



Interim Report

Q4 and YTD 2014

targovax

# Interim report to shareholders of Targovax AS – Fourth Quarter and YTD 2014

## THE COMPANY IN BRIEF

Targovax AS is a Norwegian company founded in 2010 by world pioneers in cancer immunotherapy, based on a substantial body of data from non-clinical and clinical research. Targovax AS develops active immunotherapy in the form of cancer specific therapeutic vaccines. The vaccines stimulate the patients' immune system to recognize and kill cancer cells having mutations in the RAS genes. There is a large unmet need for treatment of cancers with RAS mutations.

The lead product TG01 is under clinical development for the treatment of resected pancreatic cancer. TG02 is the next cancer vaccine to be developed for treatment of colorectal and lung cancer.

## HIGHLIGHTS FOR THE FOURTH QUARTER AND YTD 2014

On January 8<sup>th</sup>, Targovax reported completion of recruitment of 18 patients in the clinical trial CT TG01-01 investigating TG01 in operable pancreatic cancer.

It was already reported on November 3<sup>rd</sup> that primary endpoint regarding immune response and side effects was reached for the clinical trial CT TG01-01.

Further process development and production to assure appropriate product quality for the next step of clinical development progressed according to plan.

For TG02, pre-clinical testing was initiated and production of clinical trial materials progressed according to plan.

During the last months, Targovax has expanded the experienced and professional team, totally counting 9 persons in January 2015.

KEY FIGURES				
NOK 1000	Q4 2014	Q4 2013	2014	2013
Total operating revenues	2 869	1 446	4 874	4 701
Net expenses	-11 310	-3 708	-22 289	-11 831
Operating profit/loss	-8 440	-2 262	-17 415	-7 130
Financial items, net	9	17	-2	-15
<b>NET PROFIT/LOSS</b>	<b>-8 432</b>	<b>-2 245</b>	<b>-17 417</b>	<b>-7 144</b>
Basic and diluted earnings (loss) per share	-0,89	-0,48	-2,46	-1,70
Number of employees end of period	6	4	6	4
Net change in bank deposits, cash and equivalents	-6 460	7 731	54 179	5 057
Bank deposits, cash and equivalents at the beginning of period	69 009	639	8 370	3 313
<b>BANK DEPOSITS, CASH AND EQUIVALENTS AT END OF PERIOD</b>	<b>62 549</b>	<b>8 370</b>	<b>62 549</b>	<b>8 370</b>

## OPERATIONAL REVIEW

On January 8<sup>th</sup>, Targovax reported completion of recruitment of 18 patients in the clinical trial CT TG01-01 investigating TG01 in operable pancreatic cancer.

It was already reported on November 3<sup>rd</sup> that primary endpoint for the ongoing clinical trial CT TG01-01, regarding immune response and side effects, was already reached.

The lead product TG01 is under development for the treatment of resected (operated) pancreatic cancer. Pancreatic cancer affects 116 000 patients per year in the EU and USA, of whom 16-20 000 are resectable (2011 figures, [www.globocan.iarc.fr](http://www.globocan.iarc.fr)). Approximately 90% of pancreatic cancers have RAS mutations (Prior et al, 2012). Targovax has obtained Orphan Drug Designation for TG01 for the treatment of pancreatic cancer in the EU and USA.

The phase I/II clinical trial CT TG01-01 is ongoing at internationally renowned clinical centers: Oslo University Hospital, the Norwegian Radium Hospital (Oslo, Norway), The Christie Hospital, Manchester, UK and Clatterbridge Cancer Centre, Liverpool University, Liverpool, UK. The trial is an open label, single-arm phase I/II trial, 18 patients have been recruited according to plan and timelines. The primary objectives of the trial are safety and immune response to TG01 vaccination when combined with gemcitabine (endpoint reached as reported above). The secondary objective is survival at two years.

For TG02, pre-clinical testing and production of clinical trial materials are ongoing.

During the last months, Targovax has expanded the experienced and professional team.

New employments include Cecilie Stenstadvold Sverdrup as Clinical Research Manager, Annbjørg Eide Falck as Senior Project Manager, Tina Madsen as VP Quality Assurance, Anne-Kirsti Aksnes as VP Clinical development and Gunnar Gårdemyr as CEO. With this, Targovax is well positioned to plan and execute Proof of Concept studies.

## FINANCIAL REVIEW

Figures in brackets are from the comparable period in 2013.

### Results 4th Quarter 2014 and YTD

Revenues amounted to 2.9 MNOK (1.4MNOK) in the fourth quarter and 4.9 MNOK (4.7 MNOK) in 2014. The revenues are mainly governmental grants received by Targovax to support its product development projects.

