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. Also, Vaccibody has initiated development 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 4th quarter 2016 (October-December)

- Clinical Trial VB C-01:
  - Positive results from phase I including safety and early signs of efficacy.
  - Continued analysis of longer term efficacy (6, 9 and 12 months) of patients treated in the phase I clinical trial.
  - An amended Investigational Medical Product Dossier (IMPD) made addressing the potency assay method problem reported in the Q3 Report. (***Post Q4 note**: IMPD approval was obtained in February and first vaccination in the phase IIa is now expected to take place in March*).

- Neoantigen-based individualized cancer vaccine program
  - Continued generation of preclinical data to support clinical development strategies, including work supporting strong anti-tumour efficacy and low risk of autoimmune side effects which will support filing of a Clinical Trial Application (CTA) for VB10.NEO
  - Presentation by CSO Agnete Fredriksen at "Neoantigen Summit" in Boston in November leading to strong exposure to and interest from the neoantigen vaccine community regarding the Vaccibody vaccine approach
  - Generation of data supporting the value of a specific Vaccibody prediction algorithm holding the promise of an ability to more precisely identify cancer neoantigens of importance for patient treatment.
  - Initiation of development and pilot batch manufacturing of VB10.NEO DNA vaccine under GMP at selected Contract Manufaturing Organization (CMO)
  - Continued work together with the selected clinical sites for VB10.NEO clinical trials, as well as with other clinical experts, in order to optimize successful conduction of first clinical trials with VB10.NEO

Post Q4 note: *Vaccibody's Chief Clinical Officer (CCO), Mona Welschof, resigned from her position in February. The company has engaged with an interim CCO and does not expect any delays in its clinical programs. A search for a new leadership of the clinical department in Vaccibody has been initiated*.

Key figures *Amounts in NOK 1,000*	***4rd quarter*** **2016**	 **2015**	***Full year*** **2016**	***Full year*** **2015**
Total revenue and other income	3 941	1 345	8 999	5 623
Total operating expenses	7 153	5 562	25 407	18 931
Operating profit (loss)	**-3 212**	**-4 217**	**-16 408**	**-13 307**
Net profit (loss) for the period	**-3 143**	**-4 135**	**-16 220**	**-13 091**
Net proceeds from equity issues	231	500	23 945	556
Net cash flow	-1 939	-2 090	7 914	-12 289
Cash and cash equivalents, end of per	25 002	17 088	25 002	17 088
Outstanding shares, beginning of peri	1 520 639	1 200 619	1 215 349	1 197 819
Outstanding shares, end of period	1 529 649	1 215 349	1 529 649	1 215 349
Employees, end of period	8	5	8	5

Figures for 2016 in this report are preliminary, unaudited figures.

VB10.16 Clinical Development

The Company's core focus in the VB10.16 trial in Q4 2016 has been to follow up on the longer-term data from 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 were 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.

As earlier reported VB10.16 demonstrated clear signs of clinical early efficacy. Current work is focused on analysing longer term efficacy after 6, 9 and 12 months. Results from this analysis will be released in Q2, 2017.

The upstart of the clinical phase IIa of the VB10.16 trial unfortunately has been delayed due to a request by the German regulators (PEI) to file an amendment to our existing IMPD. The background for the required IMPD amendment was a problem with the quality assurance assay determining that the potency of VB10.16 remains intact during storage, which Vaccibody also described in its report for the 3rd quarter 2016. Before vaccinating patients, it has been assured using biological tests, among other things, that the vaccine to be used is biologically active and potent. In the process leading up to the start of the phase IIa initiation, the vaccine was tested to be outside the previously set specifications. This led the Company to seek a dialogue with PEI and to start an investigation as is normal practice. The company has now scrutinised this issue and performed a series of experiments to produce data to elucidate the situation. As part of this, the company has generated convincing data demonstrating that the potency and all other relevant parameters of the VB10.16 batch remain intact. However, in order to secure a more robust potency assay for future use, a requirement to change the specifications has been identified. Based on the results showing intact potency of the VB10.16 batch within previously set specifications described in the existing and approved IMPD, the Company had requested acceptance from PEI to continue the trial immediately before submitting a formal IMPD amendment. However, PEI communicated on Dec 22 that they would have to see and approve the formal IMPD amendment before allowing the trial to start. (The Company submitted such IMPD amendment on January 16, 2017).

The phase IIa study is planned to enrol 15-20 patients with CIN 2/3 in contrast to the phase I study with only enrolled CIN2 patients.

