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 3rd quarter 2016 (July-September)

- Clinical Trial VB C-01:
  - Positive results from phase I interim analysis including:
    - i) No safety concerns observed
    - ii) Increase in T cell response (ELISpot Assays) in 12 out of 14 patients tested
    - iii) Regression to CIN 1 or no disease in 4 of 8 patients after 4 months in cohort 1 (a total of 8 patients evaluated after 4 months)
    - iv) Regression to CIN 1 or no disease in of 3 out of 4 patients after 6 months in cohort 1 (a total of 4 patients evaluated after 6 months)
    - v) Clear correlation between peripheral immune response and clinical response
  - Selection of Cohort 1 vaccination schedule (vaccination at 0, 3 and 6 weeks) for clinical phase IIa
  - Test method problems with potency assay for VB10.16 delaying start of phase IIa, most likely until December or January.

- Neoantigen-based individualized cancer vaccine programme
  - Expansion of in-house preclinical body of data to support clinical development with positive results
  - Generation of promising data together with external bioinformatics companies to optimize cancer neoantigen prediction
  - Selection of indications for first clinical trials with VB10.NEO

Key figures	3rd quarter		9 months		Full year
Amounts in NOK 1,000	**2016**	**2015**	**2016**	**2015**	**2015**
Total revenue and other income	1 884	1 427	5 058	4 278	5 623
Total operating expenses	7 217	4 030	18 254	13 369	18 931
Operating profit (loss)	**-5 333**	**-2 603**	**-13 196**	**-9 090**	**-13 307**
Net profit (loss) for the period	**-5 310**	**-2 648**	**-13 077**	**-8 956**	**-13 091**
Net proceeds from equity issue	23 609	-	23 714	556	556
Net cash flow	18 230	-10 199	9 853	-10 199	-12 289
Cash and cash equivalents, end of period	26 941	19 178	26 941	19 178	17 088
Outstanding shares, beginning of period	1 220 639	1 200 619	1 215 349	1 197 819	1 197 819
Outstanding shares, end of period	1 520 639	1 200 619	1 520 639	1 200 619	1 215 349
Employees, end of period	7	5	7	5	5

VB10.16 Clinical Development

The Company's core focus in Q3 2016 was to complete the interim analysis of the dosing phase (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)". During this first phase, two different vaccination schedules of VB10.16 are tested. The selection of the best vaccination regimen for the subsequent expansion phase (phase IIa) was based on the 4 months data available.

A total of 16 patients were included, 8 patients in each cohort have been administered with VB10.16. All patients received 3 vaccinations with 3 mg/ml VB10.16 at pre-specified time-points. The treatment has been tolerated by all patients. No dose limiting toxicities or serious adverse events have been observed. Most adverse events reported were transient mild to moderate administration site reactions. There were no significant changes over time in mean haematology and clinical chemistry variables or in vital signs or performance status.

VB10.16 induced strong HPV16 specific immune responses. Six of the seven patients tested in each cohort demonstrated an increase in HPV16-specific T cell responses in peripheral blood mononuclear cells (PBMCs) analysed by IFN-γ ELISpot assay post vaccination.

VB10.16 demonstrated clear signs of clinical efficacy. The data after 4 months show that 4 out of 8 patients in the shorter vaccination regimen (cohort 1) has regression to CIN 1 or no lesion (a total of 8 patients evaluated after 4 months). After 6 months 3 out of 4 patients have regression to CIN1 or no lesion (a total of 4 patients evaluated after 6 months). In the longer vaccination regimen (cohort 2), 2 out of 7 patients have regression to CIN1 or no lesion after 4 months (a total of 7 patients evaluated after 4 months). After 6 months 2 out of 4 patients have regression to CIN1 or no lesion (a total of 4 patients evaluated after 6 months). These clinical observations correlated with the peripheral T cell response in each individual patient. Follow up of the patients will continue until 12 months after the initial vaccination.

