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 1st quarter 2017 (January-March)

- Clinical Trial VB C-01:
  - Continued analysis of longer term efficacy (6, 9 and 12 months) of patients treated in the phase I clinical trial.
  - Re-opening of 4 clinical sites in Germany to initiate clinical phase IIa trial
  - Enrolment started with first patient in the phase IIa study vaccinated 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
  - 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.
  - Continued development and pilot batch manufacturing of VB10.NEO DNA vaccine under GMP at selected Contract Manufacturing 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

Key figures	1st quarter		Full year
Amounts in NOK 1,000	**2017**	**2016**	**2016**
Total revenue and other income	2 008	1 290	8 999
Total operating expenses	6 503	5 821	25 407
Operating profit (loss)	**-4 495**	**-4 531**	**-16 408**
Net profit (loss) for the period	**-4 381**	**-4 463**	**-16 220**
Net proceeds from equity issues	209 548	-	23 945
Net cash flow	203 123	-4 260	7 914
Cash and cash equivalents, end of per	228 125	12 828	25 002
Outstanding shares, beginning of peri	1 529 649	1 200 619	1 215 349
Outstanding shares, end of period	2 409 649	1 215 349	1 529 649
Employees, end of period	10	6	8

VB10.16 Clinical Development

The Company's core focus in the VB10.16 trial in Q1 2017 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.

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 company has also been focusing on the initiation of the clinical phase IIa of the VB10.16 trial. This trial was delayed as reported earlier, due to a request by the German regulators (PEI) to file an amendment to our existing IMPD. In February PEI approved the amendment and the work with the phasse IIa resumed. The first patient was vaccinated in March and patients are now being enrolled into 4 clinical centers in Germany.

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

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.

In order to predict the best cancer neoantigens to be included in the Vaccibody vaccine, we have had a focus on generating a solid base of preclinical data to optimize our bioinformatical tools. These data will support the establishment of a specific software tool that will be tailor-made to give the best prediction of the neoepitopes that will generate a strong immune response when used in Vaccibody vaccine format.

We have also had a focus on our 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. This work is expected also to be continued in the months to come leading up to the filing of the CTA, which we expect to submit to the German regulators at the Paul Ehrlich Institute (PEI) in Q2/Q3, 2017.

Financial review

Profit and loss statement
Other income in the first quarter 2017 was KNOK 2,008 compared to KNOK 1,284 in the first quarter 2016. Grants from the Norwegian Research Council under the BIA programme is higher in 2017 than for 2016 in line with the increased R&D expenses of the Neo-antigen project.

Total operating expenses increased to KNOK 6,503 in the first quarter 2017 from KNOK 5,821 in the first quarter 2016. *Payroll and related expenses* increased to KNOK 2,522 compared to KNOK 2,001 in 2016 due to the planned increase in staff. *Procurement of R&D services and IP expenses* was reduced to KNOK 2,232 in the first quarter 2017 compared to KNOK 2,492 in the first quarter 2016. Expenses on the Neo-antigen project increased as planned whereas expenses on the VB10.16 clinical trial was reduced due to the delayed inclusion of patients in the expansion phase IIa of the study. *Other operating expenses* increased to KNOK 1,731 in the first quarter 2017 compared to KNOK 1,298 in the first quarter 2016, mainly due to recruitment expenses and more traveling activity.

Statement of financial position
On March 31, 2017, Vaccibody had total assets of KNOK 234,657, hereunder *Cash and cash equivalents* of KNOK 228,125 and *Receivables* of KNOK 6,153. *Receivables* include mainly grants earned and to be received during the year in accordance with the applicable payment schedules. *Shareholders' equity* was KNOK 230,519.

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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)
  - Conclude enrolment of the expansion phase (Phase IIa)
  - Interim reporting from the expansion 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
  - Initiation of 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.

Profit and loss statement	*1st quarter*		*Full year*
NOK 1,000	**2017**	**2016**	**2016**
Revenue	-	6	243
Other income	2 008	1 284	8 755
Payroll and related expenses	2 522	2 001	8 507
Procurement of R&D services and IP expenses	2 232	2 492	11 153
Depreciation	18	29	84
Other operating expenses	1 731	1 298	5 662
Total operating expenses	**6 503**	**5 821**	**25 407**
Operating profit (loss)	**-4 495**	**-4 531**	**-16 408**
Net financial items	**114**	**68**	**188**
Profit (loss) before income tax	**-4 381**	**-4 463**	**-16 220**
Income tax	-	-	-
Net profit (loss) for the period	**-4 381**	**-4 463**	**-16 220**

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Statement of financial position

