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 clinical data from its 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 3rd quarter 2017 (July-September)

- Clinical Trial VB C-01:
  - Recruitment of patients with CIN2/3 for the expansion phase (Phase IIa) continues and is expected to be completed by end of 2017.

- VB10.NEO Neoantigen-based individualized cancer vaccine program:
  - The clinical trial application was submitted to the German regulatory authority Paul Ehrlich Institute August 3rd2017
  - Collaboration with the Clinical Research Organization Synteract for trial start progress according to plans.
  - Three very well renowned clinical sites in Heidelberg, Munich and Frankfurt have accepted to participate in the trial and preparations for trial start has been initiated.

Key figures	***3rd quarter***		***9 months***		***Full year***
Amounts in NOK 1,000	**2017**	**2016**	**2017**	**2016**	**2016**
Total revenue and other income	2 008	1 884	6 509	5 058	8 999
Total operating expenses	11 165	7 217	27 303	18 254	25 407
Operating profit (loss)	**-9 158**	**-5 333**	**-20 794**	**-13 196**	**-16 408**
Net profit (loss) for the period	**-8 701**	**-5 310**	**-19 391**	**-13 077**	**-16 220**
Net proceeds from equity issues	-	23 609	498	23 714	23 945
Net cash flow	-8 696	18 230	188 810	9 853	7 914
Cash and cash equivalents, end of period	213 813	26 941	213 813	26 941	25 002
Outstanding shares, beginning of period	2 417 064	1 220 639	1 529 649	1 215 349	1 215 349
Outstanding shares, end of period	2 417 064	1 520 639	2 417 064	1 520 639	1 529 649
Employees, end of period	14	7	14	7	8

VB10.16 Clinical Development

Recruitment of patients with pre-cancerous lesions of the cervix stage CIN2-3 for the expansion phase continues and is expected to be completed by end of 2017.

VB10.NEO Preclinical and Clinical Development

Substantiation and refinement of the in house neoepitope selection model is continuing with bioinformatic analysis of in vivo generated data. A user-friendly software incorporating all necessary analysis is being developed according to plan enabling a fully automated neoepitope selection process for the clinical trial.

A new potency assay in house and with external collaborators is being developed to be applicable to the concept of individual vaccine batches in the VB N-01 clinical trial.

Development work on VB10.NEO batches was completed at the primary contract manufacturing organization (CMO). Contractual work with all vendors involved in the VB10.NEO manufacturing process was moved forward. A second CMO has been identified and a collaborative agreement and tech transfer is being initiated in order to increase flexibility and capacity in VB10.NEO manufacturing. A detailed tracking system of each individual batch during manufacturing is being set up to closely monitor the process and improve logistics.

The clinical trial application was submitted to the German regulatory authority Paul Ehrlich Institut and to the Ethics Committee during August 2017. Responses from the both authorities are expected in Q4.

The clinical trial is designed

- to assess the safety/tolerability of multiple doses of 3 mg VB10.NEO immunotherapy
- to determine the overall process feasibility from biopsy, sequencing, epitope selection, vaccine manufacturing and administration of vaccine and
- to assess the immunogenicity of multiple doses of 3 mg VB10.NEO immunotherapy

In addition, the trial may provide early sign of efficacy and thus guide the design of future clinical trials

Collaboration with the Clinical Research Organization of choice for trial start progresses according to plans.
Three very well renowned clinical oncology sites (Heidelberg, Munich and Frankfurt) have accepted to participate in the trial and preparations for trial start are on-going.

Financial review

Profit and loss statement
Revenue in the first nine months of 2017 of KNOK 486 relates to an R&D collaboration of limited scope which was completed in the 2nd quarter 2017. *Other income* in the first nine months of 2017 was KNOK 6,023 compared to KNOK 5,052 in the first nine months of 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 27,303 in the first nine months of 2017 from KNOK 18,254 in the same period in 2016. *Payroll and related expenses* increased to KNOK 8,859 compared to KNOK 5,658 in 2016 due to the planned increase in staff. *Procurement of R&D services and IP expenses* increased to KNOK 12,766 in the first nine months of 2017 compared to KNOK 8,800 in the same period in 2016. Expenses on the Neo-antigen project increased as planned, including preparations for the clinical trial application and pre-clinical studies, 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 5,615 in the first nine months of 2017 compared to KNOK 3,736 in the same period in 2016, mainly due to increased internal lab expenses, recruitment expenses, more traveling activity and general and administration expenses relating to increased staff.

Statement of financial position
On September 30, 2017, Vaccibody had total assets of KNOK 221,815, hereunder *Cash and cash equivalents* of KNOK 213,813 and *Receivables* of KNOK 7,593. *Receivables* include mainly grants earned and to be received within a year in accordance with the applicable payment schedules. *Shareholders' equity* was KNOK 215,508.

Outlook

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

- Clinical Trial VB C-01 (VB10.16)
  - Conclude enrolment of the expansion phase (Phase IIa)
  - Interim reporting from the expansion phase (Phase IIa)
  - Final reporting from the expansion phase (Phase IIa)

- Clinical Trial for cancer neoantigen vaccine (VB10.NEO)
  - Approval of the clinical trial application (CTA) for a clinical phase I/IIa in cancer patients within indications with high unmet medical need
  - Initiation of phase I/IIa clinical trial evaluating the safety, feasibility and efficacy of VB10.NEO in combination with standard of care checkpoint inhibitor therapy.

