vaccibody

Company overview

Vaccibody AS is a privately held vaccine company based on the technology conceived at the University of Oslo and Oslo University Hospital in the laboratories of Professors Bjarne Bogen and Inger Sandlie. Vaccibody AS has developed a unique and innovative vaccine platform with the aim to treat and prevent pre-cancerous diseases or cancer as well as infectious diseases. Through its innovative design Vaccibody AS's proprietary vaccine platform generates rapid, durable and broad antibody and T cell responses leading to remarkably potent vaccines.

Vaccibody has developed compelling preclinical data and initiated the first clinical trial with VB10.16, a therapeutic vaccine against cervical precancerous lesion. In parallel, Vaccibody is exploring the novel and promising area of neoantigen-based individualized cancer vaccines and is using the Vaccibody technology to generate first-in-class therapeutics to treat cancers with a high unmet medical need.

Highlights for the 2nd quarter 2016 (April-June)

- Clinical Trial VB C-01:
  - Dosing of patients in phase I completed
  - No safety concerns observed
  - Data cleaning for phase I and preparation of interim analysis for dosing regimen selection
  - Analysis initiation of T cell response (ELISpot Assays) for all patients in the phase I
- Neoantigen-based individualized cancer vaccine program
  - Initiation of the cancer neoantigen program funded by BIA with NOK 20 mill
  - Selection of contract manufacturer for the GMP production of patient specific cancer neoantigen vaccines
  - Planning of an expert meeting to discuss clinical trial indications
- Closed a private placement of 300,000 new shares at a price of 80 NOK/share, raising NOK 24 million in new equity/cash. The private placement attracted subscriptions from new investors but ended up being oversubscribed by existing shareholders alone. The subscription took place in the end of June, but was registered and paid in July, hence will be recognized in the 3rd quarter

Key figures	2nd quarter		6 months		Full year
Amounts in NOK 1,000	**2016**	**2015**	**2016**	**2015**	**2015**
Total revenue and other income	1 884	1 426	3 174	2 852	5 623
Total operating expenses	5 216	3 857	11 037	9 339	18 931
Operating profit (loss)	**-3 332**	**-2 432**	**-7 863**	**-6 487**	**-13 307**
Net profit (loss) for the period	**-3 304**	**-2 327**	**-7 767**	**-6 308**	**-13 091**
Net proceeds from equity issue	106	56	106	556	556
Net cash flow	-4 117	-4 143	-8 378	-6 869	-12 289
Cash and cash equivalents, end of period	8 711	22 507	8 711	22 507	17 088
Outstanding shares, beginning of period	1 215 349	1 197 819	1 215 349	1 197 819	1 197 819
Outstanding shares, end of period	1 220 639	1 200 619	1 220 639	1 200 619	1 215 349
Employees, end of period	6	3	6	3	5

VB10.16 Clinical Development

The Company's core focus in Q2 2016 was to complete the dosing of all patients in phase I of the first-in human study for VB10.16 with the title "An exploratory, safety and immunogenicity study of the human papillomavirus (HPV16) immunotherapy VB10.16 in women with high grade cervical intraepithelial neoplasia (HSIL; CIN 2/3)". This important milestone was achieved in April 2016. During this first phase, two different vaccination schedules of VB10.16 are tested to select the best regimen for the subsequent expansion phase (phase IIa). This decision as to which vaccination schedule to move forwards with in phase IIa will be based on the assessment of the HPV16 specific immune responses as well as on the clinical responses.

The treatment has been tolerated by all patients. No serious adverse events, no significant systemic or local site reactions has been observed. A detailed analysis of the safety, immunogenicity and clinical efficacy of all patients in the phase I will be released in Q3 2016 to support the selection of dosing regimen in phase IIa.

