

## Interim report for the period 1 January to 30 September 2008

### Highlights and key ratios from Q3 2008:

- TopoTarget has streamlined its organisation with a view to reducing its burn rate, and has sufficient financial resources, to take it into 2010. This does not include future licensing revenues
- Sales increase for Savene<sup>®</sup>/Totect<sup>®</sup>, with total sales of 388 kits, including 143 in Q3, which is an increase of 104% on Q3 2007. Third-quarter sales climbed to DKK 8.4 million from DKK 4.6 million in Q3 2007, representing an increase of 84% on Q3 2007. Total sales for Q1-Q3 2008 were DKK 25.0 million, compared with DKK 12.9 million in Q1-Q3 2007, representing a 94% increase and in line with TopoTarget's expectations. 2007 sales amounted to DKK 21.6 million
- Positive Special Protocol Assessment (SPA) response from the FDA concerning TopoTarget's pivotal trial with belinostat for the treatment of Pheripheral T-Cell Lymphoma (PTCL)
- Additional positive clinical results in belinostat monotherapy and in combination with chemotherapy in cutaneous lymphomas and ovarian cancer
- NCI (US) approves the transfer of its Clinical Trials Agreement (CTA) from CuraGen to TopoTarget for belinostat
- As previously announced, TopoTarget has initiated a process in order to form a partnership for belinostat with a pharmaceutical company with sufficient development and commercialisation resources to fully capitalise on belinostat's substantial commercial potential. TopoTarget maintains a positive dialogue with a number of interested potential partners, which include global as well as strong regional companies dedicated to cancer therapeutics. The Company remains confident of achieving a belinostat licensing deal, however recent turbulence in financial markets has increased the uncertainty of achieving it in 2008. As a consequence TopoTarget has undertaken a restructuring and refocusing of its resources to ensure that the next key steps in belinostat's development will be supported financially, providing the company with a stronger negotiation position
- As a result of the focus on belinostat TopoTarget will seek to out-license a number of projects in its pipeline or to postpone development of such projects. This leads to a reduction in expenditure. The cost savings will have a limited effect on financial performance in 2008 and will materialise in the forecasts for 2009 and 2010. The forecast for 2008 is unchanged in the range of DKK 195-220 mio. These numbers do not include future licensing revenues. The cost reductions are intended to ensure the highest possible added value by directing TopoTarget's resources towards the achievement of two important belinostat milestones: approval of belinostat for the treatment of PTCL in the US and obtaining randomised Phase II proof of belinostat's efficacy in the so-called BelCaP combination in patients with solid tumours
- In undertaking the restructuring the Company has ensured that the key competencies necessary for achieving its goals have been retained. The number of employees has been reduced to 58 of which 18 are in the sales organisation. In connection with the restructuring of the Company it has been agreed that CFO Leif Hamø will retire from the company as at 31 December 2008 and Tim Corcoran, Executive Vice President Corporate Affairs, will take over the position as from today
- Third-quarter loss before tax of DKK 160,3 million, as compared to a loss of DKK 139,6 million in the same period of 2007.

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After the end of the reporting period, at the AACR/NCI/EORTC conference from 21-24 October in Geneva, Switzerland, TopoTarget reported new Phase I and II results for belinostat monotherapy and as combination therapy for relapsed bladder cancer after platinum chemotherapy (BelCaP) and soft tissue sarcoma (BelDox) respectively. The BelDox study suggests that a full dose of doxorubicin can be administered with a full dose of belinostat. We have shown that BelCaP with carboplatin, paclitaxel and belinostat administered as long-term (3-6 hour) infusions is also safe, and we have presented results for oral belinostat in solid tumours.

The four belinostat studies have re-confirmed the company's conviction that belinostat is a unique and best in class compound; it is tolerable in full doses together with maximum dosage of the most effective and modern chemotherapeutics, it has shown efficacy also in bladder cancer and the patient may be treated intravenously, through long-term infusion in a vein and through oral therapy (capsules).

### **Conference call**

TopoTarget will host a conference call this afternoon, 12 November at 2.00 pm (CET), at which management will present and discuss the results for Q3 2008 in English.

A presentation will be available on TopoTarget's website, [www.topotarget.com](http://www.topotarget.com), 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 19 November, 2008 at 5.00 pm (CET) at the following number: +353 1 436 4267 pin code 1469588#.

## **Interim report for the period 1 January to 30 September 2008**

**Copenhagen, Denmark – 12 November 2008 - The Board of Directors of TopoTarget A/S (OMX: TOPO) today adopted the company's interim report for the period 1 January to 30 September 2008.**

Sales increase for Savene<sup>®</sup>/Totect<sup>®</sup>, with total sales of 388 kits, including 143 in Q3, which is an increase of 104% on Q3 2007. Third-quarter sales climbed to DKK 8.4 million from DKK 4.6 million in Q3 2007, representing an increase of 84% on Q3 2007. Total sales for Q1-Q3 2008 were DKK 25.0 million, compared with DKK 12.9 million in Q1-Q3 2007, representing a 94% increase and in line with TopoTarget's expectations. 2007 sales amounted to DKK 21.6 million.

