



**VELKOMMEN**  
til  
**TOPOTARGET A/S'**  
**Årlige Generalforsamling**

5 April 2011

# Safe Harbour Statement

This presentation 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 exposure; 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.

# Årlig generalforsamling 2011: Agenda

1. Beretning om selskabets virksomhed i det forløbne år
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    - 6.2.3 Bemyndigelse til dirigenten



# **Topotarget A/S' årlige generalforsamling**

**Bo Jesper Hansen, MD PhD**

**Chairman of the Board**

5 April 2011

# 2010 – et år med væsentlige forandringer

- **Vi har positioneret Topotarget til en god start i 2011:**
  - Etablering af et nyt ledelses-team er på plads, og bestyrelsen er ligeledes styrket
  - Partnerskab med Spectrum Pharmaceuticals, Inc. i USA og Indien
  - Vi har nedlagt den interne grundforskning og forberedt organisationen på sen-fase udviklingen af belinostat
  - Etablering af en klar strategi med et stærkt fokus på vores ledende lægemiddelkandidat belinostat

# Stærkt ledelseshold på plads



**Axel Mescheder**  
**CMO, MD**

- 20 års erfaring inden for lægemiddeludvikling samt bred regulatorisk erfaring fra internationale lægemiddelselskaber som Roche, Aventis Behring, Genetics Institute/Wyeth



**Anders Vadsholdt**  
**CFO**

- Mange års erfaring fra biotekindustrien, venture kapital og corporate finance fra sin ansættelse i selskaber som 7TM Pharma, BankInvest og Carnegie Bank



**Inge Holm Lauritzen**  
**VP BD&L/Strategic Planning**

- Senior biotek- og farma leder gennem 15 år inden for kontraktforhandling og ledelse af alliancer via industrierfaring fra bl.a. Lundbeck og Novozymes



# Annual General Meeting

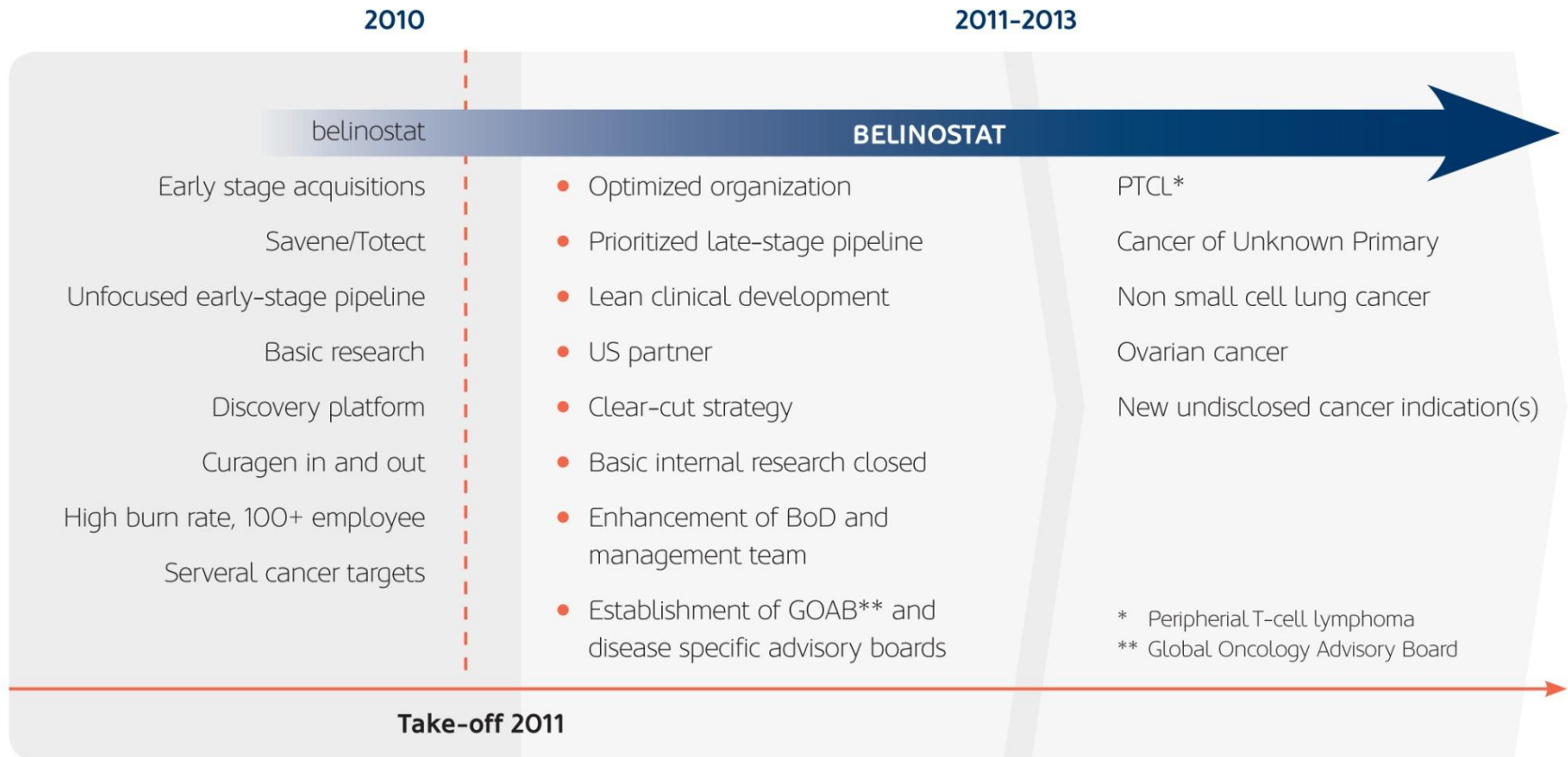
**Francois Martelet, CEO**  
**Anders Fink Vadsholt, CFO**

