vaccibody

Report 3rd quarter 2018

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 as well as urothelial cancer or squamous cell carcinoma of the 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 3rd quarter 2018

VB10.NEO Neoantigen-based individualized cancer vaccine program:

- 10 patients are now enrolled in the neoantigen clinical phase I/IIa trial, and patient treatment has started. This trial is enrolling patients with locally advanced or metastatic melanoma, non-small cell lung carcinoma, clear renal cell carcinoma as well as urothelial cancer or squamous cell carcinoma of the head and neck.

- Clinical collaboration agreement signed with Nektar Therapeutics for evaluation of Vaccibody's personalized cancer neoantigen vaccine in combination with Nektar's CD-122-biased agonist, NKTR-214.

Clinical Trial VB C-01:

- Positive results from the 6-months interim analysis of the phase IIa clinical study in high grade cervical dysplasia (CIN2/3) provides proof-of-concept for Vaccibody's immunotherapy platform.

- Continued follow-up of patients with CIN2/3 in the expansion phase (Phase IIa). On track to report 12-months data in Q1, 2019.

Key figures	3rd quarter		9 months		Full year
Amounts in NOK 1,000	**2018**	**2017**	**2018**	**2017**	**2017**
Total revenue and other income	3 126	2 008	8 972	6 509	9 763
Total operating expenses	20 190	11 164	50 508	27 302	43 731
Operating profit (loss)	**-17 064**	**-9 156**	**-41 536**	**-20 793**	**-33 968**
Net profit (loss) for the period	**-16 903**	**-8 700**	**-40 940**	**-19 390**	**-31 371**
Net proceeds from equity issues	-	-	337	209 548	209 548
Net cash flow	-12 915	-8 696	-42 146	188 810	182 070
Cash and cash equivalents, end of period	164 927	213 813	164 927	213 813	207 073
Outstanding shares, beginning of period (*)	48 479 880	2 417 064	2 417 064	1 529 649	1 529 649
Outstanding shares, end of period (*)	48 479 880	2 417 064	48 479 880	2 417 064	2 417 064
Employees, end of period	17	14	17	14	15

(*) The share was split 1:20 in 1Q18

VB10.NEO: Preclinical and Clinical Development; Nektar collaboration

The Vaccibody bioinformatic neo-epitope selection algorithm (NeoSELECT™) to be used in clinical trial has been optimized to enable a more rapid and automated neoepitope selection process. The latest version of NeoSELECT™ has high performance and a proven ability to identify >50% immunogenic neoepitopes dominated by CD8 activating neoepitopes in several mouse models. This is a unique feature that substantiates both NeoSELECT™ and the Vaccibody platform.

The patient enrollment process in the neoantigen clinical phase I/IIa trial started in April. The study is now enrolling patients with locally advanced or metastatic melanoma, non-small cell lung carcinoma, clear renal cell carcinoma as well as urothelial cancer or squamous cell carcinoma of the head and neck. We have enrolled 10 patients and patient treatment has started. Each patient needs to have a vaccine tailormade for his/her treatment and at this stage in the development we aim to produce the vaccine in 12-16 weeks. This means that there is a lag period between when a patient is enrolled and when that patient is vaccinated first time.

Approval by the German regulators to use a 2nd Contract Manufacturing Organization (CMO) in order to expand the production capacity of the VB10.NEO vaccines was obtained in Q3.

Manufacturing of the individual patient's personalized VB10.NEO vaccines are ongoing with a tight quality control system and dedicated tracking system in place. Continuous work on optimizing the manufacturing process and reducing the lead time is performed. A dedicated tracking software system is under development.

A clinical collaboration agreement has been signed with Nektar Therapeutics for evaluation of Vaccibody's personalized cancer neoantigen vaccine in combination with Nektar's CD-122-

biased agonist, NKTR-214. VB10.NEO is designed to specifically activate the patient's immune system against tumour specific neoantigens. NKTR-214 will lead to further stimulation and proliferation of the immune cells. Preclinical results indicate a synergistic effect of VB10.NEO and NKTR-214 resulting in enhanced neoantigen-specific T cell responses and anti-tumour efficacy. The first stage of the clinical trial will be a pilot study which will enroll 10 patients. Vaccibody's part of the cost for the new study can be managed within the current funds in the company.

Nektar and Vaccibody each will maintain ownership of their own compounds in the clinical collaboration, and the two companies will jointly own clinical data that relate to the combination of VB10.NEO and NKTR-214. Under the terms of the agreement and following the completion of the pilot study, the two companies will evaluate next steps for potential development of the combination regimen.

VB10.16 Clinical Development

The core focus in the VB10.16 program in Q3, 2018 was to complete the analysis of 6-months interim data from the phase IIa part of the clinical study VB C-01. This study is a first human dose, open-label, multicenter phase I/IIa study of VB10.16 immunotherapy for the treatment of high grade Cervical Intraepithelial Neoplasia (CIN 2/3) caused by human papillomavirus 16 (HPV16). 12-months data will be announced in Q1, 2019.