Operating expenses for the period Q1-3 2008 were DKK 182,0 million, compared with DKK 178,4 million in the same period of last year, primarily because, after the buyback of the global rights to belinostat, TopoTarget is now conducting all clinical studies of belinostat at its own expense except from the 10 NCI sponsored trials and because TopoTarget Switzerland S.A., which was acquired in June 2007, is included in the full nine-month period of 2008.

The operating loss for the period was DKK 152,9 million, compared with DKK 143,9 million in the same period of last year. The company posted a loss before tax for the first nine months of 2008 of DKK 160,3 million against a pre-tax loss of DKK 139,6 million in the same period of 2007. Cash, cash equivalents and marketable securities amounted to DKK 133,4 million at 30 September 2008.

## **Selected milestones met during Q3 2008**

### Q3

- Positive SPA response from the FDA concerning TopoTarget's pivotal trial with belinostat for the treatment of the cancer indication PTCL in September
- Additional positive belinostat data in cutaneous T-cell lymphomas (CTCL) presented at the EORTC lymphoma meeting in Copenhagen in September
- BelCaP update on positive results for ovarian cancer presented at Biennial Ovarian Cancer Research Symposium in Seattle in September
- NCI (US) approves the transfer of its Clinical Trials Agreement (CTA) from CuraGen to TopoTarget for belinostat.

## **Highlights for the period after 30 September 2008**

- Encouraging belinostat results presented at AACR/NCI/EORTC (European Organisation for Research and Treatment of Cancer) 21-24 October in Geneva, Switzerland:
  - Phase II data from BelCaP i.v. (intravenous) in bladder cancer
  - Phase II data from BelDox (belinostat + doxorubicin) i.v. in solid tumours, including soft tissue sarcoma
  - 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.

## **Expected key milestones for the remainder of 2008**

### **Belinostat milestones:**

- The Company remains confident of achieving a belinostat licensing deal, however recent turbulence in financial markets has increased the uncertainty of achieving it in 2008
- Initiation of pivotal trial with belinostat in the cancer type PTCL
- Results will be presented at ASH (American Society of Hematology) 6-9 December in San Francisco
  - Phase Ib data from BelIda (belinostat + idarubicin) i.v. and 24-48 hour continuous infusion (CIV) in patients with Acute Myeloid Leukaemia (AML)
- Initiation of a randomised Phase II study of BelCaP in solid tumours (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 Myeloid Dysplastic Syndrome (MDS).

### **Other milestones:**

Additional milestones, unchanged from previous announcements.



## **Strategy revised and organisation adjusted**

**During 2008, TopoTarget has revised its strategy and adjusted its organisation to a dedicated focus on belinostat based on the continuing development with highly promising data reported from clinical studies, which has shown beneficial effect in the treatment of patients in solid tumours and haematological tumours in a broad range of studies giving rise to a substantial commercial potential. TopoTarget sees belinostat as the best in class Histone deacetylase inhibitor (HDACi) currently under development with significant advantages relative to the only currently marketed HDAC inhibitor. TopoTarget therefore successfully took advantage of a unique opportunity to buy back the global rights to the compound earlier this year and now focuses its resources on advancing belinostat to registration in PTCL and delivering data in solid tumours.**

TopoTarget has reduced its headcount to 58, of which 18 are in the sales organisation. The company seeks to out-license a number of projects in its pipeline or to postpone development of such projects until warranted by circumstances. TopoTarget has streamlined its business procedures and capitalised on the synergies of an organisation now-centralised at its Copenhagen headquarters. The restructuring was made to ensure belinostat's market access, while maximising the value of the programme and increasing the likelihood of signing a partnership agreement. In the process of refocusing the organisation, the company has kept its core functions intact to the effect that projects which the company may subsequently wish to continue have been retained and may be scaled up once warranted by circumstances.

TopoTarget pursues three primary goals with belinostat:

- bringing belinostat to market as quickly as possible
- documenting its broad applicability in cancer therapy
- forming a partnership with (a) global or regional pharmaceutical company(ies) with sufficient development and commercialisation resources to successfully capitalise on belinostat's substantial commercial potential.

Peripheral T-Cell Lymphoma (PTCL), a haematological disease is the first priority indication for registering belinostat for commercialisation. TopoTarget has received a positive SPA response from the FDA. TopoTarget has reached an agreement with the FDA on the design (including endpoints and statistics) of this pivotal trial in order to receive FDA approval. The ongoing study in T-cell lymphomas (CTCL and PTCL) has therefore been discontinued so that it will not compete with the pivotal trial, in which an accelerated recruitment plan has been initiated. An up date will be announced for the patients ongoing in the "old" protocol/trial.

PTCL is an attractive target in terms of strategy and business potential as, among other things, it is a cancer for which no standard therapy has yet been approved. TopoTarget has been granted a Fast Track designation for belinostat in this indication and is working closely with recognised investigators (doctors in charge of the trials at the hospitals) as part of an accelerated recruitment strategy.

The registration study in PTCL is expected to be initiated in Q4 2008 for a market approval by 2010.