Other operations

Vaccibody is exploring the exciting field of targeted personalized neoantigen-based cancer vaccines. With the support from NRC's BIA Program (20 million NOK over a four-year period), Vaccibody has performed a number of preclinical proof of concept studies. Results confirm that the Vaccibody DNA vaccine platform is ideally suited to induce rapid and strong neoantigen-specific immune responses. The ideal format concerning number and order of neoepitopes, linkers and vaccination regimens to support further clinical development has now been established. Therapeutic vaccination in the B16 model supports VB10.NEO's strong potential to fight tumours. Vaccibody has initiated a collaboration with three different bioinformatic companies developing algorithms to improve prediction of immunogenic neoepitopes. Novel Vacccibody experimental vaccines based on these analysis are being produced and will be evaluated in the B16 melanoma model and CT26 colon carcinoma model in mice.

A patient-specific manufacturing procedure has been designed and an experienced manufacturer has been selected.

At a Scientific Advice Meeting on 2 June 2016 with the German regulatory authorities, the Paul Ehrlich Institute, supported our proposed manufacturing strategy enabling rapid manufacturing of patient-specific vaccines on demand with high quality. Development work to further support the clinical trial application is now under preparation. Importantly, the Paul Ehrlich Institute also accepted the preclinical and clinical safety documentation with VB10.16 as sufficient to move into the clinic with VB10.NEO without further preclinical safety and toxicity studies. A subsequent Scientific Advice Meeting will be performed to in detail discuss the clinical trial design of the potential study(ies).

Financial review

Profit and loss statement
Other income in the first six months of 2016 was KNOK 3,168 compared to KNOK 2,852 in the same period of 2015. The new BIA-grant for the neoantigen program is effective from 2Q16, and the Skattefunn-grant is expected to be higher for 2016 than 2015 due to higher R&D expenses.

Total operating expenses were increased to KNOK 11,037 in the first six months of 2016 from KNOK 9,339 in the same period in 2015. *Payroll and related expenses* was KNOK 3,115 compared to KNOK 1,797 in the same period of 2015. In the first six months of 2015 the Company had an interim CEO on a consultancy contract, hence the expenses were recognized as Other operating expenses. Further, staff has increased by two employees in addition to the new CEO in first six months of 2016 compared to the same period in 2015. *Procurement of R&D services and IP expenses* was stable at KNOK 5,298 in the first six months of 2016 compared to KNOK 5,329 in the same period of 2015, as increased costs for the clinical development (VB10.16) was offset by lower expenses for pre-clinical development and GMP manufacturing. *Other operating expenses* increased to KNOK 2,575 in the first six months of 2016 compared to KNOK 2,155 in the same period of 2015, mainly due to expenses for the neoantigen program.

Statement of financial position
On June 30, 2016, Vaccibody had total assets of KNOK 14,742, hereunder *Cash and cash equivalents* of KNOK 8,711 and *Receivables* of KNOK 5,597. *Receivables* include mainly grants earned and to be received later in 2016. *Shareholders' equity* was KNOK 9,966.

The Company has recently closed a private placement of 300,000 new shares at a price of 80 NOK/share, raising NOK 24 million in new equity/cash. The private placement attracted subscriptions from new investors but ended up being oversubscribed by existing shareholders alone. The subscription took place in the end of June, but was registered and paid in July, hence will be recognized in the 3rd quarter.

Outlook

For the upcoming twelve months, the Company's plans include:

- Clinical Trial VB C-01

- Final analysis of the dosing phase (Phase I)
- Selection of vaccination schedule for extension phase (phase IIa)
- Initiation of the extension phase (phase IIa)
- Interim reporting from the extension phase (phase IIa)

Continued work towards clinical development of targeted personalized neoantigen-based cancer vaccines including more supportive preclinical experiments. The Company is in continuous dialogue with academic and industrial entities and will announce new collaborations and partnerships when they may occur.

The Company now has cash and expected grants receivable sufficient to carry out the phase I and phase IIa clinical trial VB C-01, as well as preparatory work towards clinical development of targeted personalized neoantigen-based cancer vaccines. Based on the current plan for R&D activities, the Company has a cash runway through 2017. For the longer term financing and for financing of the neoantigen-based individualized cancer vaccine program, the Company will need additional funding and will announce the plan for such funding in due course.

