vaccibody

Report 1st quarter 2019

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 or squamous cell carcinoma of head and neck. Vaccibody has a collaboration with Nektar Therapeutics, planning to start testing VB10.NEO in combination with bempegaldesleukin (NKTR-214) in squamous cell carcinoma of head and neck in Q3 2019. 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), evaluating the safety and immunogenicity of VB10.16 in women with high grade cervical intraepithelial neoplasia (HSIL; CIN 2/3) has published positive 12 months data. Vaccibody has recently started a collaboration with Roche, exploring VB10.16 in combination with their checkpoint inhibitor atezolizumab (Tecentriq™) in up to 50 patients with advanced or recurrent cervical cancer. First patient is expected to be vaccinated in Q1 2020.

Highlights for the 1st quarter 2019

VB10.NEO Neoantigen-based individualized cancer vaccine program:

- 18 patients are enrolled in the neoantigen clinical phase I/IIa trial by March 31, and patient treatment is on-going. 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.

- Protocol amendment to the neoantigen trial including a treatment arm combining VB10.NEO and NKTR-214 in head & neck cancer (as part of the Nektar Therapeutics collaboration) has been submitted to the German regulators.

- Additional study sites have been contacted to expand the total number of recruiting sites to eight sites.

Clinical Trial VB C-01:

- Positive results from the 12-months analysis of the phase IIa clinical study in high grade cervical dysplasia (CIN2/3) have been published. This provides proof-of-concept for Vaccibody's immunotherapy platform. Final report will be ready during Q2 2019.

Other

- A Private Placement has been successfully placed, raising gross proceeds of NOK 230 mio.

Key figures *Amounts in NOK 1,000*	***1st quarter*** **2019**	 **2018**	***Full year*** **2018**
Total revenue and other income	2 904	2 963	12 042
Total operating expenses	22 628	15 263	77 879
Operating profit (loss)	**-19 724**	**-12 300**	**-65 837**
Net profit (loss) for the period	**-19 598**	**-12 071**	**-63 793**
Net proceeds from equity issues	219 420	138	337
Net cash flow	196 604	-16 774	-62 525
Cash and cash equivalents, end of period	341 151	190 298	144 547
Outstanding shares, beginning of period (*)	48 479 880	2 417 064	2 417 064
Outstanding shares, end of period (*)	54 229 880	48 396 480	48 479 880
Employees, end of period	21	14	19

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

VB10.NEO: Preclinical and Clinical Development; Nektar collaboration

The patient enrollment process in the neoantigen clinical phase I/IIa trial started in April 2018. 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 18 patients and patient treatment is on-going. 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.

New clinical sites are being contacted in order to speed up the enrollment of patients in the current study and in order to secure sufficient patient enrollment for both the Nektar-arm (up to 10 patients) and the expansion cohorts. We plan to include 5 extra sites on top of the 3 sites already recruiting patients. The Nektar study is expected to start in Q3 2019 and the first expansion cohort (enrolling up to 17 extra patients in a specific indication) in the phase IIa phase of the neoantigen study could start enrolling in Q4 2019.

The protocol amendment to the neoantigen trial including the NKTR-214 arm in head & neck cancer together with an updated Investigators Brochure (IB) was submitted to the German regulators in March.

Manufacturing of the individual patient's personalized VB10.NEO vaccines are ongoing with a tight quality control system and dedicated tracking system in place. The political situation in United Kingdom around Brexit had created uncertainty, however, mitigation efforts are now in place.

VB10.16 Clinical Development

The core focus in the VB10.16 program in Q1, 2019 was to complete the analysis of 12-months data from the phase IIa part of the clinical study VB C-01, and getting to an agreement with Roche on a collaboration to explore a combination of Vaccibody's VB10.16 and Roche's PD-L1-blocking immune-checkpoint inhibitor atezolizumab (Tecentriq®) in patients with advanced cervical cancer.

The VB C-01 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). The final report is expected in Q2 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. 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.

Two patients had conization and one patient withdrew after 9 months and could not be assessed at 12 months visit. Of the remaining 14 patients 12 patients showed a reduction in the lesion size; 8 had more than a 50% reduction in lesion size. All patients tested positive for HPV16 at study entry and 8 of the 14 patients had negative HPV16 in one or both of the two tests at 12 months, indicating clearance of the HPV16 infection. Regression to low grade neoplasia (CIN1) or no disease was seen in 8 patients. Of the 6 patients that has not regressed to CIN1 or less at 12 months, 5 patients showed upregulation of the natural immune checkpoint modulator 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.

