vaccibody

Company overview

Vaccibody is a clinical-stage biopharmaceutical company dedicated to the discovery and development of novel immunotherapies. The company is a leader in the rapidly developing field of individualized cancer neoantigen vaccines and is using the Vaccibody technology to generate best-in-class therapeutics to treat cancers with a high unmet medical need. A phase I/IIa neoantigen clinical trial is now enrolling patients with locally advanced or metastatic melanoma, non-small cell lung carcinoma, clear renal cell carcinoma, urothelial or squamous cell carcinoma off head and neck. Vaccibody's front runner program (VB10.16) is a therapeutic DNA vaccine against HPV16 induced pre-malignancies and malignancies. The first-in-human study (phase I/IIa), which is now fully enrolled, evaluates the safety and immunogenicity of VB10.16 in women with high grade cervical intraepithelial neoplasia (HSIL; CIN 2/3).

Highlights for the 1st quarter 2018 (January-March)

- VB10.NEO Neoantigen-based individualized cancer vaccine program:
  - Approval of the clinical trial application (CTA) by the German regulatory authority Paul Ehrlich Institute.
  - Pre-clinical data showing improved ability to elicit killer T-cell responses thus supporting the promise of DNA-platform for anti-cancer therapy
  - Finalization of bioinformatic neo-epitope selection algorithm (Neo-SELECT™) for use in clinical trial.
  - **Post Quarter Event:** Patient enrollment process started in April in the neoantigen clinical phase I/IIa trial and is now enrolling patients with locally advanced or metastatic melanoma, non-small cell lung carcinoma, clear renal cell carcinoma, urothelial or squamous cell carcinoma off head and neck.

- Clinical Trial VB C-01:
  - Continued treatment of patients with CIN2/3 in the expansion phase (Phase IIa). On track to report 6 months data in Q3, 2018.
  - **Post Quarter Event:** immunogenicity data for the first 10 patients in phase IIa, showed a vaccine-induced immune response in 10 out of 10 vaccinated patients. Moreover, the Vaccibody DNA vaccine platform showed induction of strong killer T cell (CD8+) responses which is believed to be important for clinical efficacy.

Key figures *Amounts in NOK 1,000*	*1st quarter* **2018**	 **2017**	*Full year* **2017**
Total revenue and other income	2 963	2 008	9 763
Total operating expenses	15 263	6 503	43 731
Operating profit (loss)	**-12 300**	**-4 495**	**-33 968**
Net profit (loss) for the period	**-12 134**	**-4 381**	**-31 371**
Net proceeds from equity issues	138	209 548	209 548
Net cash flow	-16 837	203 123	182 070
Cash and cash equivalents, end of period	190 235	228 125	207 073
Outstanding shares, beginning of period	2 417 064	1 529 649	1 529 649
Outstanding shares, end of period (*)	48 396 480	2 409 649	2 417 064
Employees, end of period	15	8	15

(*) Following a share split 1:20 which took place in Q1, 2018

VB10.NEO Preclinical and Clinical Development

To further substantiate the potential in the Vaccibody vaccine platform technology, the immune response induced by different neoantigen vaccines has been investigated in mice models in more detail. The results clearly suggest that Vaccibody neoantigen vaccines are able to induce a broader immune response to the neoepitopes than when these epitopes are delivered to mice in peptide or RNA vaccine formats as is being used by other neoantigen vaccine companies. Most importantly and highly encouraging, the T cell response consisted of a sound balance between CD8+ killer T cells and CD4+ helper T cell responses with half of the neoepitopes inducing dominant CD8+ T cell responses. A strong CD8+ T cell response is believed to be important for clinical efficacy.

Approval of the Clinical Trial Application (CTA) for our cancer neoantigen phase I/IIa trial by German regulatory authorities (Paul Ehrlich Institute (PEI)) was obtained in March. This came on the back of a conditional approval obtained in January, with remaining conditions relating to securing and documenting certain aspects of the quality of the vaccine.

The Vaccibody bioinformatic neo-epitope selection algorithm (Neo-SELECT™) to be used in clinical trial has been finalized. This work has included substantiation and refinement of the neoepitope selection model using bioinformatic analysis of in vivo generated data. A more user-friendly software is being developed to enable a fully automated neoepitope selection process.

Collaboration with the three very renowned clinical oncology sites (Heidelberg, Munich and Frankfurt) continued to prepare for the clinical trial to start. A successful Site Initiation Visit (SIT) took place in Heidelberg and this clinical center opened for patient enrolment in March.