Profit and loss statement	*2nd quarter*		*6 months*		*Full year*
NOK 1,000	**2016**	**2015**	**2016**	**2015**	**2015**
Revenue	-	-	6	-	-
Other income	1 884	1 426	3 168	2 852	5 623
Payroll and related expenses	1 114	952	3 115	1 797	5 269
Procurement of R&D services and IP expenses	2 807	1 778	5 298	5 329	9 209
Depreciation	18	29	48	58	116
Other operating expenses	1 277	1 098	2 575	2 155	4 337
Total operating expenses	**5 216**	**3 857**	**11 037**	**9 339**	**18 931**
Operating profit (loss)	**-3 332**	**-2 432**	**-7 863**	**-6 487**	**-13 307**
Net financial items	**28**	**104**	**96**	**179**	**216**
Profit (loss) before income tax	**-3 304**	**-2 327**	**-7 767**	**-6 308**	**-13 091**
Income tax	-	-	-	-	-
Net profit (loss) for the period	**-3 304**	**-2 327**	**-7 767**	**-6 308**	**-13 091**

Statement of financial position							
NOK 1,000	**30.06.16**	**31.03.16**	**31.12.15**	**30.09.15**	**30.06.15**	**31.03.15**	**31.12.14**
Intangible assets	300	300	300	300	300	300	300
Property, plant and equipment	134	152	117	156	175	204	233
Total non-current assets	**434**	**452**	**417**	**455**	**475**	**504**	**532**
Trade receivables	***164***	***55***	***238***	***59***	***213***	***186***	***148***
Grants receivable	***5 433***	***4 061***	***3 679***	***4 247***	***3 722***	***3 198***	***3 981***
Receivables	5 597	4 116	3 917	4 306	3 935	3 384	4 130
Cash and cash equivalents	8 711	12 828	17 088	19 178	22 507	26 651	29 377
Total current assets	**14 308**	**16 944**	**21 005**	**23 484**	**26 442**	**30 034**	**33 506**
Total assets	**14 742**	**17 396**	**21 422**	**23 940**	**26 917**	**30 538**	**34 039**
Share capital	1 221	1 215	1 215	1 201	1 201	1 198	1 198
Share premium	55 254	55 154	55 154	54 669	54 669	54 616	54 616
Retained earnings (accumulated losses)	-46 509	-43 205	-38 742	-34 607	-31 959	-29 631	-25 651
Shareholders' equity	**9 966**	**13 164**	**17 627**	**21 262**	**23 910**	**26 182**	**30 162**
Accounts payable	1 420	408	1 293	468	707	2 687	1 785
Other current liabilities	3 356	3 824	2 502	2 209	2 299	1 669	2 092
Current liabilities	**4 776**	**4 232**	**3 795**	**2 678**	**3 007**	**4 356**	**3 876**
Total liabilities	**4 776**	**4 232**	**3 795**	**2 678**	**3 007**	**4 356**	**3 876**
Total Equity and Liabilities	**14 742**	**17 396**	**21 422**	**23 940**	**26 917**	**30 538**	**34 039**

Statement of changes in equity				
NOK 1,000				
	Share capital	**Share premium**	**Accumulated losses**	**Total equity**
Balance at 01.01.2015	**1 198**	**54 616**	**-25 651**	**30 162**
Loss for the period			-13 091	-13 091
Issue of ordinary shares	18	538		556
Balance at 31.12.2015	**1 215**	**55 154**	**-38 742**	**17 627**
Balance at 01.01.2016	**1 215**	**55 154**	**-38 742**	**17 627**
Loss for the period			-7 767	-7 767
Issue of ordinary shares	5	101		106
Balance at 30.06.2016	**1 221**	**55 254**	**-46 509**	**9 966**

Statement of cash flow *NOK 1,000*	*6 months* **2016**	 **2015**	*Full year* **2015**
Loss for the period	**-7 767**	**-6 308**	**-13 091**
Adjustments for:			
Interest income	-139	-145	-426
Interest expenses	104	0	205
Depreciation	48	58	116
Change in trade receivables	74	-65	-90
Change in trade payables	127	-1 077	-492
Change in receivables related to grants	-1 754	260	303
Change in other current liabilities	854	208	410
Net cash flow from operating activities	**-8 454**	**-7 070**	**-13 065**
Purchase of property, plant and equipment	-65	0	0
Interest income	139	145	426
Net cash flow from investing activities	**74**	**145**	**426**
Interest expenses	-104	0	-205
Proceeds from equity issue	106	56	556
Net cash flow from financing activities	**2**	**56**	**351**
Net change in cash and cash equivalents	**-8 378**	**-6 869**	**-12 289**
Cash and cash equivalents at begining of period	17 088	29 377	29 377
Cash and cash equivalents at end of period	**8 711**	**22 507**	**17 088**