Immunological analyses of the peripheral T cell responses demonstrated a strong HPV16-specific T cell immune response in 17 of 17 patients. The response was increased after vaccination in 16 of 17 patients against both HPV16 E6 and E7 antigens used in the vaccine. One patient had a strong baseline response and the response was not further increased.

These results constitute a proof-of-concept for VB10.16 and the Vaccibody DNA vaccine technology delivered by jet injection to induce rapid, strong and long-lasting immune responses which can lead to elimination of pre-malignant and malignant cells. Interestingly, the observed PD-L1 upregulation provides a strong rationale for moving VB10.16 into HPV16 positive cancer in combination with anti-PD-1/PD-L1 checkpoint inhibitor therapy.

Based on the above data, a clinical collaboration agreement has been signed with Roche for evaluation of Vaccibody's VB10.16 HPV16 vaccine in combination with Roche's PD-L1-blocking immune-checkpoint inhibitor atezolizumab (Tecentriq®) in patients with advanced or recurrent cervical cancer. The planned study will assess the safety, tolerability, immunogenicity and efficacy of the VB10.16-atezolizumab combination in up to 50 patients. Roche will supply atezolizumab free of charge and Vaccibody's part of the cost for the new study will be managed with the funds raised in the Private Placement.

Roche 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 atezolizumab.

The combination study will be named C-02 and first patient is expected to be dosed in Q1 2020.

Financial review

Profit and loss statement

Other income in the first three months of 2019 was KNOK 2,904 compared to KNOK 2,963 in the same period of 2018. Grants from the Norwegian Research Council under the BIA programme and expected Skattefunn-grant for 2019 are at the same level as in 2018.

Total operating expenses increased to KNOK 22,628 in the first three months of 2019 from KNOK 15,263 in the same period of 2018. *Payroll and related expenses* increased to KNOK 6,341 compared to KNOK 4,408 in 2018 due to the planned increase in staff. *Procurement of R&D services and IP expenses* increased to KNOK 13,465 in the first three months of 2019 compared to KNOK 7,821 in the same period of 2018, mainly relating to expenses on the Neo-antigen project where the first patient was enrolled in April 2018. *Other operating expenses* were slightly reduced to KNOK 2,806 in the first three months of 2019 compared to KNOK 3,018 in the same period of 2018.

Statement of financial position

Vaccibody announced in February 2019 that a Private Placement has been successfully placed, raising gross proceeds of NOK 230 million by allocating 5,750,000 shares at a subscription price of NOK 40.00 per Offer Share. The Private Placement received strong interest from existing shareholders and new investors. The net proceeds from the Private Placement will i.a. be used to conduct a Phase IIa clinical study combining Vaccibody's product candidate VB10.16 with Roche's checkpoint inhibitor atezolizumab, prepare for expansion cohorts in Vaccibody's

VB10.NEO cancer neoantigen program and initiation of two expansion cohorts, as well as for general corporate purposes.

On March 31, 2019, Vaccibody had total assets of KNOK 350,592, hereunder *Cash and cash equivalents* of KNOK 341,151 and *Receivables* of KNOK 9,046. *Receivables* include mainly grants earned and to be received within a year in accordance with the applicable payment schedules. *Shareholders' equity* was KNOK 339,894.

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 and first patient dosed.

- Clinical Trial VB C-02 (VB10.16)
  - Submission of the clinical trial application (Ph IIa) to the regulatory bodies.
  - Initiation of the clinical trial evaluating the combination of VB10.16 and atezolizumab and first patient dosed

- 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 *NOK 1,000*	*1st quarter* **2019**	 **2018**	*Full year* **2018**
Revenue	-	-	129
Other income	2 904	2 963	11 913
Payroll and related expenses	6 341	4 408	20 882
Procurement of R&D services and IP expenses	13 465	7 821	43 428
Depreciation	15	16	58
Other operating expenses	2 806	3 018	13 511
Total operating expenses	**22 628**	**15 263**	**77 879**
Operating profit (loss)	**-19 724**	**-12 300**	**-65 837**
Net financial items	**126**	**228**	**2 044**
Profit (loss) before income tax	**-19 598**	**-12 071**	**-63 793**
Income tax	-	-	-
Net profit (loss) for the period	**-19 598**	**-12 071**	**-63 793**

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Statement of financial position

