10,587 8,961	7,857 17,437	18,782 25,142		
Total	10,141	15,378	20,058	25,796	44,890		

The Groups assets and additions to licences and rights plus other fixtures and fittings, tools and equipment are divided into the following secondary geografical segments:

	Assets			Additions to aquired research & development projects plus other fixtures and fittings, tools and equipment			
	30 June 2008 DKK ´000	30 June 2007 DKK ´000	2007 DKK ´000	H1, 2008 DKK ´000	H1, 2007 DKK ´000	2007 DKK ´000	
Denmark Europe USA	421,548 369,293 7,145	574,049 373,783 1,468	441,913 381,358 10,904	208,237 88 301	4,769 206,346 413	7,151 210,699 426	
Total	797,987	949,300	834,175	208,626	211,528	218,276	



# 4. STAFF COSTS

	Q2, 2008 DKK ' 000	Q2, 2007 DKK ' 000	H1, 2008 DKK ' 000	H1, 2007 DKK ' 000	2007 DKK ' 000
Allocated by function:					
Production costs Research and development costs Sales and distribution costs Administrative expenses	328 15,752 6,532 6,441	167 12,133 4,400 7,705	654 29,783 11,964 13,982	1,585 21,422 7,421 14,956	4,172 51,022 18,478 31,746
Total	29,053	24,405	56,383	45,384	105,418
Hereof share-based payments	2,382	1,453	4,771	2,891	6,862
Average number of employees			124	112	141



## **5. INTANGIBLE ASSETS**

	30 June 2008 DKK ' 000	30 June 2007 DKK ' 000	2007 DKK ' 000
Acquired research- and development projects still in progress			
Cost at 1 January Adjustment of acquisition value, c.f. note 7 Addition by acquisiton of subsidiary Additions Disposals	357,438 (9,262) 0 207,575 0	153,172 0 199,815 4,592 -141	153,172 0 199,815 4,592 (141)
Cost at 30 June	555,751	357,438	357,438
Carrying amount at 30 June	555,751	357,438	357,438
Acquired research- and development projects - available for use			
Cost at 1 January	15,076	15,076	15,076
Cost at 30 June	15,076	15,076	15,076
Amortisation at 1 January Amortisation	(1,875) (750)	(375) (750)	(375) (1,500)
Amortisation at 30 June	(2,625)	(1,125)	(1,875)
Carrying amount at 30 June	12,451	13,951	13,201
The weighted average residual term of acquired research and development projects - available for use is approximately (number of years)	8.25	9.25	8.75
Total acquired research and development projects	568,202	371,389	370,639
Amortisation and impairment by function:			
	H1, 2008 DKK ' 000	H1, 2007 DKK ' 000	2007 DKK ' 000
Production costs	750	750	<u> </u>

#### **6. SECURITIES**

Securities comprise:

		30 June 2008 DKK ' 000	30 June 2007 DKK ' 000	2007 DKK ' 000
Callable loans	DKK	35,295	51,526	70,135
Non callable loans	DKK	0	64,334	46,370
Total	_	35,295	115,860	116,505
Securities expire:				
Up to 1 year		35,295	23,942	13,493
One to five years		0	993	15,919
More than five years	_	0	90,925	87,093
Total	_	35,295	115,860	116,505

All bonds are mortgage or government bonds with low risk and a fixed nominal interest of 4% p.a. (2007: 2-10 % p.a.).

## **7. LONG TERM COMMITMENTS**

	30 June 2008 DKK ' 000	30 June 2007 DKK ' 000	2007 DKK ' 000
Deferred tax	45,007	45,793	45,741
Leasing commitments	314	477	315
Pension commitments	2,685	2,599	2,599
Other debt	62,624	61,740	0
Total	110,630	110,609	48,655

Pension commitments are related to the employees of TopoTarget Switzerland SA. Other debt is debt in relation to the APO866-milestone.



In June 2007 TopoTarget acquired the development project APO866 together with the acquisition of Apoxis S.A. The purchase price included a conditional payment (APO866 milestone) payable when certain clinical endpoints were met. At acquisition the discounted value of the APO866 milestone was included in the calculation of the purchase price. The assumption for the calculation is now changed compared to initial recognition, leading to a reduction of the liability end June 2008 amounting to DKK 9,2 million and a similar adjustment in acquired research and development projects in progress c.f. note 5. As at 31.12.2007 the APO866 milestone was included in current liabilities.