***Post Q4 note**: IMPD approval was obtained in February and first vaccination in the phase IIa is now expected to take place in March*.

VB10.NEO Preclinical and Clinical Development

Vaccibody continued the generation of strong preclinical data to support clinical development strategies, including work to support filing of a Clinical Trial Application (CTA) for VB10.NEO. In-house preclinical capabilities as well as work done by external partners are instrumental in this work and will be continued in the months to come.

At the so-called “Neoantigen Summit” in Boston in November, which was the first conference launched with a specific focus on the new cancer neoantigen vaccine field, our CSO Agnete Fredriksen gave a presentation, which lead to strong exposure of Vaccibody and interest from the neoantigen vaccine community in the Vaccibody vaccine approach. We will continue to build network in the neoantigen community including pharma companies active in the field as well as key contract research organizations.

In Q4 we have also generated a solid base of bioinformatics data supporting the value of continuous optimization of a specific Vaccibody prediction algorithm. Such algorithm holds the promise of an ability to very precisely identify cancer neoantigens of importance for

patient treatment, thus leading to a more efficacious and safe therapy. As part of this work, we have generated reassuring data showing strong anti-tumor efficacy and low risk of autoimmunity when using Vaccibody DNA vaccines. Finally, we have continued our work together the selected clinical sites for the VB10.NEO clinical trials, as well as with other clinical experts, in order to optimize successful conduction of first clinical trials with VB10.NEO.

Financial review

Figures for 2016 in this report are preliminary, unaudited figures.

Profit and loss statement
The Company had *revenue* of KNOK 243 in 2016 relating mainly to an R&D collaboration agreement. The agreement has a limited scope and will run through 2017. *Other income* in 2016 was KNOK 8,755 compared to KNOK 5,623 in 2015. Grants from the Norwegian Research Council under the BIA programme increased in 2016 as the Neo-antigen project was initiated and "Skattefunn" increased as a function of higher R&D expenses.

Total operating expenses increased to KNOK 25,407 in 2016 from KNOK 18,931 in 2015. *Payroll and related expenses* was KNOK 8,507 compared to KNOK 5,269 in 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 and a half person-years in addition to the new CEO in 2016 compared to 2015. *Procurement of R&D services and IP expenses* increased to KNOK 11,153 in 2016 compared to KNOK 9,209 in 2015, due to increased costs for clinical development following the initiation of the clinical trial VB C-01 in September 2015 and initiation of the neoantigen-based individualized cancer vaccine program in 2016. *Other operating expenses* increased to KNOK 5,662 in 2016 compared to KNOK 4,337 in 2015, due to expenses for the neoantigen program.

Statement of financial position
On December 31, 2016, Vaccibody had total assets of KNOK 241,058, hereunder *Cash and cash equivalents* of KNOK 25,002 and *Receivables* of KNOK 215,658. *Receivables* include a KNOK 209,050 net receivable from the share issue subscribed in December which was registered in January 2017. In addition, *receivables* include mainly grants earned and to be received in 2017 in accordance with the applicable payment schedules. *Shareholders' equity* was KNOK 234,402, including the share issue of net NOK 209 million completed in December 2016.

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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)

- Clinical Trial for cancer neoantigen vaccine (VB10.NEO)
  - Filing of a clinical trial application (CTA) for a clinical phase I/Ib in cancer patients within indications with high unmet medical need

- Building the Vaccibody organization to match the needs of the increased activities in a cost effective manner with a focus on establishing a lean organization with the correct balance between own employees and outsourcing of activities.

- The Company is in continuous dialogue with academic and industrial entities and will announce new key collaborations and partnerships when they may occur.

In December 2016, the Company concluded the subscription of a share issue with net proceeds of MNOK 209. This allows the Company to initiate its clinical development of targeted personalized neoantigen-based cancer vaccines for the 2017-20 period.

Profit and loss statement *NOK 1,000*	***4rd quarter*** **2016**	 **2015**	***Full year*** **2016**	***Full year*** **2015**
Revenue	237	-	243	-
Other income	3 703	1 345	8 755	5 623
Payroll and related expenses	2 849	2 186	8 507	5 269
Procurement of R&D services and IP expenses	2 354	2 185	11 153	9 209
Depreciation	24	39	84	116
Other operating expenses	1 925	1 152	5 662	4 337
Total operating expenses	**7 153**	**5 562**	**25 407**	**18 931**
Operating profit (loss)	**-3 212**	**-4 217**	**-16 408**	**-13 307**
Net financial items	**69**	**82**	**188**	**216**
Profit (loss) before income tax	**-3 143**	**-4 135**	**-16 220**	**-13 091**
Income tax	-	-	-	-
Net profit (loss) for the period	**-3 143**	**-4 135**	**-16 220**	**-13 091**