Operating expenses amounted to 11.3 MNOK (3.7 MNOK) in the fourth quarter and 22.3 MNOK (11.8 MNOK) YTD 2014. The increase in other operating costs reflects increased product testing activities.

The net loss for the period amounted to 8.4 MNOK (2.2 MNOK) in the fourth quarter and NOK 17.4 MNOK (7.1 MNOK) YTD 2014.

### Financial position and cash flow

The shareholders' equity and bank deposits decreased 8.4 MNOK and 6.5 MNOK in Q4 2014 due to operational activities. Shareholders' equity was 60.7 MNOK (0.2 MNOK) and the bank deposits amounted to 62.5 MNOK (8.4 MNOK) at the end of Q4 2014. The cash amounted 93% of total assets.

## RISK FACTORS AND FORWARD-LOOKING STATEMENTS

This report contains certain forward-looking statements based on uncertainty, since they relate to events and depend on circumstances that will occur in future and which, by their nature, will have an impact on the results of operations and the financial condition of Targovax. Such forward-looking statements reflect the current views of Targovax and are based on the information currently available to the company. Targovax cannot give any assurance as to the correctness of such statements. There are a number of factors that could cause actual results and developments to differ materially from those expressed or implied in these forward-looking statements. These factors include, among other things, risks or uncertainties associated with the success of future clinical trials; risks relating to personal injury or death in connection with clinical trials or following commercialization of the company's products, and liability in connection therewith; risks relating to the company's freedom to operate (competitors patents) in respect of the products it develops; risks of non-approval of patents not yet granted and the company's ability to adequately protect its intellectual property and know-how; risks relating to obtaining regulatory approval and other regulatory risks relating to the development and future commercialization of the company's products; risks that research and development will not yield new products that achieve commercial success; risks relating to the company's ability to successfully commercialize and gain market acceptance for Targovax's products; risks relating to the future development of the pricing environment and/or regulations for pharmaceutical products; risks relating to the company's ability to secure additional financing in the future, which may not be available on favorable terms or at all; risks relating to currency fluctuations; risks associated with technological development, growth management, general economic and business conditions; risks relating to the company's ability to retain key personnel; and risks relating to the impact of competition.

## OUTLOOK

Targovax's focus in the next 12 months will be on continued development of its lead product TG01 and other products in the pipeline:

- › Produce TG02 for clinical development
- › Establish pre-clinical documentation to support a Clinical Trial Application for phase I development of TG02
- › Develop protocol for first clinical trial with TG02
- › Develop the clinical trial design of a randomized phase II clinical trial with TG01 in resected pancreatic cancer
- › 12 months interim results of CT TG01-01 will be published Q1 2016
- › Final selection of GM-CSF manufacturer initiated. GM-CSF is used as immune-modulator to enhance TG01 and TG02 immune-responses

Targovax will continue to strengthen its organization and infrastructure to meet its objectives.

<b>STATEMENT OF PROFIT AND LOSS, UNAUDITED</b>				
<b>NOK 1000</b>	<b>Q4 2014</b>	<b>Q4 2013</b>	<b>2014</b>	<b>2013</b>
<b>OPERATING REVENUES</b>				
Grants	2 848	1 417	4 801	4 337
Other revenues	21	29	72	364
<b>TOTAL OPERATING REVENUES</b>	<b>2 869</b>	<b>1 446</b>	<b>4 874</b>	<b>4 701</b>
<b>OPERATING EXPENSES</b>				
Payroll expenses	-3 215	-1 420	-6 600	-4 721
Other operating expenses	-8 095	-2 289	-15 689	-7 110
<b>TOTAL OPERATING EXPENSES</b>	<b>-11 310</b>	<b>-3 708</b>	<b>-22 289</b>	<b>-11 831</b>
<b>OPERATING PROFIT/LOSS</b>	<b>-8 440</b>	<b>-2 262</b>	<b>-17 415</b>	<b>-7 130</b>
<b>NET FINANCIAL ITEMS</b>	<b>9</b>	<b>17</b>	<b>-2</b>	<b>-15</b>
<b>PROFIT/LOSS FOR THE PERIOD</b>	<b>-8 432</b>	<b>-2 245</b>	<b>-17 417</b>	<b>-7 144</b>
<b>ALLOCATION OF PROFIT/LOSS FOR THE PERIOD</b>				
Transferred to other equity	-8 432	-2 245	-17 417	-7 144
<b>TOTAL ALLOCATIONS</b>	<b>-8 432</b>	<b>-2 245</b>	<b>-17 417</b>	<b>-7 144</b>