The company believes that belinostat is a best-in-class product. Discussions with several prospective partners and the encouraging data regularly reported from doctors using belinostat in trials for their patients have confirmed that belinostat is considered a highly promising pharmaceutical candidate in tomorrow's cancer therapy.



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

### **Belinostat status**

**Belinostat is an intravenous (i.v.), continuous intravenous (CIV) and oral (capsule) 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 belinostat to exploit the product's potential. TopoTarget aims to provide market access for belinostat as quickly as possible, and the strategy for achieving this involves initiating a pivotal trial scheduled to commence in Q4 2008 in PTCL (haematological malignancy) and to commence a randomized phase II trial of BelCaP in solid tumours (CUP) around the turn of the year. Intravenous and orally administered belinostat is currently evaluated in 18 clinical studies run by TopoTarget and the NCI (US).**

**Running 18 clinical trials belinostat has a broad potential including multiple possibilities treating different cancers - belinostat represents "a pipeline drug". More than 500 patients have been treated with belinostat, which has shown effect in solid tumours and haematological cancers as well as a positive toxicity profile.**

### **Clinical Trial Agreement with the NCI very valuable for belinostat**

The Clinical Trial Agreement (CTA) for belinostat with the NCI (National Cancer Institute, US) is very valuable for the development of belinostat. Since 2004, the NCI has initiated ten Phase I and II trials with belinostat for patients suffering from different cancers (i.e. in different indications) and using different drug combinations. The NCI remains highly interested in conducting and, by extension, also sponsoring clinical trials of belinostat activity, either alone or in combination with other cancer therapies and for the treatment of solid cancers and haematological malignancies. In 2008, the NCI has also commenced and planned studies of belinostat in cancer patients.

The NCI is part of the public health system in the US and as such is financed hereby. As part of its mission to improve cancer therapy, the NCI cooperates with the industry, including TopoTarget in Denmark, to develop new cancer medicine. TopoTarget supplies the belinostat compound for patients in the trials, while the NCI sponsors and conducts the trials. Data derived from the trials is the property of TopoTarget and may consequently be applied to registration of belinostat for commercialisation.

TopoTarget also has a CRADA (Cooperative Research and Development Agreement) with the NCI for laboratory research with belinostat.

### **T-cell lymphoma: PTCL and CTCL treated with belinostat monotherapy**

The FDA has granted Fast Track designation for the development programme of belinostat for treatment of recurrent or refractory PTCL. TopoTarget has received a positive response from the FDA in connection with the SPA process, allowing for initiation of the final registration trial (study designed with a view to obtaining regulatory approval in the US) in about 120 patients at the end of Q4 2008.

At the EORTC Lymphoma conference in Copenhagen on 8 September, 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, 2 CR and 2 PR (Partial Response) in 21 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 was observed in both diseases. Intravenous belinostat was shown to be safe and well tolerated.

### **Ovarian cancer treated with BelCaP**

At the Biennial Ovarian Cancer Research Symposium in Seattle on 4-5 September 2008 and later on 17 September at the ESMO conference in Stockholm, TopoTarget presented an update of positive data concerning the BelCaP combination (belinostat+carboplatin+taxol) in ovarian cancer. Substantial anti-tumour activity with BelCaP was evident. The study includes 35 patients. The overall response rate (OR) was 43%, and 4 patients continue on therapy. 3 complete remissions (CR) and 12 partial remissions (PR) by RECIST criteria (Response Evaluation Criteria in Solid Tumours) were reported. Median time to response was 2.5 months and the median duration of response was +5.3 months (range +1.2 to 12.7 months) with 6 responses still ongoing. 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.

Finally, Phase I results were presented at ESMO. It was reported that 23 patients were treated to find the recommended dose for the subsequent Phase II part of the study, which was belinostat 1000 mg/m<sup>2</sup> i.v. once daily on days 1-5 in combination with standard doses of carboplatin and taxol administered on day 3 of each treatment cycle. In this group of heavily pretreated patients 2 confirmed partial remissions (PR) were documented in rectal cancer and in pancreatic cancer, respectively, and activity was observed in patients with unknown primary tumour (CUP), ovarian, rectal, pancreatic and bladder cancer. 11 patients experienced stable disease (SD) ranging from 2 to +28 cycles.

### **After the reporting period, encouraging results were presented at AACR/NCI/EORTC (European Organisation for Research and Treatment of Cancer) on 21-24 October in Geneva, Switzerland:**

#### **Bladder cancer treated with BelCaP**

Promising data with the BelCaP treatment of bladder cancer was presented, including 1 complete response (CR), 3 partial responses (PR) and 10 patients out of 14 experiencing stable disease (SD). BelCaP (belinostat in combination with standard doses of carboplatin and paclitaxel) was administered to patients with bladder cancer, who had previously relapsed from treatment with carboplatin/cisplatin.

#### **BelDox in solid tumours and soft tissue sarcoma**

At the conference, positive data was reported from a study of full-dose belinostat in combination with a full dose of doxorubicin for the treatment of patients with solid tumours in a dose-escalation setting, which proved safe and well-tolerated. Among 13 evaluable patients, one partial response (PR) and 8 stable disease (SD) were observed.