5 April 2011

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# Focus on belinostat



# Strong management team in place (cont'd)



**Lars Damstrup**  
**Medical Director, MD, PhD**

- Oncology specialist with experience from Department of Oncology, Finsen Center, basic research and drug development from Novartis and Genmab A/S – early to late stage



**Elisabeth V. Carstensen**  
**Director of Pharmaceutical Operations**

- Responsible for CMC during the registration process of Topotarget's first two products on the market, Savene® and Totect®

# Strong management team in place (cont'd)



**Annette Lykke**  
**Director of IR and PR**

- Investment banker with 20 years' experience as senior pharma and biotech analyst with in Nordic investment banks, including Carnegie, ABN AMRO Alfred Berg



**John Parsons**  
**CCO**

- 36 years of extensive experience in general management, sales and marketing based on experience from companies like Innovex and BASF Pharma (Abbott/Knoll)

# Global Oncology Advisory Board

- **Chairman of GOAB: Pr. Jean-Louis Misset, FRA**

Professor of Oncology at the University and at the St. Louis Hospital Oncology Division in Paris

- **Dr. Matti Aapro, CH**

Dean of the Multidisciplinary Oncology Institute, Genolier

- **Pr. James Cassidy, UK**

Professor of Oncology and Head of Academic Unit, University of Glasgow, Scotland

- **Pr. Hans-Joachim Schmoll, GER**

Professor of Internal Medicine and Director of the Department of Hematology and Oncology at the Martin Luther University, Halle-Wittenberg,

- **Assistant Pr. Alain Catalin Mita, US**

Assistant Professor of Medicine at the University of Texas Health Science Center San Antonio

- **Dr. Daniel D. Von Hoff, US**

Physician in Chief, Senior Investigator and Director of Clinical Translational Research Division at TGen (Translational Genomics Research Institute) in Phoenix, AZ

# 2010 belinostat drug development achievements

- Articulated clinical development strategy
  - Establishing of a strong internal drug development team
  - Establishing of strong global oncology advisory board (GOAB)
  - Establishing of disease specific advisory boards (DSAB), within CUP (cancer of unknown primary), CRC (colorectal cancer), NSCLC (non-small cell lung cancer), ovarian cancer and bladder cancer
- Continued patients' enrollment in the pivotal BELIEF trial
  - Drug-to-drug interaction study (CLN-20)
- Completed Phase II randomized CUP study
- Design and set up of Phase I/II NSCLC (Non-Small Cell Lung Cancer)