NOK 1,000	31.03.19	31.12.18	30.09.18	30.06.18	31.03.18	31.12.17
Intangible assets	300	300	300	300	300	300
Property, plant and equipment	95	110	99	77	74	89
Total non-current assets	**395**	**410**	**399**	**377**	**373**	**389**
Trade receivables	1 032	1 034	807	530	626	603
Grants receivable	8 014	7 347	9 444	8 714	7 985	6 401
Receivables	9 046	8 381	10 251	9 244	8 611	7 004
Cash and cash equivalents	341 151	144 547	164 927	177 842	190 298	207 073
Total current assets	**350 197**	**152 928**	**175 177**	**187 086**	**198 909**	**214 077**
Total assets	**350 592**	**153 338**	**175 576**	**187 463**	**199 283**	**214 466**
Share capital	2 711	2 424	2 424	2 424	2 420	2 417
Share premium	506 907	287 775	287 775	287 775	287 580	287 445
Unregistered share issue	-	-	-	-	-	-
Retained earnings (accumulated losses)	-169 724	-150 126	-127 273	-110 370	-98 404	-86 333
Shareholders' equity	**339 894**	**140 072**	**162 926**	**179 829**	**191 595**	**203 529**
Accounts payable	3 609	5 521	8 472	2 926	2 666	6 084
Other current liabilities	7 088	7 745	4 179	4 709	5 021	4 853
Current liabilities	**10 697**	**13 266**	**12 651**	**7 634**	**7 687**	**10 937**
Total liabilities	**10 697**	**13 266**	**12 651**	**7 634**	**7 687**	**10 937**
Total Equity and Liabilities	**350 592**	**153 338**	**175 576**	**187 463**	**199 283**	**214 466**

Statement of changes in equity

NOK 1,000

	Share capital	Share premium	Accumulated losses	Other equity	Total equity
Balance at 01.01.2018	**2 417**	**287 445**	**-86 333**	**-**	**203 529**
Loss for the period			-63 793		-63 793
Warrants exercised	7	330			337
Balance at 31.12.2018	**2 424**	**287 775**	**-150 126**	**-**	**140 072**
Balance at 01.01.2019	**2 424**	**287 775**	**-150 126**	**-**	**140 072**
Loss for the period			-19 598		-19 598
Share issue	288	219 133			219 420
Balance at 31.03.2019	**2 711**	**506 907**	**-169 724**	**-**	**339 894**

Statement of cash flow *NOK 1,000*	*3 months* **2019**	 **2018**	*Full year* **2018**
Loss for the period	**-19 598**	**-12 071**	**-63 793**
Adjustments for:			
Interest income	-611	-411	-1 518
Interest expenses	42	28	100
Depreciation	15	16	58
Change in trade receivables	2	-22	-430
Change in trade payables	-1 912	-3 418	-564
Change in receivables related to grants	-666	-1 584	-946
Change in other current liabilities	-657	168	2 892
Net cash flow from operating activities	**-23 385**	**-17 295**	**-64 200**
Purchase of property, plant and equipment	0	0	-79
Interest income	611	411	1 518
Net cash flow from investing activities	**611**	**411**	**1 438**
Interest expenses	-42	-28	-100
Proceeds from equity issues	219 420	138	337
Net cash flow from financing activities	**219 378**	**110**	**236**
Net change in cash and cash equivalents	**196 604**	**-16 774**	**-62 525**
Cash and cash equivalents at begining of period	144 547	207 073	207 073
Cash and cash equivalents at end of period	**341 151**	**190 298**	**144 547**

Notes to the Quarterly Financial Statement

Note 1 Accounting policies

The financial statements of Vaccibody AS for 2018 and 2019 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, MNOK 6.5 in 2018 and MNOK 1.6 in the first three months of 2019.

Vaccibody AS is eligible for grant under the Norwegian Skattefunn programme. The Company has recognized MNOK 3.9, 5.1 and 5.1 of the grants in 2016, 2017 and 2018 respectively, and MNOK 1.3 in the first three months of 2019.

Note 3 Share capital and shareholders

Table of shareholders as of March 31, 2019:

Shareholder	Shares	Ownership
Sarsia Seed AS	4 874 800	8,99 %
Radiumhospitalets Forskningsstiftelse	4 811 400	8,87 %
Datum Invest AS	4 152 600	7,66 %
Arctic Funds PLC	2 654 140	4,89 %
Portia AS	2 545 000	4,69 %
Norron Sicav - Target	2 135 000	3,94 %
Kreftforeningen	1 945 600	3,59 %
Tanja A/S	1 890 000	3,49 %
OM Holding AS	1 652 000	3,05 %
Norda ASA	1 626 800	3,00 %
Others	*25 942 540*	*47,84 %*
Total	**54 229 880**	**100,00 %**

At March 31st, 2019, The Company had 3,996,137 active 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.