#### **Orally administered belinostat**

Furthermore, data was presented from the Phase I study of belinostat administered orally (as a capsule) in different schedules/regimens. Prolonged stable disease was observed in a number of patients. The optimum dose was established in two out of three regimens and the study continues.

#### **Belinostat administered as continuous treatment**

Finally, data was presented from a Phase I study with belinostat being administered as a continuous intravenous treatment over 3 or 6 hours in combination with carboplatin and paclitaxel (BelCaP) to, so far, 7 patients with solid tumours. The regimens are well-tolerated, increasing the time of high belinostat plasma



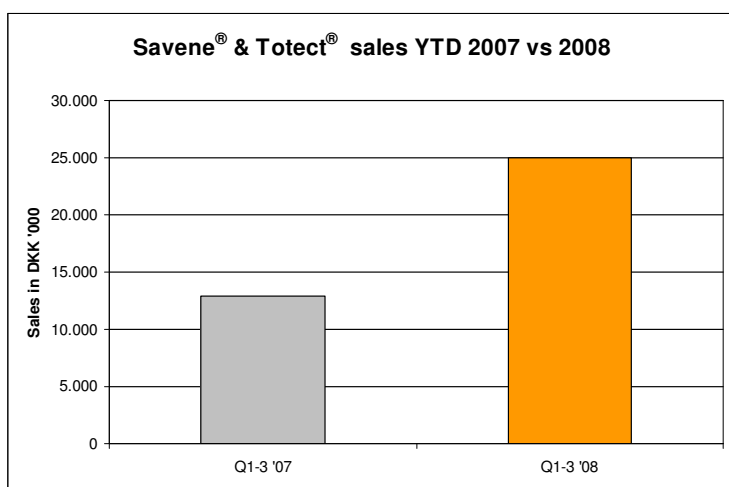
concentrations in the blood. Preclinical studies show that this will lead to improved tumour cell destruction.

### Savene®/Totect® status

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

Sales increase for Savene®/Totect®, with total sales of 388 kits, including 143 in Q3, which is an increase of 104% on Q3 2007. Third-quarter sales climbed to DKK 8.4 million from DKK 4.6 million in Q3 2007, representing an increase of 84% on Q3 2007. Total sales for Q1-Q3 2008 were DKK 25.0 million, compared with DKK 12.9 million in Q1-Q3 2007, representing a 94% increase and in line with TopoTarget's expectations. 2007 sales amounted to DKK 21.6 million

Figure 1 illustrates sales for the first nine month of 2008 compared with 2007 for Savene® and Totect®, measured in TDKK.



Savene® has been recommended as the standard treatment of anthracycline extravasation in the guidelines from the ONS (Oncology Nurses Society, US), EONS (European Oncology Nursing Society) and UKONS (United Kingdom Oncology Nursing Society).

Moreover, an international ICD-9-CM diagnosis code has been established to register anthracycline extravasations. The diagnosis code will facilitate coding of the disease and, by extension, the process of obtaining reimbursement for Savene®/Totect® therapy.

### New product strategy for Totect® in the US

Sales in the US are still in the build-up phase. The US oncology market differs from the European one in many ways for example in that there are many small treatment units offering cancer therapy, whereas the European market is more centralised. The strategy for Totect® has been a price of USD 14,750 combined with a replacement policy, under which Totect® will be replaced at the end of the shelf life if the hospital has not used it. Many of the small cancer units were unable to buy Totect® as the reimbursement does not fully cover the USD 14,750 price and would consequently involve a net expense when patients are treated with TopoTarget's product. Following financial analysis and considerations, TopoTarget has launched a product variant which means that Totect® is now also available without a replacement guarantee at a lower price. We expect that this strategy will lead to an increase in sales on numbers of kits and to a revenue in accordance with the announced expectations.



## TopoTarget's refocusing of its portfolio

**As a result of the focus on belinostat, TopoTarget will seek to out-license a number of projects in its pipeline or to postpone development of such projects until warranted by circumstances. Also the development pace for certain products in the remaining pipeline will be reduced:**

- APO010 is still in the dose-escalating Phase I stage. There is no competition with compounds with the same mechanism of action. Manufacture of the product has been secured and a pause will not involve any technical risk but will of course slow down the development
- The development of APO866 continues without any changes with final reporting in the Chronic lymphocytic leukemia (CLL) and melanoma protocols and will continue with the accrual of the 5 remaining evaluable patients in the Phase II Cutaneous T-Cell Lymphoma (CTCL) study. In addition the project was strengthened in 2008 through the synthesis of a number of novel pre-clinical and highly efficacious APO866 analogues for oral use and the filing of a patent application
- A number of efficacious mTOR analogues have also been synthesised and patent applications filed. The mTOR analogues and the APO866 analogues are both first in class without any direct competition. Until further notice, no animal toxicity trials will be initiated with either mTOR or APO866 analogues. This causes a delay in the clinical development. However, this delay may produce a more thorough evaluation of the most promising candidates, providing development benefits
- Zemab was recently enhanced and a patent application has been filed for the enhanced and more potent product. Manufacture of the product has been secured and a pause will not involve any technical risk but will of course slow down the development
- Baceca<sup>®</sup> and Avugane<sup>™</sup> have completed the scheduled trials. Publication of results for Avugane are still pending. TopoTarget is not planning to conduct further studies until a partnership agreement has been concluded. Accordingly, the company does not believe that the belinostat prioritisation will lead to a loss of value.