The phase IIa enrolled 18 CIN 2/3 patients, 1 patient was withdrawn and 17 patients each received four doses of 3 mg of VB10.16 at week 0, 3, 6 and 16 weeks. The primary objective of the study was to evaluate the safety and tolerability of VB10.16. The secondary objectives were to assess T cell mediated immune responses in the peripheral blood and to evaluate early signs of efficacy by means of CIN regression and HPV clearance. The vaccine was delivered with a pain-less PharmaJet® Stratis Needle-free Injection System.

The treatment with the four doses of VB10.16 was well tolerated in the phase IIa part as it was in the phase I part of the study. No serious adverse advents (SAEs) or unexpected adverse events were reported. The most frequently reported AEs were transient mild to moderate reactions at the injection site.

Immunological analyses of the peripheral blood demonstrated a strong HPV16-specific T cell immune response in 17 of 17 patients evaluated. The response was induced by the vaccine in 16 of 17 patients against both antigens used in the vaccine (HPV16 proteins E6 and E7). One patient had a strong baseline response and thus was not further induced by the vaccine. These results constitute a proof-of-concept for the Vaccibody DNA vaccine technology delivered by jet injection regarding its ability to generate a rapid, strong and long-lasting response.

One patient had conization at 4 months and could not be assessed at 6 months. Of the remaining 16 patients, 15 patients showed a partial or complete response at 6 months (13 partial responders, 2 complete responders, 1 stable disease). 14 patients showed a reduction in lesion size from colposcopic examination at 6 months (median reduction for these 14

patients were 50%). Histopathological regression to low grade neoplasia (CIN 1) or no disease was seen in 8 patients. Of the 8 patients that has not regressed to CIN1 or less at 6 months, 6 patients showed upregulation of PD-L1 in the lesions which may delay or inhibit elimination of all affected cells. Three of these patients had also persistent co-infection with other high-risk HPV strains, including one patient which had cleared HPV16.

Adding a 4th vaccination at 4 months significantly boosted the T cell response and the strongest response was observed at 6 months. Change in lesion size and CIN regression will be monitored until 12 months after first vaccination. These results will be reported in Q1, 2019.

Financial review

Profit and loss statement

Other income in the first nine months of 2018 was KNOK 8,843 compared to KNOK 6,023 in the same period 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. *Revenue* in the first nine months of 2018 of KNOK 129 and KNOK 486 in 2017 respectively relate to two preclinical R&D collaborations of limited scope.

Total operating expenses increased to KNOK 50,508 in the first nine months of 2018 from KNOK 27,302 in the same period of 2017. *Payroll and related expenses* increased to KNOK 13,780 compared to KNOK 8,859 in 2017 due to the planned increase in staff. *Procurement of R&D services and IP expenses* increased to KNOK 26,911 in the first nine months of 2018 compared to KNOK 12,832 in the same period of 2017, mainly relating to expenses on the Neo-antigen project increasing as planned, including preparations for and initiation of the clinical trial and the associated manufacturing. Expenses on the VB10.16 clinical trial increased compared to the first nine months of 2017 as well, since the expansion phase IIa of the study was on hold until late in 1Q17. *Other operating expenses* increased to KNOK 9,776 in the first nine months of 2018 compared to KNOK 5,548 in the same period of 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 September 30, 2018, Vaccibody had total assets of KNOK 175,576, hereunder *Cash and cash equivalents* of KNOK 164,927 and *Receivables* of KNOK 10,251. *Receivables* include mainly grants earned and to be received within a year in accordance with the applicable payment schedules. *Shareholders' equity* was KNOK 162,926.

Outlook

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

- Clinical Trial for cancer neoantigen vaccine (VB10.NEO)
  - Complete enrolment of the clinical phase I trial of patients with locally advanced or metastatic melanoma, non-small cell lung carcinoma, clear renal cell carcinoma, urothelial cancer or squamous cell carcinoma of the head and neck.
  - Reporting from measurement of systemic immune responses in patients receiving the neoantigen vaccine.
  - Interim report on safety, immunogenicity and early signs of efficacy.

- Nektar collaboration
  - Initiation of the clinical trial evaluating the combination of VB10.NEO and NKTR-214.

