vaccibody

Report 2nd 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. 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 in this study is expected to be vaccinated in Q1 2020.

Highlights for the 2nd quarter 2019

VB10.NEO Neoantigen-based individualized cancer vaccine program:

- 23 patients are enrolled in the neoantigen clinical phase I/IIa trial, and patient treatments are 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.

- In June the company announced its initial preliminary evaluation of the first four patients and showed a strong immunogenicity in all four patients. Immunogenicity was assessed in two patients with renal cell carcinoma (RCC) and two patients with squamous cell carcinoma of the head and neck (SCCHN) after treatment with a VB10.NEO in combination with checkpoint inhibitor therapy (CPI) as per protocol.

- Protocol amendment to the neoantigen trial including the NKTR-214 arm (Nektar Therapeutics collaboration) in head and neck cancer has been submitted and is being processed by to the German regulators.

- Additional six new study sites have been selected and the first is expected to start enrolling in August. The target is to enroll from a total number of nine clinical sites.

VB10.16 HPV16 vaccine program:

- The final clinical report from the phase IIa clinical study in HPV16+ high grade cervical dysplasia (CIN2/3) is now complete. This study showed that the Vaccibody vaccine technology is able to provide a rapid, strong and long-lasting immune response in patients and has served to provide proof-of-concept for Vaccibody's immunotherapy platform.

- In the 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, we have now selected the clinical research organization (CRO) which will run the clinical trial. Also, selection of clinical sites to perform the study has been initiated.

Key figures	***2nd quarter***		***6 months***		***Full year***
Amounts in NOK 1,000	**2019**	**2018**	**2019**	**2018**	**2018**
Total revenue and other income	2 829	2 883	5 733	5 846	12 042
Total operating expenses	22 840	15 055	45 469	30 318	77 879
Operating profit (loss)	**-20 011**	**-12 172**	**-39 736**	**-24 472**	**-65 837**
Net profit (loss) for the period	**-19 246**	**-11 965**	**-38 845**	**-24 037**	**-63 793**
Net proceeds from equity issues	-	199	219 420	337	337
Net cash flow	-19 130	-12 457	177 474	-29 231	-62 525
Cash and cash equivalents, end of period	322 021	177 842	322 021	177 842	144 547
Outstanding shares, beginning of period (*)	54 229 880	48 396 480	48 479 880	2 417 064	2 417 064
Outstanding shares, end of period (*)	54 229 880	48 479 880	54 229 880	48 479 880	48 479 880
Employees, end of period	24	15	24	15	19

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

VB10.NEO: Clinical Development; Nektar collaboration

Strong early immunogenicity response from the neoantigen cancer vaccine clinical trial VB N-01 was announced at the end of June. Preliminary immunogenicity was assessed in two patients with RCC and two patients with SCCHN after treatment with VB10.NEO in combination with CPI as per protocol. Before VB10.NEO vaccination, these patients had been treated with the CPI nivolumab for 12-32 months with stable disease as best response. One patient was progressing at start of vaccination. All patients had low tumour mutational burden ranging from 1.7-3.2 mutations/Mb. The top 20 neoepitopes predicted by Vaccibody's proprietary NeoSELECT™ algorithm was selected for each of the fully personalized VB10.NEO neoantigen vaccines. Immunogenicity to each individual neoepitope has so far been assessed after 3 to 6 vaccinations of VB10.NEO by an in vitro stimulated IFN-γ ELISpot. Strong T cell responses were observed in all these first four patients tested. T cell responses were significantly increased in post-vaccination samples towards 63% of the neoepitopes. The

response to the vaccine was very solid with an average increase of more than 1200 SFU per million PBMC which is on average a 250-fold increase from baseline. The breadth and the strength increased with number of vaccinations. An amplification of existing neoepitope-specific T cells as well as de novo responses were observed in all patients.

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. Vaccibody has enrolled 23 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 approx. 12 weeks. This means that there is a lag period between when a patient is enrolled and when that patient is vaccinated first time.