STATEMENT OF BALANCE SHEET, UNAUDITED		
NOK 1000	31.12.2014	31.12.2013
<b>ASSETS</b>		
Office furnitures	150	-
<b>TOTAL FIXED ASSETS</b>	<b>150</b>	<b>-</b>
<b>Receivables</b>		
Trade debtors	26	189
Other receivables	4 634	5 637
<b>TOTAL RECEIVABLES</b>	<b>4 660</b>	<b>5 826</b>
Bank deposits	62 549	8 370
<b>TOTAL CURRENT ASSETS</b>	<b>67 209</b>	<b>14 197</b>
<b>TOTAL ASSETS</b>	<b>67 359</b>	<b>14 197</b>
<b>EQUITY AND LIABILITIES</b>		
<b>EQUITY</b>		
<b>Paid-up equity</b>		
Share capital	943	470
Share premium reserve	97 792	20 368
<b>TOTAL PAID-UP EQUITY</b>	<b>98 735</b>	<b>20 839</b>
<b>Retained earnings</b>		
Other equity	-38 054	-20 637
<b>TOTAL RETAINED EARNINGS</b>	<b>-36 905</b>	<b>-20 637</b>
<b>TOTAL EQUITY</b>	<b>60 681</b>	<b>201</b>
<b>LIABILITIES</b>		
<b>Short-term liabilities</b>		
Trade creditors	2 564	2 657
Unpaid public charges	768	454
Other short-term liabilities	3 346	10 884
<b>TOTAL SHORT-TERM LIABILITIES</b>	<b>6 678</b>	<b>13 996</b>
<b>TOTAL LIABILITIES</b>	<b>6 678</b>	<b>13 996</b>
<b>TOTAL SHORT-TERM LIABILITIES</b>	<b>67 359</b>	<b>14 197</b>

## NOTES TO THE INTERIM FINANCIAL STATEMENTS, UNAUDITED

### 1. GENERAL INFORMATION

Targovax AS is a limited company, domiciled in Norway. Its headquarters are situated in Vollsveien 6, 1366 Lysaker.

The figures in this fourth quarter report 2014 are non-audited figures.

The financial statements were approved for issue by the Board of Directors on 12 December 2014.

### 2. BASIS FOR PREPERATION AND SIGNIFICANT ACCOUNTING POLICIES

The accounting principles for this interim report are based on the Norwegian Accounting Act and the Norwegian accounting standard for small businesses (NRS 8).

There are no changes in principles described in the annual report issued for 2013.

### 3. CHANGE IN BANK DEPOSITS, CASH AND EQUIVALENTS

NOK 1000	Q4 2014	Q4 2013	2014	2013
Loss for the period	-8 432	-2 245	-17 417	-7 144
Adjustmentes for net financials	-9	-17	2	15
Adjustments for change in working capital	1 971	1 786	3 860	-1 289
<b>NET CASH FLOW FROM OPERATING ACTIVITIES</b>	<b>-6 469</b>	<b>-476</b>	<b>-13 556</b>	<b>-8 418</b>
Purchase of office furnitures	-	-	-160	-
<b>NET CASH FLOW FROM INVESTMENT ACTIVITIES</b>	<b>-</b>	<b>-</b>	<b>-160</b>	<b>-</b>
Net financials and share issue expenses	9	17	-4 605	-15
Proceeds from debt	-	8 190	-10 000	5 990
Proceeds from equity issue	-	-	82 500	7 500
<b>NET CASH FLOW FINANCING ACTIVITIES</b>	<b>9</b>	<b>8 207</b>	<b>67 895</b>	<b>13 475</b>
Net change in bank deposits, cash and equivalents	-6 460	7 731	54 179	5 057
Bank deposits, cash and equivalents at beginning of period	69 009	639	8 370	3 313
<b>BANK DEPOSITS, CASH AND EQUIVALENTS AT END OF PERIOD</b>	<b>62 549</b>	<b>8 370</b>	<b>62 549</b>	<b>8 370</b>

### 4. CHANGE IN EQUITY

NOK 1000	Share capital	Share premium reserve	Other equity	Total
Equity 01.01.2013	370	12 968	-13 493	-155
Share issue	100	7 400	0	7 500
Profit/loss YTD Q32013	0	0	-4 900	-4 900
Equity 30.09.2013	470	20 368	-18 393	2 446
Profit/loss Q4 2013	-	-	-2 245	-2 245
<b>EQUITY 31.12.2013</b>	<b>470</b>	<b>20 368</b>	<b>-20 637</b>	<b>201</b>
Equity 01.01.2014	470	20 368	-20 637	201
Share issue *)	473	77 424	0	77 896
Profit/loss YTD Q32014	0	0	-8 985	-8 985
Equity 30.09.2014	943	97 792	-29 623	69 112
Profit/loss Q4 2014	-	-	-8 432	-8 432
<b>EQUITY 31.12.2014</b>	<b>943</b>	<b>97 792</b>	<b>-38 054</b>	<b>60 681</b>

\*) Share issue expenses, 4,6 million NOK charged directly to share premium reserve.