- Clinical Trial VB C-01 (VB10.16)
  - 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	*3rd quarter*		*9 months*		*Full year*
NOK 1,000	**2018**	**2017**	**2018**	**2017**	**2017**
Revenue	129	-	129	486	486
Other income	2 997	2 008	8 843	6 023	9 277
Payroll and related expenses	5 545	3 826	13 780	8 859	14 372
Procurement of R&D services and IP expenses	11 310	5 626	26 911	12 832	21 267
Depreciation	13	24	41	63	82
Other operating expenses	3 321	1 688	9 775	5 548	8 011
Total operating expenses	**20 190**	**11 164**	**50 508**	**27 302**	**43 731**
Operating profit (loss)	**-17 064**	**-9 156**	**-41 536**	**-20 793**	**-33 968**
Net financial items	**161**	**457**	**596**	**1 403**	**2 597**
Profit (loss) before income tax	**-16 903**	**-8 700**	**-40 940**	**-19 390**	**-31 371**
Income tax	-	-	-	-	-
Net profit (loss) for the period	**-16 903**	**-8 700**	**-40 940**	**-19 390**	**-31 371**

Statement of financial position								
NOK 1,000	**30.09.18**	**30.06.18**	**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	300	300
Property, plant and equipment	99	77	74	89	109	105	79	97
Total non-current assets	**399**	**377**	**373**	**389**	**408**	**405**	**379**	**397**
Receivables	10 251	9 244	8 611	7 004	7 593	6 912	6 153	226 608
Cash and cash equivalents	164 927	177 842	190 298	207 073	213 813	222 509	228 125	25 002
Total current assets	**175 177**	**187 086**	**198 909**	**214 077**	**221 406**	**229 421**	**234 278**	**251 611**
Total assets	**175 576**	**187 463**	**199 283**	**214 466**	**221 815**	**229 826**	**234 657**	**252 008**
Share capital	2 424	2 424	2 420	2 417	2 417	2 417	2 410	1 530
Share premium	287 775	287 775	287 580	287 445	287 445	287 445	286 954	78 784
Unregistered share issue	-	-	-	-	-	-	498	209 050
Retained earnings (accumulated losses)	-127 273	-110 370	-98 404	-86 333	-74 352	-65 653	-59 343	-54 962
Shareholders' equity	**162 926**	**179 829**	**191 595**	**203 529**	**215 509**	**224 209**	**230 519**	**234 402**
Accounts payable	8 472	2 926	2 666	6 084	3 155	2 811	1 466	3 411
Other current liabilities	4 179	4 709	5 021	4 853	3 151	2 806	2 672	14 195
Current liabilities	**12 651**	**7 634**	**7 687**	**10 937**	**6 305**	**5 617**	**4 138**	**17 606**
Total liabilities	**12 651**	**7 634**	**7 687**	**10 937**	**6 305**	**5 617**	**4 138**	**17 606**
Total Equity and Liabilities	**175 576**	**187 463**	**199 283**	**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 01.01.2018	**2 417**	**287 445**	**-86 333**	**-**	**203 529**
Loss for the period			-40 940		-40 940
Warrants exercised	7	330			337
Balance at 30.09.2018	**2 424**	**287 775**	**-127 272**	**-**	**162 926**

Statement of cash flow *NOK 1,000*	*9 months* **2018**	 **2017**	*Full year* **2017**
Loss for the period	**-40 940**	**-19 390**	**-31 371**
Adjustments for:			
Interest income	-1 245	-1 085	-1 584
Interest expenses	73	1	14
Depreciation	41	63	82
Change in trade receivables	-204	240	-75
Change in trade payables	2 387	-256	2 674
Change in receivables related to grants	-3 043	-1 225	-321
Change in other current liabilities	-674	-95	1 608
Net cash flow from operating activities	**-43 603**	**-21 746**	**-28 973**
Purchase of property, plant and equipment	-51	-74	-74
Interest income	1 245	1 085	1 584
Net cash flow from investing activities	**1 193**	**1 011**	**1 509**
Interest expenses	-73	-1	-14
Proceeds from equity issues	337	209 548	209 548
Net cash flow from financing activities	**264**	**209 546**	**209 534**
Net change in cash and cash equivalents	**-42 146**	**188 810**	**182 070**
Cash and cash equivalents at begining of period	207 073	25 002	25 002
Cash and cash equivalents at end of period	**164 927**	**213 813**	**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 4.9 in the first nine months of 2018.

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 grants in 2015, 2016 and 2017 respectively, and MNOK 3.8 in the first nine months of 2018.

Note 3 Share capital and shareholders

Table of shareholders as of September 30, 2018:

Shareholder	Shares	Ownership
SARSIA SEED AS	6 074 800	12,53 %
RADIUMHOSPITALETS	4 811 400	9,92 %
DATUM INVEST AS	4 152 600	8,57 %
ARCTIC FUNDS PLC	3 793 490	7,82 %
NORDA ASA	3 235 600	6,67 %
PORTIA AS	2 200 000	4,54 %
KREFTFORENINGEN	1 945 600	4,01 %
Norron Sicav - Target	1 930 000	3,98 %
OM Holding AS	1 477 000	3,05 %
INVEN2 AS (1)	1 340 400	2,76 %
OTHERS	*17 518 990*	*36,14 %*
Total	**48 479 880**	100,00 %

(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 4,128,369 warrants outstanding to key 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.