The upstart of the clinical phase IIa unfortunately has been postponed as we have experienced a test problem with the assay determining the potency of VB10.16. This issue has been scrutinised and a series of experiments have been set up to produce data to elucidate the situation. As we have already generated data strongly suggesting that the potency of VB10.16 is acceptable, we are hopeful that we can start enrolling patients in the phase IIa in December or January. The phase IIa study is planned to enrol 15-20 patients with CIN2/3 in contrast to the phase I study which only enrolled CIN2 patients.

Other operations

Vaccibody is continuing to build a strong preclinical package for the neoantigen-based cancer vaccine programme. The company has strongly emphasised development of bioinformatic strategies to improve prediction of immunogenic neoepitopes in collaboration with three bioinformatics companies including in vivo analysis of immunogenicity and anti-tumour efficacy.

Vaccibody has signed a contract with a manufacturer with expertise in patient-specific vaccine manufacturing on demand. A development batch and a pilot batch will be initiated in Q4 2016 to generate manufacturing and stability data to support the clinical trial application.

Vaccibody has together with our advisors and KOLs in the field selected two indications for the first clinical trials with VB10.NEO. A process is ongoing to fine-tune patient selection, study design and the planning of the overall conduct of the clinical study in the context of an individualized approach. The evaluation of clinical research organisations capable to support Vaccibody with such a complex clinical trial has been initiated.

Financial review

Profit and loss statement
Other income in the first nine months of 2016 was KNOK 5,052 compared to KNOK 4,278 in the same period of 2015. The new BIA-grant for the neoantigen programme 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 18,254 in the first nine months of 2016 from KNOK 13,369 in the same period in 2015. *Payroll and related expenses* was KNOK 5,658 compared to KNOK 3,082 in the same period of 2015. In the first seven 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 person-years in addition to the new CEO in first nine months of 2016 compared to the same period in 2015. *Procurement of R&D services and IP expenses* increased to KNOK 8,800 in the first nine months of 2016 compared to KNOK 7,024 in the same period of 2015, due to increased costs for clinical development following the initiation of the clinical trial VB C-01 in September 2015. *Other operating expenses* increased to KNOK 3,736 in the first nine months of 2016 compared to

KNOK 3,185 in the same period of 2015, mainly due to expenses for the neoantigen programme.

Statement of financial position
On September 30, 2016, Vaccibody had total assets of KNOK 34,208, hereunder *Cash and cash equivalents* of KNOK 26,941 and *Receivables* of KNOK 6,845. *Receivables* include mainly grants earned and to be received later in accordance with the applicable payment schedules. *Shareholders' equity* was KNOK 28,264, following the share issue of KNOK 24 million completed in July 2016.

Outlook

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

- Clinical Trial VB C-01
  - Final analysis of the dosing phase (Phase I)
  - 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, with special focus on improved, VB10.NEO-specific neoepitope selection tools.
- The Company is in continuous dialogue with academic and industrial entities and will announce new collaborations and partnerships when they may occur.

The Company 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 programme, the Company will need additional funding and will announce the plan for such funding in due course.

Profit and loss statement	*3rd quarter*		*9 months*		*Full year*
NOK 1,000	**2016**	**2015**	**2016**	**2015**	**2015**
Revenue	-	-	6	-	-
Other income	1 884	1 427	5 052	4 278	5 623
Payroll and related expenses	2 543	1 285	5 658	3 082	5 269
Procurement of R&D services and IP expenses	3 501	1 695	8 800	7 024	9 209
Depreciation	12	19	60	77	116
Other operating expenses	1 161	1 030	3 736	3 185	4 337
Total operating expenses	**7 217**	**4 030**	**18 254**	**13 369**	**18 931**
Operating profit (loss)	**-5 333**	**-2 603**	**-13 196**	**-9 090**	**-13 307**
Net financial items	**23**	**-45**	**119**	**134**	**216**
Profit (loss) before income tax	**-5 310**	**-2 648**	**-13 077**	**-8 956**	**-13 091**
Income tax	-	-	-	-	-
Net profit (loss) for the period	**-5 310**	**-2 648**	**-13 077**	**-8 956**	**-13 091**

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Statement of financial position