Enrolment has been slower than expected in H1 2019, in part due to unexpected personnel shortage at one key site. Vaccibody is continuously working to optimize recruitment and new clinical sites have been identified in order to speed up the enrollment of patients. These patients will go into the current neoantigen study as well as into the Nektar-arm of the study (up to 10 patients) and the expansion cohorts. We now plan to include six extra sites on top of the three sites already recruiting patients. The first new site is expected to be ready to enroll during August.

The discussions with the German regulators (PEI) regarding the protocol amendment and updated Investigators Brochure (IB) for the NKTR-214 arm in head & neck cancer are on-going. Due to several rounds of interactions with PEI, patient enrolment is expected to start late Q3 or early Q4, 2019.

VB10.16: Clinical Development

The core focus in the VB10.16 program in Q2, 2019 was to write up and conclude on the positive results from the phase IIa part of the clinical study VB C-01 in the final clinical trial report, and to prepare for the VB C-02 trial in 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 clinical trial report has been signed off by all relevant parties and the study is now complete. The results have been submitted for publication. The positive 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.

The positive clinical results in the VB C-01 study triggered a strategic shift in focus for VB10.16 from pre-malignant conditions to established cancer, where the medical need as well as market potential is greater.

In the 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, a vendor selection process has been conducted during Q2 for the selection of the CRO which will run the VB C-02 trial. Five CROs were invited to bid and one selected. The preparations have continued including protocol and writing of an Investigators Brochure (IB). Also, a site selection process has been initiated identifying sites in Norway, Germany, Belgium, Poland, Czech Republic, Bulgaria and eventually other countries. Similarly, a vendor selection process has been conducted for the contract manufacturing organization which will supply the bulk drug substance. The study is on track for clinical trial submission in Q3, 2019 and first patient is expected to be dosed in Q1 2020.

Financial review

Profit and loss statement

Other income in the first six months of 2019 was KNOK 5,733 compared to KNOK 5,846 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 45,469 in the first six months of 2019 from KNOK 30,318 in the same period of 2018. *Payroll and related expenses* increased to KNOK 11,474 compared to KNOK 8,235 in 2018 due to the planned increase in staff. *Procurement of R&D services and IP expenses* increased to KNOK 27,719 in the first six months of 2019 compared to KNOK 15,601 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* was slightly reduced to KNOK 6,229 in the first six months of 2019 compared to KNOK 6,455 in the same period of 2018.

Statement of financial position

On June 30, 2019, Vaccibody had total assets of KNOK 332,733, hereunder *Cash and cash equivalents* of KNOK 322,021 and *Receivables* of KNOK 9,735. *Receivables* include mainly grants earned and to be received within a year in accordance with the applicable payment schedules. *Shareholders' equity* was KNOK 320,647.

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.
  - Interim report on safety, immunogenicity and early signs of efficacy (autumn 2019).

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

- Clinical Trial in cervical cancer combining VB10.16 and checkpoint inhibitor atezolizumab
  - Submission of the clinical trial application (Ph IIa) to the relevant 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.

- As announced earlier the Company is evaluating a possible public listing.

Profit and loss statement	***2nd quarter***		***6 months***		***Full year***
NOK 1,000	**2019**	**2018**	**2019**	**2018**	**2018**
Revenue	-	-	-	-	129
Other income	2 829	2 883	5 733	5 846	11 913
Payroll and related expenses	5 133	3 827	11 474	8 235	20 882
Procurement of R&D services and IP expenses	14 254	7 780	27 719	15 601	43 428
Depreciation	32	12	47	28	58
Other operating expenses	3 422	3 437	6 229	6 455	13 512
Total operating expenses	**22 840**	**15 055**	**45 469**	**30 318**	**77 879**
Operating profit (loss)	**-20 011**	**-12 172**	**-39 736**	**-24 472**	**-65 837**
Net financial items	**765**	**207**	**891**	**435**	**2 044**
Profit (loss) before income tax	**-19 246**	**-11 965**	**-38 845**	**-24 037**	**-63 793**
Income tax	-	-	-	-	-
Net profit (loss) for the period	**-19 246**	**-11 965**	**-38 845**	**-24 037**	**-63 793**