Finally, the preclinical studies of Siramesine have been completed. The studies were conducted to determine whether TopoTarget should examine the compound as an anti-cancer therapeutic for use in humans. As Siramesine did not demonstrate any anti-cancer effect in our models, TopoTarget has ended the project, returning all data and rights to Lundbeck.

## TopoTarget A/S





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

The Board of Directors and Senior Management today discussed and adopted the interim report for the nine months ended 30 September 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 September 2008 and of the results of the Group's operations and cash flows for the nine months ended 30 September 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, 12 November 2008**

#### ***Senior Management***

Peter Buhl Jensen  
CEO

#### ***Board of Directors***

Håkan Åström  
Chairman

Jesper Zeuthen

Jeffrey Buchalter

Anders Gersel Pedersen

Ingelise Saunders

Torbjørn Bjerke

Peter Buhl Jensen



**Highlights and key figures**

<b>Consolidated income statements</b>	<b>9 months 2008 DKK ' 000</b>	<b>9 months 2007 DKK ' 000</b>	<b>2007 DKK ' 000</b>
Revenues	29,208	34,460	44,890
Production costs	(7,564)	(20,869)	(25,838)
Research and development costs	(108,449)	(80,254)	(129,111)
Sales and distribution costs	(35,411)	(39,668)	(57,722)
Administrative expenses	(30,660)	(37,605)	(52,020)
Financial income and expenses	(7,441)	4,385	5,754
Loss before tax	(160,317)	(139,551)	(214,047)
Basic and diluted EPS (DKK)	(2.48)	(2.71)	(3.92)

<b>Consolidated balance sheets</b>	<b>30 September 2008 DKK ' 000</b>	<b>30 September 2007 DKK ' 000</b>	<b>31 December 2007 DKK ' 000</b>
Cash and cash equivalents and marketable securities	133,392	463,126	403,617
Assets	760,617	890,069	834,175
Equity	569,687	735,806	665,068

<b>Consolidated cash flow statements</b>	<b>9 months 2008 DKK ' 000</b>	<b>9 months 2007 DKK ' 000</b>	<b>2007 DKK ' 000</b>
Cash flows from operating activities	(142,947)	(151,801)	(208,933)
Cash flows from investing activities	(45,696)	28,165	25,666
Cash flows from financing activities	(372)	332,147	332,026

<b>Consolidated key figures</b>	<b>30 September 2008 DKK ' 000</b>	<b>30 September 2007 DKK ' 000</b>	<b>31 December 2007 DKK ' 000</b>
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	63,658,525	51,469,385	53,955,186
Assets/equity	1.34	1.21	1.25
Share price, closing (DKK)	9.30	30.00	16.76
Share price, book value (DKK)	8.59	12.00	10.85
Average number of employees	119	122	141

The financial ratios have been calculated in accordance with "Recommendations & Ratios 2005", issued by the Danish Society of Financial Analysts.

The interim financial statements are unaudited.

More detailed information is provided in the appendices.



### **Comments on the interim financial statements for the nine months ended 30 September 2008**

The company generated revenue of DKK 29.2 million during the period 1 January to 30 September 2008 compared with DKK 34.5 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. The lower revenue in 2008 is due to lower re-invoicing of research and development costs to CuraGen. In line with expectations, sales of Savene<sup>®</sup> in Europe and Totect<sup>®</sup> in the US were higher in Q1, Q2 and Q3 2008 relative to the same quarters of 2007.

In the first nine months of 2008, production costs amounted to DKK 7.6 million as compared with DKK 20.9 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 September 2008, research and development costs amounted to DKK 108.4 million as compared with DKK 80.3 million in the year-earlier period. The company recorded higher research and development costs primarily because, after the buyback of the global rights to belinostat, TopoTarget is now conducting all clinical studies of belinostat at its own expense except from the 10 NCI sponsored trials and because TopoTarget Switzerland S.A., which was acquired in June 2007, is included in the full nine-month period of 2008.

Sales and distribution costs amounted to DKK 35.4 million in the first nine months, down from DKK 39.7 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 adjustments which also in Q3 2008 resulted in lower costs relative to the same period of 2007.

In the period 1 January to 30 September 2008, administrative expenses amounted to DKK 30.7 million as compared with DKK 37.6 million in the year-earlier period. In 2008, the amount includes higher costs due to the operation of our Swiss subsidiary following the acquisition of that company at the end of June 2007. Administrative expenses in Q3 2008 amounted to DKK 5.5 million as compared with DKK 12.7 million in the year-earlier period. In addition to reduced liabilities in respect of holiday allowance due to the lower number of staff, the reduction is attributable to a reclassification of subsidiary activities, which now exclusively comprise research and development operations after a reduction of administrative functions in the subsidiaries.