Development work on VB10.NEO batches and preparatory work for the manufacture to the clinical trial continued in Q1. To secure flexibility and capacity, two different Contract Manufacture Organizations (CMOs) have been chosen to manufacture the vaccine. Final contracts were signed with the two CMOs in Q1.

Collaboration with the Clinical Research Organization of choice for trial start progresses according to plans.

Post Quarter Event: Patient enrollment process started in April in the neoantigen clinical phase I/IIa trial and is now enrolling patients with locally advanced or metastatic melanoma, non-small cell lung carcinoma, clear renal cell carcinoma, urothelial or squamous cell carcinoma off head and neck.

VB10.16 Clinical Development

Continued treatment of patients with CIN2/3 in the expansion phase (phase IIa). The clinical study is on track to report 6 months data in Q3, 2018.

Post Quarter Event: immunogenicity data for the first 10 patients in phase IIa, showed a vaccine-induced immune response in 10 out of 10 vaccinated patients. Moreover, the Vaccibody DNA vaccine platform was shown to induce strong killer T cell (CD8+) responses which is believed to be important for clinical efficacy.

Financial review

Profit and loss statement
Other income in the first three months of 2018 was KNOK 2,963 compared to KNOK 2,008 in the first three months of 2017. Grants from the Norwegian Research Council under the BIA programme is higher in 2018 than for 2017 in line with the increased R&D expenses of the Neo-antigen project.

Total operating expenses increased to KNOK 15,263 in the first three months of 2018 from KNOK 6,503 in the same period in 2017. *Payroll and related expenses* increased to KNOK 4,408 compared to KNOK 2,522 in 2017 due to the planned increase in staff. *Procurement of R&D services and IP expenses* increased to KNOK 7,745 in the first three months of 2018 compared to KNOK 2,232 in the same period in 2017. Expenses on the Neo-antigen project increased as planned, including preparations for the clinical trial application and pre-clinical studies, and expenses on the VB10.16 clinical trial increased as the expansion phase IIa of the study was on hold until late in 1Q17. *Other operating expenses* increased to KNOK 3,094 in the first three months of 2018 compared to KNOK 1,731 in the same period in 2017, mainly due to business development activities, increased internal lab expenses and general and administration expenses relating to increased staff.

Statement of financial position
On March 31, 2018, Vaccibody had total assets of KNOK 199,219, hereunder *Cash and cash equivalents* of KNOK 190,235 and *Receivables* of KNOK 8,611. *Receivables* include mainly grants earned and to be received within a year in accordance with the applicable payment schedules. *Shareholders' equity* was KNOK 191,532.

Outlook

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

- Clinical Trial for cancer neoantigen vaccine (VB10.NEO)
  - Continued enrolment into the clinical phase I/IIa trial of patients with locally advanced or metastatic melanoma, non-small cell lung carcinoma, clear renal cell carcinoma, urothelial or squamous cell carcinoma off head and neck.
  - Reporting from measurement of systemic immune responses in patients receiving the neoantigen vaccine.

- Clinical Trial VB C-01 (VB10.16)
  - 6 months reporting from the expansion phase (Phase IIa)
  - 12 months reporting from the expansion phase (Phase IIa)

- 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	**2018**	**2017**	**2017**
Revenue	-	-	486
Other income	2 963	2 008	9 277
Payroll and related expenses	4 408	2 522	14 372
Procurement of R&D services and IP expenses	7 745	2 232	21 180
Depreciation	16	18	82
Other operating expenses	3 094	1 731	8 097
Total operating expenses	**15 263**	**6 503**	**43 731**
Operating profit (loss)	**-12 300**	**-4 495**	**-33 968**
Net financial items	**165**	**114**	**2 597**
Profit (loss) before income tax	**-12 134**	**-4 381**	**-31 371**
Income tax	-	-	-
Net profit (loss) for the period	**-12 134**	**-4 381**	**-31 371**