NOK 1,000	31.03.17	31.12.16	30.09.16	30.06.16	31.03.16	31.12.15
Intangible assets	300	300	300	300	300	300
Property, plant and equipment	79	97	122	134	152	117
Total non-current assets	**379**	**397**	**422**	**434**	**452**	**417**
Receivables	6 153	226 608	6 845	5 597	4 116	3 917
Cash and cash equivalents	228 125	25 002	26 941	8 711	12 828	17 088
Total current assets	**234 278**	**251 611**	**33 786**	**14 308**	**16 944**	**21 005**
Total assets	**234 657**	**252 008**	**34 208**	**14 742**	**17 396**	**21 422**
Share capital	2 410	1 530	1 521	1 221	1 215	1 215
Share premium	286 954	78 784	78 563	55 254	55 154	55 154
Unregistered share issue	498	209 050	-	-	-	-
Retained earnings (accumulated losses)	-59 343	-54 962	-51 819	-46 509	-43 205	-38 742
Shareholders' equity	**230 519**	**234 402**	**28 264**	**9 966**	**13 164**	**17 627**
Accounts payable	1 466	3 411	2 423	1 420	408	1 293
Other current liabilities	2 672	14 195	3 520	3 356	3 824	2 502
Current liabilities	**4 138**	**17 606**	**5 943**	**4 776**	**4 232**	**3 795**
Total liabilities	**4 138**	**17 606**	**5 943**	**4 776**	**4 232**	**3 795**
Total Equity and Liabilities	**234 657**	**252 008**	**34 208**	**14 742**	**17 396**	**21 422**

Statement of changes in equity

NOK 1,000

	Share capital	Share premium	Accumulated losses	Other equity	Total equity
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			23 945
Issue of ordinary shares, not registered				209 050	209 050
Balance at 31.12.2016	**1 530**	**78 784**	**-54 962**	**209 050**	**234 402**
Balance at 01.01.2017	**1 530**	**78 784**	**-54 962**	**209 050**	**234 402**
Loss for the period			-4 381		-4 381
Registration of share issue	880	208 170		-209 050	0
Warrants exercised				498	498
Balance at 31.03.2017	**2 410**	**286 954**	**-59 343**	**498**	**230 519**

Statement of cash flow *NOK 1,000*	*1st quarter* **2017**	 **2016**	*Full year* **2016**
Loss for the period	**-4 381**	**-4 463**	**-16 220**
Adjustments for:			
Interest income	-148	-86	-356
Interest expenses	1	0	160
Depreciation	18	29	84
Change in trade receivables	263	183	-290
Change in trade payables	-1 945	-885	2 118
Change in receivables related to grants	192	-382	-2 402
Change in other current liabilities	-573	1 322	743
Net cash flow from operating activities	**-6 571**	**-4 282**	**-16 163**
Purchase of property, plant and equipment	0	-65	-65
Interest income	148	86	356
Net cash flow from investing activities	**148**	**21**	**292**
Interest expenses	-1	0	-160
Proceeds from equity issues	209 548	0	23 945
Net cash flow from financing activities	**209 546**	**0**	**23 786**
Net change in cash and cash equivalents	**203 123**	**-4 260**	**7 914**
Cash and cash equivalents at begining of period	25 002	17 088	17 088
Cash and cash equivalents at end of period	**228 125**	**12 828**	**25 002**

Notes to the Quarterly Financial Statement

Note 1 Accounting policies

The financial statements of Vaccibody AS for 2016 and 2017 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 received a grant from the Norwegian Research Council under the BIA-programme for the development of VB10.16 at a total of MNOK 15.5 for the period 2012-2016. The Company recognized MNOK 0.4, 4.4, 6.4, 2.7 and 1.5 of the grant in 2012, 2013, 2014, 2015 and 2016 respectively.

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 and MNOK 0.98 in the first quarter 2017.

Vaccibody AS is eligible for grant under the Norwegian Skattefunn programme. The Company has recognized MNOK 1.77, 2.8 and 3.9 of the grant in 2014, 2015 and 2016 respectively, and MNOK 1.03 in the first quarter 2017.

Note 3 Share capital and shareholders

Table of shareholders as of March 31, 2017:

Shareholder	Shares	Ownership
SARSIA SEED AS	336 240	14,0 %
RADIUMHOSPITALETS FORSKNINGSSTIFTELSE	253 070	10,5 %
ARCTIC FUNDS PLC	196 457	8,2 %
DATUM INVEST AS	167 700	7,0 %
NORDA ASA	141 600	5,9 %
NORRON SICAV - TARGET	112 000	4,6 %
PORTIA AS	103 500	4,3 %
INVEN2 AS	100 020	4,2 %
KREFTFORENINGEN	97 280	4,0 %
OM HOLDING AS	73 850	3,1 %
OTHERS	*827 932*	*34,4 %*
Total	**2 409 649**	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 Company has 172,248 (81,945 on March 31, 2017) 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.