# Topotarget 2011 strategy

Our strategy is aiming at making belinostat the most successful HDAC-inhibitor in selected indications

- We will develop belinostat in selected indications where we have reasons to believe belinostat will have efficacy
- Subject to potential positive trial outcomes we will seek global registrations
- We are developing and will commercialize belinostat in North America and India together with our partner
- We will build our commercial business in the rest of the world in order to maximize shareholder value



# 2011 belinostat clinical trial plan

1. Topotarget has a solid base in the on-going clinical programs
  - Pivotal study in PTCL, expected to NDA rolling submission H2 2011/H1 2012
  - Phase I/II study in NSCLC first patient dosed March 2011
2. Topotarget has completed one study
  - Randomized phase II study in CUP, expected to report headline data during H2 2011

# Expand belinostat clinical program

Additional studies in unmet medical oncology indications. Our present core options are:

- Depending on data from completed CUP trial we will explore potential future strategy in CUP
- Initiate randomized phase II study in bladder cancer for Europe, strong support from pre-clinical, clinical data and our GOAB
- Consider initiation of a randomized study in ovarian cancer, strong support from in-house clinical and preclinical results with the triple combination (BelCaP)
- Decision to commit funds for trials will be based on thorough financial planning

# Financial position

- Cash at hand was DKK 205M as of YE 2010
- With current clinical program and the achievement of milestones according to Spectrum agreement: no new funds needed for 2011-2012

# Commercial strategy for North America and India

## Licensing agreement with Spectrum Pharmaceuticals

- Agreement 2 February 2010
- \$30M cash upfront
- Additional value \$320M in potential milestone payments
- + Double digit royalties
- Spectrum funds PTCL BELIEF trial; Topotarget funds ongoing randomized Phase II CUP study
- Resources for co-development in promising indications, cost sharing with Spectrum contributing 70% and Topotarget 30% of future development costs
- Joint development and commercialization committees
- Spectrum territory: North America and India as well as first right of negotiation to China



# Commercial strategy for Europe

Topotarget is determined to explore the full potential of belinostat:



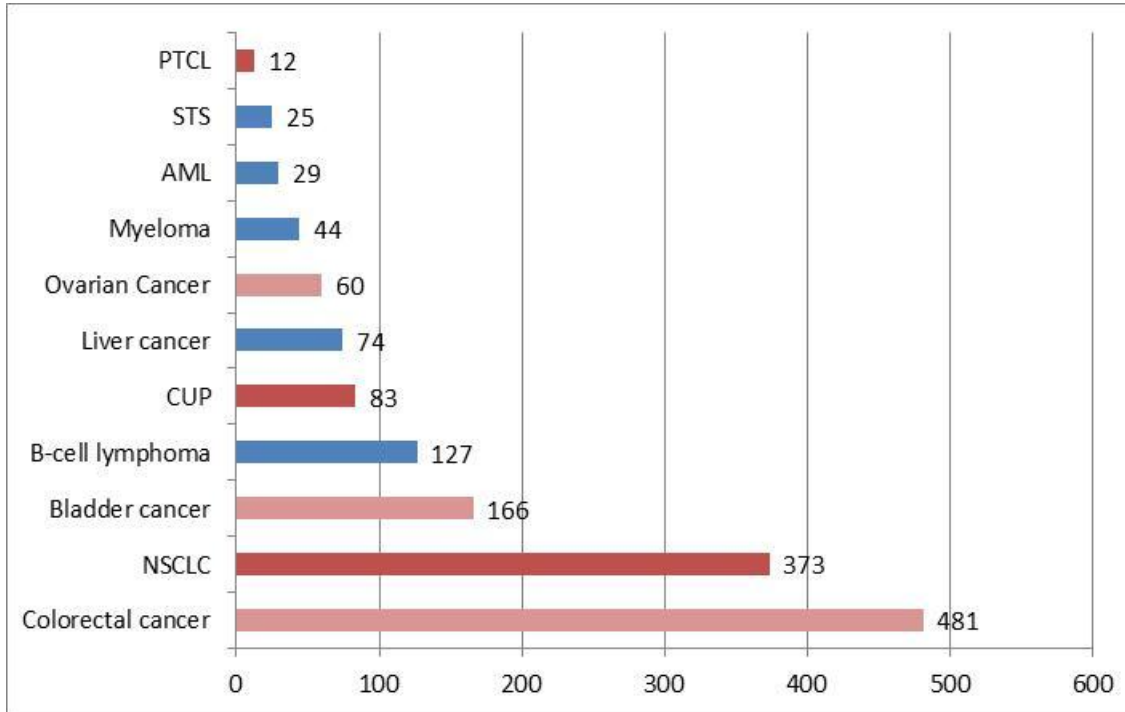
- Commercialize in Europe and RoW, together with a partner or by building our own market presence in selected indications
- Expand belinostat clinical program in these regions