NOK 1,000	30.09.16	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	300
Property, plant and equipment	122	134	152	117	156	175	204	233
Total non-current assets	**422**	**434**	**452**	**417**	**455**	**475**	**504**	**532**
Receivables	6 845	5 597	4 116	3 917	4 306	3 935	3 384	4 130
Cash and cash equivalents	26 941	8 711	12 828	17 088	19 178	22 507	26 651	29 377
Total current assets	**33 786**	**14 308**	**16 944**	**21 005**	**23 484**	**26 442**	**30 034**	**33 506**
Total assets	**34 208**	**14 742**	**17 396**	**21 422**	**23 940**	**26 917**	**30 538**	**34 039**
Share capital	1 521	1 221	1 215	1 215	1 201	1 201	1 198	1 198
Share premium	78 563	55 254	55 154	55 154	54 669	54 669	54 616	54 616
Retained earnings (accumulated loss	-51 819	-46 509	-43 205	-38 742	-34 607	-31 959	-29 631	-25 651
Shareholders' equity	**28 264**	**9 966**	**13 164**	**17 627**	**21 262**	**23 910**	**26 182**	**30 162**
Accounts payable	2 423	1 420	408	1 293	468	707	2 687	1 785
Other current liabilities	3 520	3 356	3 824	2 502	2 209	2 299	1 669	2 092
Current liabilities	**5 943**	**4 776**	**4 232**	**3 795**	**2 678**	**3 007**	**4 356**	**3 876**
Total liabilities	**5 943**	**4 776**	**4 232**	**3 795**	**2 678**	**3 007**	**4 356**	**3 876**
Total Equity and Liabilities	**34 208**	**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			-13 077	-13 077
Issue of ordinary shares	305	23 409		23 714
Balance at 30.09.2016	**1 521**	**78 563**	**-51 819**	**28 264**

Statement of cash flow *NOK 1,000*	*9 months* **2016**	 **2015**	*Full year* **2015**
Loss for the period	**-13 077**	**-8 956**	**-13 091**
Adjustments for:			
Interest income	-29	-210	-426
Interest expenses	0	69	205
Depreciation	60	77	116
Change in trade receivables	198	89	-90
Change in trade payables	1 130	-1 316	-492
Change in receivables related to grants	-3 126	-265	303
Change in other current liabilities	1 018	118	410
Net cash flow from operating activities	**-13 825**	**-10 395**	**-13 065**
Purchase of property, plant and equipment	-65	0	0
Interest income	29	210	426
Net cash flow from investing activities	**-36**	**210**	**426**
Interest expenses	0	-69	-205
Proceeds from equity issue	23 714	56	556
Net cash flow from financing activities	**23 714**	**-13**	**351**
Net change in cash and cash equivalents	**9 853**	**-10 199**	**-12 289**
Cash and cash equivalents at begining of period	17 088	29 377	29 377
Cash and cash equivalents at end of period	**26 941**	**19 178**	**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 0.5, MNOK 4.4, MNOK 6.4 and MNOK 2.7 of the grant in 2012, 2013, 2014 and 2015 respectively, and MNOK 1.2 in the first nine 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 1.2 in the first nine 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 2.7 in the first nine months of 2016.

Note 3 Share capital and shareholders

Table of shareholders as of September 30, 2016:

Shareholder	Shares	Ownership
SARSIA SEED AS	316 240	20,8 %
RADIUMHOSPITALETS FORSKNINGSSTIFTELSE	243 070	16,0 %
DATUM INVEST AS	167 700	11,0 %
INVEN2 AS (1)	94 020	6,2 %
ARCTIC FUNDS PLC	82 557	5,4 %
KREFTFORENINGEN	77 280	5,1 %
PORTIA AS	60 000	3,9 %
OM HOLDING AS	57 850	3,8 %
BREKKE HOLDING AS	42 089	2,8 %
H5 VEKST AS	26 600	1,7 %
OTHERS	*353 233*	*23,2 %*
Total	**1 520 639**	100,0 %

(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 September 39, 2016, the Company had 98,370 warrants outstanding to inventors, key employees, former employees and members of the board, of which 3,410 had been exercised and the corresponding new shares are in the process of being registered. After September 30, an additional 5,600 warrants have been exercised.

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.