Notes to the Quarterly Financial Statement

Note 1 Accounting policies

The financial statements of Vaccibody AS for 2015 and 2016 are presented in accordance with the Norwegian Accounting Act and generally accepted accounting principles for small-size companies.

Note 2 Other income

Vaccibody AS has a contract with the Norwegian Research Council regarding a grant under the BIA-programme for the development of VB10.16. The total amount available to the Company under the contract is MNOK 15.5 for the period 2012-2016. The Company has recognized MNOK 4.4, MNOK 6.4 and MNOK 2.7 of the grant in 2013, 2014 and 2015 respectively, and MNOK 0.8 in the first six months of 2016.

Vaccibody AS has a contract with the Norwegian Research Council regarding a grant under the BIA-programme for its neo-antigen programme. The total amount available to the Company under the contract is MNOK 19.9 for the period 2016-2020. The Company has recognized MNOK 0.6 in the first six months of 2016.

Vaccibody AS is part of a consortium in the ADITEC-programme, which is funded by the European Union's Seventh Programme. The Company recognized MNOK 0.5, MNOK 0.3 and MNOK 0.1 of this grant in 2013, 2014 and 2015 respectively.

Vaccibody AS is part of the consortium "SAPHIR", which is funded by the European Union's Horizon 2020 programme. The Company recognized MNOK 0.04 of this grant in 2015.

Vaccibody AS is eligible for grant under the Norwegian Skattefunn programme. The Company has recognized MNOK 1.33, MNOK 1.77 and MNOK 2.77 of the grant in 2013, 2014 and 2015 respectively, and MNOK 1.8 in the first six months of 2016.

Note 3 Share capital and shareholders

Table of shareholders as of June 30, 2016:

Shareholder	Shares	Ownership
Sarsia Seed AS	291 240	23,86 %
Radiumhospitalets forskningsstiftelse	205 570	16,84 %
Datum Invest AS	134 500	11,02 %
Inven2 AS *(1)*	90 270	7,40 %
Kreftforeningen	61 800	5,06 %
Portia AS	52 200	4,28 %
OM Holding AS	39 100	3,20 %
Arctic Funds PLC	28 500	2,33 %
MP Pensjon PK	26 100	2,14 %
Oslotech AS	20 670	1,69 %
Other	270 689	22,18 %
Total	**1 220 639**	100,00 %

(1) Inven2 AS holds 33 000 shares on behalf of the inventors of the Company's technology, Bjarne Bogen, Inger Sandlie and Agnete B. Fredriksen.

On June 21, 2016, the Company closed a subscription for 300,000 new shares in a private placement. The new shares were registered and issued in July 2016.
The Company has issued 98,370 warrants to inventors, key employees, former employees and members of the board.

Disclaimer

This quarterly report contains certain forward-looking statements relating to the business, financial performance and results of the Company and/or the industry in which it operates. Forward-looking statements concern future circumstances and results and other statements that are not historical facts, sometimes identified by the words "believes", "expects", "intends", "anticipates", "targets", and similar expressions. The forward-looking statements contained in this quarterly report, including assumptions, opinions and views of the Company or cited from third party sources are solely opinions and forecasts, which are subject to risks,

uncertainties and other factors that may cause actual events to differ materially from any anticipated development. Neither the Company nor any of its Directors, officers or employees provides any assurance that the assumptions underlying such forward-looking statements are free from errors nor does any of them accept any responsibility for the future accuracy of the opinions expressed in this quarterly report or the actual occurrence of the forecasted developments. The Company assumes no obligation, except as required by law, to update any forward-looking statements or to conform these forward-looking statements to our actual results.