Statement of financial position							
NOK 1,000	**30.06.19**	**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	300
Property, plant and equipment	677	95	110	99	77	74	89
Total non-current assets	**977**	**395**	**410**	**399**	**377**	**373**	**389**
Receivables	9 735	9 046	8 381	10 251	9 244	8 611	7 004
Cash and cash equivalents	322 021	341 151	144 547	164 927	177 842	190 298	207 073
Total current assets	**331 756**	**350 197**	**152 928**	**175 177**	**187 086**	**198 909**	**214 077**
Total assets	**332 733**	**350 592**	**153 338**	**175 576**	**187 463**	**199 283**	**214 466**
Share capital	2 711	2 711	2 424	2 424	2 424	2 420	2 417
Share premium	506 907	506 907	287 775	287 775	287 775	287 580	287 445
Unregistered share issue	-	-	-	-	-	-	-
Retained earnings (accumulated losses)	-188 971	-169 725	-150 126	-127 273	-110 370	-98 404	-86 333
Shareholders' equity	**320 647**	**339 893**	**140 072**	**162 926**	**179 829**	**191 595**	**203 529**
Accounts payable	5 867	3 610	5 521	8 472	2 926	2 666	6 084
Other current liabilities	6 219	7 088	7 745	4 179	4 709	5 021	4 853
Current liabilities	**12 086**	**10 698**	**13 266**	**12 651**	**7 634**	**7 687**	**10 937**
Total liabilities	**12 086**	**10 698**	**13 266**	**12 651**	**7 634**	**7 687**	**10 937**
Total Equity and Liabilities	**332 733**	**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			-38 845		-38 845
Share issue	288	219 133			219 420
Balance at 30.06.2019	**2 711**	**506 907**	**-188 971**	**-**	**320 647**

Statement of cash flow *NOK 1,000*	*6 months* **2019**	 **2018**	*Full year* **2018**
Loss for the period	**-38 845**	**-24 037**	**-63 793**
Adjustments for:			
Interest income	-1 482	-888	-1 518
Interest expenses	82	53	100
Depreciation	47	28	58
Change in trade receivables	52	73	-430
Change in trade payables	346	-3 159	-564
Change in receivables related to grants	-1 406	-2 313	-946
Change in other current liabilities	-1 526	-144	2 892
Net cash flow from operating activities	**-42 732**	**-30 387**	**-64 200**
Purchase of property, plant and equipment	-614	-16	-79
Interest income	1 482	888	1 518
Net cash flow from investing activities	**868**	**872**	**1 438**
Interest expenses	-82	-53	-100
Proceeds from equity issues	219 420	337	337
Net cash flow from financing activities	**219 338**	**284**	**236**
Net change in cash and cash equivalents	**177 474**	**-29 231**	**-62 525**
Cash and cash equivalents at begining of period	144 547	207 073	207 073
Cash and cash equivalents at end of period	**322 021**	**177 842**	**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 3.1 in the first six 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 2.5 in the first six months of 2019.

Note 3 Share capital and shareholders

Table of shareholders as of June 30, 2019:

Shareholder	Shares	Ownership
Sarsia Seed AS	4 874 800	8,99 %
Radiumhospitalets Forskningsstiftelse	4 811 400	8,87 %
Datum Invest AS	4 102 600	7,57 %
Arctic Funds PLC	2 629 140	4,85 %
Tanja A/S	2 290 000	4,22 %
Portia AS	2 220 000	4,09 %
Norron Sicav - Target	2 135 000	3,94 %
Kreftforeningen	1 945 600	3,59 %
OM Holding AS	1 652 000	3,05 %
Vatne Equity AS	1 376 740	2,54 %
Others	*26 192 600*	*48,30 %*
Total	**54 229 880**	100,00 %

At June 30th, 2019, the Company had 4,099,470 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.