# Belinostat key clinical trials (Topotarget and Spectrum)

Study	Sponsor	Indication	Phase I	Phase II	Pivotal	Target	Status	Milestone	Time
BELIEF	SPPI	PTCL	→			100-120	Recruiting	NDA Rolling Submission	H2 2011
CLN-17	TT	CUP	→			88	Complete	Top-line results	H2 2011
CLN-9	TT	Solid tumor	→			92	Complete	Scientific publ.	H2 2011
CLN-9	TT	Lymphoma	→			30	Recruiting	LPFV *) Top-line results	H1 2011 H2 2011
CLN-14	TT	Solid + STS	→			55	Phase I Phase II	LPFV stage I in Phase II Results stage I	H2 2011 H2 2011
CLN-20	SPPI/TT	Drug-Drug	→			24	Recruiting	Top-line results	H2 2011
SPI-1014 Bel	SPPI/TT	NSCLC	→			35	Initiated	FPFV **)	H2 2011
*) Last Patient First Visit									
**) First Patient First Visit									

# Belinostat – commercial potential

New cancer patients per year in US, Japan and 5 major EU



Source: Datamonitor estimate (US + Japan + 5 major EU)

- Primary focus
- Secondary focus
- Other

- Estimated annual global peak market sale of belinostat in the current PTCL indication ~ \$100-130M
- Estimated annual global market sale of the CUP indication ~ USD 500-600M
- Price of Istodax<sup>®</sup> (romidepsin) approved November 2009 for CTCL is 30,000 \$\* per patient per month
- Expansion into new cancer indications will significantly add market opportunity

\*New York Times

# Belinostat news flow 2011

News flow							
		Indication	Design	Target accrual	Status	Milestones	Time frame
BELIEF	Spectrum 100%	PTCL	Single arm pivotal trial with belinostat monotherapy	100-120	Recruiting	Rolling NDA submission	H2 2011
CLN-17	Topotarget 100%	CUP	Randomized Phase II with BelCaP versus CaP	88	Enrollment complete	Top-line results	H2 2011
CLN-9	Topotarget	Lymphoma	Single arm Phase I dose and schedule finding study	30	Recruiting	Top-line results	H2 2011
CLN-14	Topotarget & Spectrum	Solid tumors - Soft Tissue Sarcoma	Single arm Phase I/II dose finding study with Bel and doxorubicin with cohort expansion at MTD	55	Recruiting	Results of stage 1 in cohort expansion	H2 2011
SPI-1014-Bel	Spectrum (70%) Topotarget (30%)	NSCLC	Single arm Phase I/II dose finding and efficacy study with BelCaP	35	Recruiting	FPFV	H1 2011

# Achievements and Goals

- Belinostat unique HDACi with both oral and IV formulation available
- > 30 clinical studies completed or ongoing
- > 900 patients being exposed to belinostat
- Good safety profile
- Ongoing registration trial in PTCL
- Randomized Phase II in CUP enrollment completed
- Substantial and untapped potential in expansion into new oncology indications
- Strong pre-clinical and emerging clinical rationale for use in treatment of several solid tumor indications with high unmet medical need
- Improved news flow in 2011

# One of Topotarget key strengths is people...

- Approximately 50 full time employees who are dedicated, experienced, focused and flexible
- Key experts within Oncology on board (GOAB)

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# FY 2010 – financial highlights