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Statement of financial position									
NOK 1,000	**31.12.16**	**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	300
Property, plant and equipment	97	122	134	152	117	156	175	204	233
Total non-current assets	**397**	**422**	**434**	**452**	**417**	**455**	**475**	**504**	**532**
Receivables	215 658	6 845	5 597	4 116	3 917	4 306	3 935	3 384	4 130
Cash and cash equivalents	25 002	26 941	8 711	12 828	17 088	19 178	22 507	26 651	29 377
Total current assets	**240 661**	**33 786**	**14 308**	**16 944**	**21 005**	**23 484**	**26 442**	**30 034**	**33 506**
Total assets	**241 058**	**34 208**	**14 742**	**17 396**	**21 422**	**23 940**	**26 917**	**30 538**	**34 039**
Share capital	1 530	1 521	1 221	1 215	1 215	1 201	1 201	1 198	1 198
Share premium	78 784	78 563	55 254	55 154	55 154	54 669	54 669	54 616	54 616
Unregistered share issue	209 050	-	-	-	-	-	-	-	-
Retained earnings (accumulated losses)	-54 962	-51 819	-46 509	-43 205	-38 742	-34 607	-31 959	-29 631	-25 651
Shareholders' equity	**234 402**	**28 264**	**9 966**	**13 164**	**17 627**	**21 262**	**23 910**	**26 182**	**30 162**
Accounts payable	3 411	2 423	1 420	408	1 293	468	707	2 687	1 785
Other current liabilities	3 245	3 520	3 356	3 824	2 502	2 209	2 299	1 669	2 092
Current liabilities	**6 656**	**5 943**	**4 776**	**4 232**	**3 795**	**2 678**	**3 007**	**4 356**	**3 876**
Total liabilities	**6 656**	**5 943**	**4 776**	**4 232**	**3 795**	**2 678**	**3 007**	**4 356**	**3 876**
Total Equity and Liabilities	**241 058**	**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**	**Other equity**	**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			-16 220		-16 220
Issue of ordinary shares	314	23 631		209 050	232 995
Balance at 31.12.2016	**1 530**	**78 784**	**-54 962**	**209 050**	**234 402**

Statement of cash flow *NOK 1,000*	*Full year* **2016**	*Full year* **2015**
Loss for the period	**-16 220**	**-13 091**
Adjustments for:		
Interest income	-286	-426
Interest expenses	1	205
Depreciation	84	116
Change in trade receivables	-290	-90
Change in trade payables	2 118	-492
Change in receivables related to grants	-2 402	303
Change in other current liabilities	743	410
Net cash flow from operating activities	**-16 251**	**-13 065**
Purchase of property, plant and equipment	-65	0
Interest income	286	426
Net cash flow from investing activities	**221**	**426**
Interest expenses	-1	-205
Proceeds from equity issues	23 945	556
Net cash flow from financing activities	**23 944**	**351**
Net change in cash and cash equivalents	**7 914**	**-12 289**
Cash and cash equivalents at begining of period	17 088	29 377
Cash and cash equivalents at end of period	**25 002**	**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 recognized MNOK 4.4, MNOK 6.4 and MNOK 2.7 of the grant in 2013, 2014 and 2015 respectively, and MNOK 1.5 in 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 recognized MNOK 2.8 in 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, MNOK 0.1 and MNOK 0.1 of this grant in 2013, 2014, 2015 and 2016 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 and MNOK 0.5 in 2016.

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 3.88 in 2016.

Note 3 Share capital and shareholders

Table of shareholders as of December 31, 2016:

Shareholder	**Shares**	**Ownership**
SARSIA SEED AS	316 240	20,7 %
RADIUMHOSPITALETS FORSKNINGSSTIFTELSE	243 070	15,9 %
DATUM INVEST AS	167 700	11,0 %
INVEN2 AS (1)	94 020	6,1 %
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	24 150	1,6 %
OTHERS	*364 693*	*23,8 %*
Total	**1 529 649**	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.

The share issue of net NOK 209 million completed in December 2016 is not reflected in the above table.

The Company has 89,360 warrants outstanding to inventors, key employees, former employees and members of the board. The Company also has an agreement with Inven2 AS, under which Inven2 AS on certain specific conditions may claim shares equivalent to 1.5% of the number of shares outstanding at the time of exercise of the option.

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.