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Statement of financial position						
NOK 1,000	**31.03.18**	**31.12.17**	**30.09.17**	**30.06.17**	**31.03.17**	**31.12.16**
Intangible assets	300	300	300	300	300	300
Property, plant and equipment	74	89	109	105	79	97
Total non-current assets	**373**	**389**	**408**	**405**	**379**	**397**
Receivables	8 611	7 004	7 593	6 912	6 153	226 608
Cash and cash equivalents	190 235	207 073	213 813	222 509	228 125	25 002
Total current assets	**198 846**	**214 077**	**221 406**	**229 421**	**234 278**	**251 611**
Total assets	**199 219**	**214 466**	**221 815**	**229 826**	**234 657**	**252 008**
Share capital	2 420	2 417	2 417	2 417	2 410	1 530
Share premium	287 580	287 445	287 445	287 445	286 954	78 784
Unregistered share issue	-	-	-	-	498	209 050
Retained earnings (accumulated losses)	-98 467	-86 333	-74 352	-65 653	-59 343	-54 962
Shareholders' equity	**191 532**	**203 529**	**215 509**	**224 209**	**230 519**	**234 402**
Accounts payable	2 666	6 084	3 155	2 811	1 466	3 411
Other current liabilities	5 021	4 853	3 150,557	2 806	2 672	14 195
Current liabilities	**7 687**	**10 937**	**6 305**	**5 617**	**4 138**	**17 606**
Total liabilities	**7 687**	**10 937**	**6 305**	**5 617**	**4 138**	**17 606**
Total Equity and Liabilities	**199 219**	**214 466**	**221 815**	**229 826**	**234 657**	**252 008**

Statement of changes in equity					
NOK 1,000					
	Share capital	**Share premium**	**Accumulated losses**	**Other equity**	**Total equity**
Balance at 01.01.2017	**1 530**	**78 784**	**-54 962**	**209 050**	**234 402**
Loss for the period			-31 371		-31 371
Registration of share issue	880	208 170		-209 050	-
Warrants exercised	7	490			498
Balance at 31.12.2017	**2 417**	**287 445**	**-86 333**	**-**	**203 529**
Balance at 01.01.2017	**2 417**	**287 445**	**-86 333**	**-**	**203 529**
Loss for the period			-12 134		-12 134
Warrants exercised	3	135			138
Balance at 31.03.2018	**2 420**	**287 580**	**-98 467**	**-**	**191 532**

Statement of cash flow *NOK 1,000*	*3 months* **2018**	 **2017**	*Full year* **2017**
Loss for the period	**-12 134**	**-4 381**	**-31 371**
Adjustments for:			
Interest income	-348	-117	-1 584
Interest expenses	28	1	14
Depreciation	16	18	82
Change in trade receivables	-22	263	-75
Change in trade payables	-3 418	-1 945	2 674
Change in receivables related to grants	-1 584	192	-321
Change in other current liabilities	168	-573	1 608
Net cash flow from operating activities	**-17 295**	**-6 541**	**-28 973**
Purchase of property, plant and equipment	0	0	-74
Interest income	348	117	1 584
Net cash flow from investing activities	**348**	**117**	**1 509**
Interest expenses	-28	-1	-14
Proceeds from equity issues	138	209 548	209 548
Net cash flow from financing activities	**110**	**209 546**	**209 534**
Net change in cash and cash equivalents	**-16 837**	**203 123**	**182 070**
Cash and cash equivalents at begining of period	207 073	25 002	25 002
Cash and cash equivalents at end of period	**190 235**	**228 125**	**207 073**

Notes to the Quarterly Financial Statement

Note 1 Accounting policies

The financial statements of Vaccibody AS for 2017 and 2018 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 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, MNOK 3.9 in 2017 and MNOK 1.6 in the first three months of 2017.

Vaccibody AS is eligible for grant under the Norwegian Skattefunn programme. The Company has recognized MNOK 2.8, 3.9 and 5.1 of the grant in 2015, 2016 and 2017 respectively, and MNOK 1.3 in the first three months of 2018.

Note 3 Share capital and shareholders

Table of shareholders as of March 31, 2018:

Shareholder	Shares	Ownership
SARSIA SEED AS	6 724 800	13,9 %
RADIUMHOSPITALETS	5 061 400	10,5 %
ARCTIC FUNDS PLC	3 929 140	8,1 %
DATUM INVEST AS	3 872 600	8,0 %
NORDA ASA	3 235 600	6,7 %
NORRON SICAV - TARGET	2 240 000	4,6 %
PORTIA AS	2 000 000	4,1 %
KREFTFORENINGEN	1 945 600	4,0 %
OM HOLDING AS	1 477 000	3,1 %
INVEN2 AS (1)	1 340 400	2,8 %
OTHERS	*16 569 940*	*34,2 %*
Total	**48 396 480**	100,0 %

(1) Inven2 AS holds 660 000 shares on behalf of the inventors of the Company's technology – 220 000 shares to each of Agnete B. Fredriksen, Bjarne Bogen and Inger Sandlie.

The Company has 4,211,769 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.