	2010 DKK '000	2009 DKK '000
Revenues	129,038	43,979
Production costs	(10,933)	(10,125)
Research and development costs	(71,608)	(89,884)
Write-down of research and development projects	(189,541)	(21,200)
Divestiture of rights in Europe to Savene®	32,473	-
Sales and distribution costs	(19,098)	(29,136)
Administrative expenses	<u>(38,778)</u>	<u>(26,126)</u>
<b>Operating loss</b>	<b>(168,447)</b>	<b>(132,492)</b>
Financial income	80,863	2,483
Financial expenses	<u>(12,090)</u>	<u>(12,733)</u>
<b>Loss before tax</b>	<b>(99,674)</b>	<b>(142,742)</b>
Tax on profit/(loss) for the year	<u>43,985</u>	<u>2,278</u>
<b>Net loss for the year</b>	<b><u>(55,689)</u></b>	<b><u>(140,464)</u></b>

# FY 2010 – write-down of R&D projects

Project		Million DKK
APO 866		53.5
APO 010		116.0
APO 200		4.0
Top 216		11.3
Zemab		4.8
Total Value		189.6

# FY 2010 – balance sheet assets

	2010 DKK '000	2009 DKK '000
Intangible assets	235,717	431,855
Property, plant and equipment	5,991	7,044
Non-current investments	<u>972</u>	<u>1,371</u>
Non-current assets	<u>242,681</u>	<u>440,330</u>
Inventories	<u>1,625</u>	<u>1,944</u>
Receivables	<u>16,451</u>	<u>13,024</u>
Cash and cash equivalents	<u>205,068</u>	<u>130,145</u>
Current assets	<u>223,143</u>	<u>145,113</u>
Assets	<u>465,824</u>	<u>585,413</u>

# FY 2010 – balance sheet liabilities

	2010 DKK '000	2009 DKK '000
Equity	<u>360,219</u>	<u>411,798</u>
Deferred income tax	0	43,985
Pension liabilities	0	315
Other payables	<u>14,116</u>	<u>70,395</u>
Non-current liabilities	<u>14,116</u>	<u>114,695</u>
Trade payables	16,868	37,299
Deferred income	63,455	0
Other payables	<u>11,166</u>	<u>21,621</u>
Current liabilities	<u>91,489</u>	<u>58,920</u>
Liabilities	<u>48,802</u>	<u>173,615</u>
Equity and liabilities	<u>465,824</u>	<u>585,413</u>

# Outlook 2011

- Topotarget expects for the year 2011 a pre-tax loss of approximately DKK 20-40 million
- Topotarget expects a net cash position at the end of 2011 of around DKK 110-130 million

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# Election of board members



**Bo Jesper Hansen**  
**Chairman of the Board**

- MD, PHD from University of Copenhagen. Board member since 2009
- Executive Chairman of the board of Swedish Orphan Biovitrum AB
- Board member CMC AB, Mipsalus Aps, Ophazyme and Zymenex



**Anker Lundemose**

- MD, PhD from University of Aarhus. Board member since 2010
- Advisor to LD Invest



**Ingelise Saunders**

- Degree in Pharmacy from the Royal Danish School of Pharmacy and a Bachelor of Commerce degree in Marketing. Board member since 2004
- Chairman of the Board of Nordic Vaccine A/S. Board member of Scandinavian Life Science Invest AB, Evolva Holding SA, TD Vaccines A/S, and aCROnordic A/S

# Election of board members (cont'd)



**Jeffrey H. Buchalter**

- MBA from Temple University. Board member since 2006
- President, CEO, and board member of Archimedes Pharma Limited



**Per Samuelsson**

- M.Sc. from Institute of Technology in Linköping. Board member since 2009
- Board member of Algeta ASA, Biostratum Inc., Cardoz AB, Nordic. Vision Clinics AS, Oncos Therapeutics Oy, and Optivy AB

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# Election of state authorized public auditor

- The board of directors proposes that Deloitte Statsautoriseret Revisionsaktieselskab be re-appointed as the company's auditors

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# Authorization to the board of directors to issue warrants