Net financial expenses amounted to DKK 7.4 million in the first nine months, as compared with net financial income of DKK 4.4 million in the year-earlier period. The difference was primarily due to large currency translation differences on consolidation of group enterprises and interest expenses on the loan provision for payment of the expected milestone to the former owners of TopoTarget Switzerland S.A. concerning APO866.

In the first nine 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 September 2008, the company recorded a loss after tax of DKK 158.0 million as compared with a loss after tax of DKK 139.6 million in the same period of 2007.

At 30 September 2008, total assets amounted to DKK 760.6 million. Of this amount, cash, bank deposits and short-term securities amounted to DKK 133.4 million.





**Condensed income statements**

	Note	Q3, 2008 DKK ' 000	Q3, 2007 DKK ' 000	9 months 2008 DKK ' 000	9 months 2007 DKK ' 000	2007 DKK ' 000
Revenue	2,3	9,294	8,664	29,208	34,460	44,890
Production costs	4	(1,297)	(7,158)	(7,564)	(20,869)	(25,838)
Research and development costs	4,5	(38,068)	(34,168)	(108,449)	(80,254)	(129,111)
Sales and distribution costs	4	(10,041)	(13,398)	(35,411)	(39,668)	(57,722)
Administrative expenses	4	<u>(5,480)</u>	<u>(12,730)</u>	<u>(30,660)</u>	<u>(37,605)</u>	<u>(52,020)</u>
<b>Operating loss</b>		<b>(45,592)</b>	<b>(58,790)</b>	<b>(152,876)</b>	<b>(143,936)</b>	<b>(219,801)</b>
Financial income and expenses		<u>(1,045)</u>	<u>1,892</u>	<u>(7,441)</u>	<u>4,385</u>	<u>5,754</u>
<b>Loss before taxes</b>		<b>(46,637)</b>	<b>(56,898)</b>	<b>(160,317)</b>	<b>(139,551)</b>	<b>(214,047)</b>
Tax on profit/(loss) for the period		<u>0</u>	<u>0</u>	<u>2,275</u>	<u>0</u>	<u>2,447</u>
<b>Net loss for the period</b>		<b><u>(46,636)</u></b>	<b><u>(56,898)</u></b>	<b><u>(158,041)</u></b>	<b><u>(139,551)</u></b>	<b><u>(211,600)</u></b>
Basic and diluted EPS (DKK)		(0.70)	(0.93)	(2.48)	(2.71)	(3.92)



## Condensed balance sheets - assets

	Note	30 September 2008 DKK ' 000	30 September 2007 DKK ' 000	2007 DKK ' 000
Intangible assets	5	569,528	371,014	370,639
Property, plant and equipment		14,474	19,051	18,415
Non-current investments		<u>1,938</u>	<u>1,657</u>	<u>1,657</u>
<b>Non-current assets</b>		<b><u>585,940</u></b>	<b><u>391,722</u></b>	<b><u>390,711</u></b>
Inventories		6,599	2,673	3,310
Receivables		34,687	32,548	36,537
Securities	6	35,295	116,262	116,505
Cash and cash equivalents		<u>98,097</u>	<u>346,864</u>	<u>287,112</u>
<b>Current assets</b>		<b><u>174,678</u></b>	<b><u>498,347</u></b>	<b><u>443,464</u></b>
<b>Assets</b>		<b><u><u>760,617</u></u></b>	<b><u><u>890,069</u></u></b>	<b><u><u>834,175</u></u></b>



**Condensed balance sheets - equity and liabilities**

	<b>Note</b>	<b>30 September 2008 DKK ' 000</b>	<b>30 September 2007 DKK ' 000</b>	<b>2007 DKK ' 000</b>
<b>Equity</b>		<b><u>569,687</u></b>	<b><u>735,806</u></b>	<b><u>665,068</u></b>
Non-current liabilities		45,832	113,098	48,655
Current liabilities	7	<u>145,098</u>	<u>41,165</u>	<u>120,452</u>
<b>Liabilities</b>		<b><u>190,930</u></b>	<b><u>154,263</u></b>	<b><u>169,107</u></b>
<b>Equity and liabilities</b>		<b><u><u>760,617</u></u></b>	<b><u><u>890,069</u></u></b>	<b><u><u>834,175</u></u></b>
Accounting policies	1			