- 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	3rd quarter		9 months		Full year
NOK 1,000	2017	2016	2017	2016	2016
Revenue	-	-	486	6	243
Other income	2 008	1 884	6 023	5 052	8 755
Payroll and related expenses	3 826	2 543	8 859	5 658	8 507
Procurement of R&D services and IP expenses	5 620	3 501	12 766	8 800	11 153
Depreciation	24	12	63	60	84
Other operating expenses	1 695	1 161	5 615	3 736	5 662
Total operating expenses	**11 165**	**7 217**	**27 303**	**18 254**	**25 407**
Operating profit (loss)	**-9 158**	**-5 333**	**-20 794**	**-13 196**	**-16 408**
Net financial items	**457**	**23**	**1 403**	**119**	**188**
Profit (loss) before income tax	**-8 701**	**-5 310**	**-19 391**	**-13 077**	**-16 220**
Income tax	-	-	-	-	-
Net profit (loss) for the period	**-8 701**	**-5 310**	**-19 391**	**-13 077**	**-16 220**

Statement of financial position								
NOK 1,000	30.09.17	30.06.17	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	300	300
Property, plant and equipment	109	105	79	97	122	134	152	117
Total non-current assets	**408**	**405**	**379**	**397**	**422**	**434**	**452**	**417**
Receivables	7 593	6 912	6 153	226 608	6 845	5 597	4 116	3 917
Cash and cash equivalents	213 813	222 509	228 125	25 002	26 941	8 711	12 828	17 088
Total current assets	**221 406**	**229 421**	**234 278**	**251 611**	**33 786**	**14 308**	**16 944**	**21 005**
Total assets	**221 815**	**229 826**	**234 657**	**252 008**	**34 208**	**14 742**	**17 396**	**21 422**
Share capital	2 417	2 417	2 410	1 530	1 521	1 221	1 215	1 215
Share premium	287 445	287 445	286 954	78 784	78 563	55 254	55 154	55 154
Unregistered share issue	-	-	498	209 050	-	-	-	-
Retained earnings (accumulated losses)	-74 353	-65 653	-59 343	-54 962	-51 819	-46 509	-43 205	-38 742
Shareholders' equity	**215 508**	**224 209**	**230 519**	**234 402**	**28 264**	**9 966**	**13 164**	**17 627**
Accounts payable	3 155	2 811	1 466	3 411	2 423	1 420	408	1 293
Other current liabilities	3 152	2 806	2 672	14 195	3 520	3 356	3 824	2 502
Current liabilities	**6 306**	**5 617**	**4 138**	**17 606**	**5 943**	**4 776**	**4 232**	**3 795**
Total liabilities	**6 306**	**5 617**	**4 138**	**17 606**	**5 943**	**4 776**	**4 232**	**3 795**
Total Equity and Liabilities	**221 815**	**229 826**	**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			-19 391		-19 391
Registration of share issue	880	208 170		-209 050	0
Warrants exercised	7	490			498
Balance at 30.09.2017	**2 417**	**287 445**	**-74 353**	**-**	**215 508**

Statement of cash flow *NOK 1,000*	*9 months* **2017**	 **2016**	*Full year* **2016**
Loss for the period	**-19 391**	**-13 077**	**-16 220**
Adjustments for:			
Interest income	-1 085	-254	-356
Interest expenses	1	104	160
Depreciation	63	60	84
Change in trade receivables	240	198	-290
Change in trade payables	-256	1 130	2 118
Change in receivables related to grants	-1 225	-3 126	-2 402
Change in other current liabilities	-93	1 018	743
Net cash flow from operating activities	**-21 746**	**-13 947**	**-16 163**
Purchase of property, plant and equipment	-74	-65	-65
Interest income	1 085	254	356
Net cash flow from investing activities	**1 011**	**189**	**292**
Interest expenses	-1	-104	-160
Proceeds from equity issues	209 548	23 714	23 945
Net cash flow from financing activities	**209 546**	**23 610**	**23 786**
Net change in cash and cash equivalents	**188 810**	**9 853**	**7 914**
Cash and cash equivalents at begining of period	25 002	17 088	17 088
Cash and cash equivalents at end of period	**213 813**	**26 941**	**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 2.9 in the first nine months of 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 3.1 in the first nine months of 2017.

Note 3 Share capital and shareholders

Table of shareholders as of September 30, 2017:

Shareholder	**Shares**	**Ownership**
SARSIA SEED AS	336 240	13,9 %
RADIUMHOSPITALETS FORSKNINGSSTIFTELSE	253 070	10,5 %
ARCTIC FUNDS PLC	196 457	8,1 %
DATUM INVEST AS	167 700	6,9 %
NORDA ASA	141 600	5,9 %
NORRON SICAV - TARGET	112 000	4,6 %
PORTIA AS	103 500	4,3 %
INVEN2 AS *(1)*	100 020	4,1 %
KREFTFORENINGEN	97 280	4,0 %
OM HOLDING AS	73 850	3,1 %
OTHERS	*835 347*	*34,6 %*
Total	**2 417 064**	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 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.