- Under the existing authorization for the board of directors to issue warrants in Article 6(e) of the articles of association, 1,327,500 warrants remain unissued. The board of directors proposes to amend Article 6(e) to authorize the issue of a total of 2,727,500 warrants - without pre-emption rights for the existing shareholders - that give the right to subscribe up to a total of nominal DKK 2,727,500 shares in the Company to employees, the Management, board members, consultants or advisors to the Company and its subsidiaries and to implement the corresponding capital increases. Also, the board of directors proposes to prolong the authorization to expire 5 years after this year's Annual General Meeting.
- The board of directors believes that it is necessary for the Company, in order for it to be able to retain and attract a sufficient number of qualified employees, board members and consultants, to be able to offer warrants as part of the employment or affiliation with the Company.
- The revised Article 6(e) is set forth below:
- “6(e)  
*In the period until 4 April 2016, the board of directors is authorised to make one or more issues of up to a total of 2,727,500 warrants, each entitling the holder to subscribe for one share of DKK 1 nominal value in the Company and to make the relevant capital increases.*
- *The warrants may be issued to employees, the Management, board members, consultants or advisors to the Company and its subsidiaries without pre-emptive rights for the Company's shareholders. The exercise price for warrants issued under the authorisation shall correspond at least to the market price of the Company's shares at the date of issuance of the warrants. The other terms relating to warrants issued under the authorisation shall be fixed by the board of directors.”*

# Warrant pool

Year		Number of warrants	Number of shares	New warrant pool compared to number of outstanding shares
AGM 2008	Approved	1.350.000	66.304.510	2,0%
AGM 2009	Approved	1.350.000	66.304.510	2,0%
AGM 2010	Approved	1.980.000	132.609.020	1,5%
AGM 2011	Recommended to be approved	1.400.000	132.652.050	1,1%

# Warrant programs

Programme	Time of issue	Outstanding warrants	Exercise price DKK
I	2001	681.523	6,1
II	2003	649.552	12,2
III	2005	-	1,0
IV	2005	1.235.915	17,5
Va	2006	1.076.773	23,8
Vb	2007	1.258.530	17,4
Vc	2009	1.500.143	3,2
Vd	2010	142.750	5,3
Ve	2010	1.592.250	3,4
Vf	2010	255.000	3,2
Vg	2011	90.000	3,3

# Shares and warrants

<b>Shares and warrants</b>		
<b>Outstanding shares</b>	<b>132.652.050</b>	<b>92,2%</b>
<b>Outstanding allocated warrants</b>	<b>8.482.435</b>	<b>5,9%</b>
<b>AGM approved non allocated</b>	<b>1.327.500</b>	<b>0,9%</b>
<b>Proposal for 2011 AGM approval</b>	<b>1.400.000</b>	<b>1,0%</b>
<b>Total</b>	<b>143.861.985</b>	
<b>Warrant pool fully diluted</b>		
<b>Current outstanding allocated warrants</b>		<b>6,0%</b>
<b>Current approved warrant pool before AGM</b>		<b>6,9%</b>
<b>Current approved warrant pool after AGM</b>		<b>7,8%</b>

# Authorization to the board of directors to allow the Company to acquire treasury shares

- The board of directors proposes that the board of directors be authorised, until the next annual general meeting, to purchase treasury shares within a limit of 10% of the Company's share capital and at a price corresponding to the listed price plus/less 5% at the time of the purchase

# Approval of revised general guidelines for incentive remuneration of the Company's board of directors and management

- The board of directors proposes that the general meeting approves revised general guidelines for incentive remuneration of the Company's board of directors and management. The proposed changes enable the board of directors in extraordinary and specific cases to grant a cash bonus to the management of up to 100% of the aggregate annual base salary to the management
- If the general meeting approves the revised guidelines for incentive pay for board and management, article 6c will be changed to note that at the annual general meeting held on 5 April 2011, the shareholders approved general guidelines for incentive remuneration of the Company's board of directors and management. The guidelines are public at the Company's website ([www.topotarget.com](http://www.topotarget.com))

# Passing of a resolution giving authority to the chairman of the general meeting

- The board of directors proposes that the chairman of the meeting or a substitute duly appointed by him be authorised to apply for registration of the resolutions passed and to make any such amendments thereto as may be required by the Danish Commerce and Companies Agency as a condition for registration or approval