**Condensed cash flow statements**

	<b>9 months 2008</b>	<b>9 months 2007</b>	<b>9 months 2007</b>
	<b>DKK ' 000</b>	<b>DKK ' 000</b>	<b>DKK ' 000</b>
Operating loss	(152,876)	(143,936)	(219,801)
Reversal of share-based payments	7,159	4,414	6,862
Depreciation, amortisation and impairment losses	6,216	5,199	7,331
Working capital changes	(4,670)	(24,347)	(12,799)
<b>Cash flows from operating activities before interest</b>	<b>(144,170)</b>	<b>(158,670)</b>	<b>(218,407)</b>
Received and paid interest etc.	1,223	6,869	9,474
<b>Cash flows from operating activities</b>	<b>(142,947)</b>	<b>(151,801)</b>	<b>(208,933)</b>
Purchase of intangible assets	(125,475)	(4,592)	(4,451)
Purchase of property, plant and equipment	(1,330)	(6,779)	(8,577)
Sale of property, plant and equipment	181	76	612
Acquisition of subsidiary net of cash	0	23,127	23,127
Purchase of investments	(281)	(511)	(510)
Purchase of securities	(84,420)	(44,051)	(44,051)
Sale of securities	165,630	60,895	59,516
<b>Cash flows from investing activities</b>	<b>(45,696)</b>	<b>28,165</b>	<b>25,666</b>
Instalment on loans	(372)	(355)	(476)
Proceeds from the issuance of shares	0	332,502	332,502
<b>Cash flows from financing activities</b>	<b>(372)</b>	<b>332,147</b>	<b>332,026</b>
Increase/decrease in cash and cash equivalents	(189,015)	208,511	148,759
Cash and cash equivalents at 1 January	287,112	138,353	138,353
<b>Cash and cash equivalents at 30 September</b>	<b>98,097</b>	<b>346,864</b>	<b>287,112</b>
Cash and cash equivalents comprise:			
Deposit on demand and cash	98,052	78,446	287,067
Special-term deposits	45	268,419	45
<b>Total</b>	<b>98,097</b>	<b>346,864</b>	<b>287,112</b>





**Statement of equity for the period 1 January to 30 September 2008**

	Number of shares	Share- capital DKK ' 000	Share- based payments DKK ' 000	Retained earnings DKK ' 000	Total DKK ' 000
<b>Equity at 1 January 2008</b>	<b>61,304,510</b>	<b>61,304</b>	<b>17,332</b>	<b>586,432</b>	<b>665,068</b>
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)
<b>Recognised directly in equity</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
Net loss for the period	0	0	0	(158,041)	(158,041)
<b>Total net income</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>(158,041)</b>	<b>(158,041)</b>
Recognition of share-based payment	0	0	7,160	0	7,160
Share capital increase through non-cash payment	5,000,000	5,000	0	50,500	55,500
<b>Other transactions total</b>	<b>5,000,000</b>	<b>5,000</b>	<b>7,160</b>	<b>50,500</b>	<b>62,660</b>
<b>Equity 30 September 2008</b>	<b>66,304,510</b>	<b>66,304</b>	<b>24,492</b>	<b>478,891</b>	<b>569,687</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.

**Statement of equity for the period 1 January to 30 September 2007**

	Number of shares	Share- capital DKK ' 000	Share- based payments DKK ' 000	Retained earnings DKK ' 000	Total DKK ' 000
<b>Equity 1 January 2007</b>	<b>45,684,880</b>	<b>45,685</b>	<b>10,668</b>	<b>374,297</b>	<b>430,650</b>
Fair value adjustment of available-for-sale financial assets	0	0	0	(150)	(150)
Recognition of share-based payment	0	0	4,414	0	4,414
Exercise of share-based payment	0	0	(198)	198	0
<b>Recognised directly in equity</b>	<b>0</b>	<b>0</b>	<b>4,216</b>	<b>48</b>	<b>4,264</b>
Net loss for the period	0	0	0	(139,551)	(139,551)
<b>Total net income</b>	<b>0</b>	<b>0</b>	<b>4,216</b>	<b>(139,503)</b>	<b>(135,287)</b>
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
<b>Other transactions</b>	<b>15,619,630</b>	<b>15,619</b>	<b>0</b>	<b>424,824</b>	<b>440,443</b>
<b>Equity 30 September 2007</b>	<b>61,304,510</b>	<b>61,304</b>	<b>14,884</b>	<b>659,618</b>	<b>735,806</b>

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.



## 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 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.

### 2. REVENUE

	<b>Q3, 2008</b> <b>DKK '000</b>	<b>Q3, 2007</b> <b>DKK '000</b>	<b>9 months 2008</b> <b>DKK '000</b>	<b>9 months 2007</b> <b>DKK '000</b>	<b>2007</b> <b>DKK '000</b>
Sales of goods	8,382	4,566	25,019	12,914	21,613
Sales of services	912	3,466	4,189	16,673	18,404
Milestone payments	0	632	0	4,873	4,873
<b>Total</b>	<b>9,294</b>	<b>8,664</b>	<b>29,208</b>	<b>34,460</b>	<b>44,890</b>



### 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				
	Q3, 2008 DKK '000	Q3, 2007 DKK '000	9 months 2008 DKK '000	9 months 2007 DKK '000	2007 DKK '000
Denmark	291	28	801	530	966
Europe	5,396	4,885	15,983	12,742	18,782
USA	3,608	3,752	12,425	21,189	25,142
<b>Total</b>	<b>9,294</b>	<b>8,664</b>	<b>29,208</b>	<b>34,460</b>	<b>44,890</b>