## 5. NUMBER OF SHARES AND SHARE OPTIONS

Movement in the number of shares	2014	2013
Ordinary shares at 1 January	4 703 000	3 703 000
Issue of ordinary shares YTD Q3	4 726 404	1 000 000
Issue of ordinary shares Q4	-	-
<b>ORDINARY SHARES AT 31 DECEMBER</b>	<b>9 429 404</b>	<b>4 703 000</b>

The nominal value of the shares is NOK 0.10.  
All shares carry equal voting rights.

### SHARE OPTIONS

100.000 share options have been issued to key employers with an exercise price NOK 7.50.

The shareoptions can be exercised as follows:

- 34.000 between 5 November 2013 and 5 November 2017
- 33.500 between 5 November 2014 and 5 November 2017
- 32.500 between 5 November 2015 and 5 November 2017

## 6. EARNINGS PER SHARE

Movement in the number of shares	Q4 2014	Q4 2013	2014	2013
Loss for the period (NOK 1000)	-8 432	-2 245	-17 417	-7 144
Average number of outstanding shares during the period	9 429 403	4 703 000	7 066 202	4 203 000
<b>EARNING(LOSS) PER SHARE - BASIC AND FULLY DILUTED</b>	<b>-0,89</b>	<b>-0,48</b>	<b>-2,46</b>	<b>-1,70</b>

Share options issued have a potential dilutive effect on earnings per share. No dilutive effect has been recognized as the company is currently loss-making. Hence an increase of number of shares would decrease loss per share (anti-dilutive effect).

## 7. SHAREHOLDER INFORMATION

Shareholders per 31 December 2014	Shares	Owner share
RADIUMHOSPITALET FORSKNINGSTIFTELSE	3 410 589	36,2 %
DATUM INVEST AS	1 162 000	12,3 %
TIMMUNO AS	724 650	7,7 %
PRIETA AS	720 000	7,6 %
BIRK VENTURE AS	438 657	4,7 %
ALGOT INVEST AS	392 465	4,2 %
PORTIA AS	300 000	3,2 %
TRYGVE SCHIØRBECKS E	286 449	3,0 %
ARCTIC FUNDS PLC BNY MELLON SA/NV	182 000	1,9 %
OP-EUROPE EQUITY FUN C/O CITIBANK NA	157 869	1,7 %
<b>TOTAL, 10 LARGEST SHAREHOLDERS</b>	<b>7 774 679</b>	<b>82,5 %</b>
78 other shareholders, each representing an ownership of less than 1.7%	1 654 724	17,5 %
<b>TOTAL, 88 SHAREHOLDERS</b>	<b>9 429 403</b>	<b>100,0 %</b>

Key persons with shares and share options in the company:			Shares	Share options
Hans Ivar Robinson	Board member	Indirect through Birk Venture AS	438 657	-
Tom A. Thorsen	Board member	Indirect thorough Algot Invest AS	392 465	-
Hanne M. D. Kristensen	CEO	Direct ownership	10 160	50 000
Jon Amund Eriksen	COO	Indirect through Timmuno AS	724 650	-
Berit Iversen	Vice President	Direct ownership	3 254	25 000
Gustav Gaudernack	Chief Scientific Advisor	Indirect through Prieta AS	720 000	-



## **INFORMATION**

### **Targovax AS**

Vollsveien 6, 1366 Lysaker, Norway

Tel. (+47) 21 39 88 10

E-mail: [info@targovax.com](mailto:info@targovax.com)

[www.targovax.com](http://www.targovax.com)

### **Gunnar Gårdemyr**

Chief Executive Officer

Tel. (+41) 798 340 585

E-mail: [ggardemyr@targovax.com](mailto:ggardemyr@targovax.com)

### **Gunnar Aarnes**

Chief Financial Officer

Tel. (+47) 93 40 38 49

E-mail: [gaarnes@targovax.com](mailto:gaarnes@targovax.com)