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

	Assets			Additions to aquired research & development projects plus other fixtures and fittings, tools and equipment		
	30 September 2008 DKK '000	30 September 2007 DKK '000	2007 DKK '000	9 months 2008 DKK '000	9 months 2007 DKK '000	2007 DKK '000
Denmark	390,009	527,732	441,913	210,046	6,250	7,151
Europe	364,862	360,856	381,358	88	206,405	210,699
USA	5,747	1,481	10,904	301	426	426
<b>Total</b>	<b>760,617</b>	<b>890,069</b>	<b>834,175</b>	<b>210,435</b>	<b>213,081</b>	<b>218,276</b>



#### 4. STAFF COSTS

	<b>Q3, 2008</b> <b>DKK ' 000</b>	<b>Q3, 2007</b> <b>DKK ' 000</b>	<b>9 months 2008</b> <b>DKK ' 000</b>	<b>9 months 2007</b> <b>DKK ' 000</b>	<b>2007</b> <b>DKK ' 000</b>
Allocated by function:					
Production costs	0	3,349	654	4,934	4,172
Research and development costs	11,636	12,064	41,419	33,486	51,022
Sales and distribution costs	4,761	5,771	16,725	13,192	18,478
Administrative expenses	2,076	7,962	16,058	22,918	31,746
<b>Total</b>	<b>18,473</b>	<b>29,146</b>	<b>74,856</b>	<b>74,530</b>	<b>105,418</b>
Hereof share-based payments	2,522	1,523	7,293	4,414	6,862
<b>Average number of employees</b>			<b>119</b>	<b>122</b>	<b>141</b>



**5. INTANGIBLE ASSETS**

	<b>30 September 2008 DKK ' 000</b>	<b>30 September 2007 DKK ' 000</b>	<b>2007 DKK ' 000</b>
<b>Acquired research- and development projects still in progress</b>			
Cost at 1 January	357,438	153,172	153,172
Adjustment of acquisition value	(9,262)	0	0
Addition by acquisition of subsidiary	0	199,815	199,815
Additions	209,276	4,592	4,592
Disposals	0	-141	(141)
<b>Cost at 30 September</b>	<b><u>557,452</u></b>	<b><u>357,438</u></b>	<b><u>357,438</u></b>
<b>Carrying amount at 30 September</b>	<b><u>557,452</u></b>	<b><u>357,438</u></b>	<b><u>357,438</u></b>
<b>Acquired research- and development projects - available for use</b>			
Cost at 1 January	15,076	15,076	15,076
<b>Cost at 30 September</b>	<b><u>15,076</u></b>	<b><u>15,076</u></b>	<b><u>15,076</u></b>
<b>Amortisation at 1 January</b>	<b>(1,875)</b>	<b>(375)</b>	<b>(375)</b>
Amortisation	(1,125)	(1,125)	(1,500)
<b>Amortisation at 30 September</b>	<b><u>(3,000)</u></b>	<b><u>(1,500)</u></b>	<b><u>(1,875)</u></b>
<b>Carrying amount at 30 September</b>	<b><u>12,076</u></b>	<b><u>13,576</u></b>	<b><u>13,201</u></b>
The weighted average residual term of acquired research and development projects - available for use is approximately (number of years)	8.00	9.00	8.75
<b>Total acquired research and development projects</b>	<b><u>569,528</u></b>	<b><u>371,014</u></b>	<b><u>370,639</u></b>

Amortisation and impairment by function:

	<b>9 months 2008 DKK ' 000</b>	<b>9 months 2007 DKK ' 000</b>	<b>2007 DKK ' 000</b>
Production costs	<b><u>1,125</u></b>	<b><u>1,125</u></b>	<b><u>1,500</u></b>



## 6. SECURITIES

Securities comprise:

		<b>30 September 2008 DKK ' 000</b>	<b>30 September 2007 DKK ' 000</b>	<b>2007 DKK ' 000</b>
Callable loans	DKK	35,295	59,027	70,135
Non callable loans	DKK	<u>0</u>	<u>57,235</u>	<u>46,370</u>
<b>Total</b>		<b><u>35,295</u></b>	<b><u>116,262</u></b>	<b><u>116,505</u></b>

Securities expire:

Up to 1 year		35,295	23,964	13,493
One to five years		0	996	15,919
More than five years		<u>0</u>	<u>91,302</u>	<u>87,093</u>
<b>Total</b>		<b><u>35,295</u></b>	<b><u>116,262</u></b>	<b><u>116,505</u></b>

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. SHORT TERM COMMITMENTS

		<b>30 September 2008 DKK ' 000</b>	<b>30 September 2007 DKK ' 000</b>	<b>2007 DKK ' 000</b>
Leasing commitments		442	454	499
Trade payables		41,192	20,199	38,256
Other payables		100,072	20,512	75,612
Deferred income		<u>3,393</u>	<u>0</u>	<u>6,085</u>
<b>Total</b>		<b><u>145,098</u></b>	<b><u>41,165</u></b>	<b><u>120,452</u></b>

Other debt is debt in relation to the APO866-milestone and the belinostat-milestone.

